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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–24–0076]

Walnuts Grown in California; Changes to Administrative Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule implements a recommendation from the California Walnut Board (Board) to make changes to the administrative requirements prescribed under the Federal marketing order for walnuts grown in California (Order). This final rule provides a schedule for required handler assessment payments, establishes interest and late payment charges on overdue assessments owed, and modifies the existing reporting requirements for handler acquisitions of walnuts.

DATES: Effective September 16, 2026.

FOR FURTHER INFORMATION CONTACT: Jeffery Rymer, Marketing Specialist, or Abigail Maharaj, Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; telephone: (559) 487–5901; or email: *JefferyM.Rymer@usda.gov* or *Abigail.Maharaj@usda.gov*.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674) (the Act), amending Marketing Order No. 984, (7 CFR part 984, the Order), regulating the handling of walnuts grown in California. The Board locally administers the Order and is comprised of growers and handlers of California walnuts operating within the area of production, and a public member.

This action is exempt from the Office of Management and Budget (OMB) review process required by Executive Order 12866. This final rule amends existing Marketing Order No. 984, as amended (7 CFR part 984), Walnuts Grown in California, and is necessary for the continued operation of Marketing Order No. 984. Additionally, this action is exempt from the requirements of Executive Order 14192, ''Unleashing Prosperity Through Deregulation,'' pursuant to section 5(c).

This final rule has been reviewed under Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' which requires Federal agencies to consider whether their rulemaking actions would have Tribal implications. The Agricultural Marketing Service (AMS) has determined that this final rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This final rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This final rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608(c)(15)(A) of the Act, any handler subject to an order may file with the U.S. Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule provides a defined payment schedule for required handler assessment payments. Additionally, the rule establishes interest and late payment charges on overdue handler assessments owed under the Order. Lastly, this action modifies the reporting requirements for walnut acquisitions. These changes were unanimously approved by the Board, in two separate votes, with eight in favor and none opposed, during Board meetings held on August 8, and November 6, 2024.

Section 984.69(a) of the Order provides that each handler shall pay the Board, on demand, his or her pro rata share of the Board's authorized expenses. Currently, each handler's assessment obligation is invoiced throughout the marketing year based upon the quantity of walnuts the handler has acquired and reported to the Board by January 15 of each year on the Order's CWB Form #1. However, the schedule of when assessments are invoiced, and payments are due, is not yet specified in the Order's regulations.

Further, § 984.69(c) of the Order provides the authority to establish late payment charges and interest charges on assessments that are not paid within the time period specified by the Board. While such late payment penalties are authorized under the Order, specific late payment charges and interest rate charges on past due assessments have not yet been established in the Order's regulations.

Additionally, § 984.73 of the Order provides the authority to require handlers to submit reports of their walnut receipts. Under that authority, § 984.473, ''Report of walnut receipts,'' was established to require handlers to report walnut acquisitions, on or before January 15 of each marketing year, on forms supplied by the Board. Currently, under that section of the Order, handlers are only required to submit one report each marketing year, with no provision providing instruction for reporting walnuts that may be acquired after January 15.

This final rule modifies the Order's current administrative requirements to enhance the efficient collection of assessments from handlers, strengthening the Board's oversight of the program operations and administration of the Order. The Board believes that these changes and additions will augment the Order's administrative requirements and incentivize compliance. AMS determined that these amendments

would effectuate the declared policy of the Act by strengthening administrative requirements that support the effective operation of the Order.

Specifically, this final rule adds a new § 984.348, ''Payment of assessments,'' to the Order's requirements to establish the payment schedule for handler assessments. Each handler would pay assessments, based on the quantity of walnut receipts reported by the handler pursuant to § 984.473, in three equal installments invoiced by the Board, on January 31, April 30, and July 31 of each marketing year. This specific payment schedule is based on industry practice. Based on Board discussions, establishing this schedule in the Order itself will help stabilize and smooth revenue streams by distributing assessment collection evenly over staggered payments. Such stability will help the Board's operability by reducing uncertainty about when assessments are due and provide handlers with clear expectations and timeframe. This schedule is not clear in the Order or provided for in its administrative regulations.

In addition, through the authority provided by § 984.69(c) of the Order, this final rule also establishes late payment penalties and interest charges for handler assessment payments under a new § 984.349, ''Late payment and interest charges.'' This, in conjunction with the establishment of the payment schedule, will help the Board address issues of handler confusion with late payment submissions. A late payment charge of ten percent (10%) will be imposed on any assessment payment that has not been received within sixty (60) days of the invoice date on the handler's assessment statement. Further, assessment payments not received within sixty (60) days after the invoice date will also be subject to an ongoing one and one-half percent (1.5%) per month interest charge, accruing monthly until the total balance due, including any late payment charge, is paid. The inclusion of a late payment penalty and interest charges provision establishes a clear formula for the Board to apply to a handler's account when in arrears. This final rule also provides an incentive for handlers to comply with the payment installment schedule.

Finally, this action modifies the reporting requirements in § 984.473, ''Report of walnut receipts,'' which requires handlers to report walnut acquisitions on or before January 15 of each marketing year on forms supplied by the Board. This final rule adds provisions for reporting walnuts that are acquired after the January 15 reporting deadline. Although the occurrence of walnuts arriving to handlers after January 15 is not common, when it does occur, it creates confusion concerning how the reporting requirements and assessment collections are applied to those late arriving walnuts. As such, the Board's solution is: each handler acquiring walnuts from growers after submission of his or her initial report of walnut receipts will also be required to file a revised report of walnut receipts by the 15th of the month following such receipt. Handlers must pay assessments on such receipts upon demand, as requested by the Board, following receipt of the revised report.

These changes collectively aim to reinforce the integrity of the Order, promote compliance, and reduce reliance on legal remedies for collection. By requiring transparency, timely reporting, and punctual payments, these measures are expected to facilitate the orderly marketing of California walnuts and enhance the continued effectiveness of the program for the benefit of industry stakeholders.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this final rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique regulations in that they are brought about through group action of typically small entities.

There are approximately 68 handlers subject to regulation under the Order and approximately 4,500 growers of California walnuts in the production area. At the time this analysis was prepared, the Small Business Administration (SBA) defined small agricultural service firms as those having annual receipts of less than $34,000,000 (North American Industry Classification System (NAICS) code 115114, Postharvest Crop Activities), and small agricultural producers of walnuts as those having annual receipts of less than $3,750,000 (NAICS code 111335, Tree Nut Farming) (13 CFR 121.201).

Data from USDA's National Agricultural Statistics Service (NASS), indicate a three-year average value of utilized inshell walnut production of $737.1 million for the most recent seasons for which data is available (2022 through 2024 crop years). Dividing that figure by the number of walnut growers (4,500) yields an average annual crop value per grower of approximately $163,787. This figure is well below the SBA small agricultural producer threshold of $3,750,000 in annual sales. Assuming a normal distribution, this provides evidence that a large majority of walnut growers would likely be considered small agricultural producers according to the SBA definition. Additionally, data from NASS's 2022 Agricultural Census show that 96 percent of California farms growing walnuts at the time had walnut sales of less than $1 million.

Further, based on information from the Board, approximately 78 percent of California's walnut handlers shipped assessable walnuts valued under $34 million during the 2023–2024 marketing year and would, therefore, be considered small handlers according to the SBA definition. Considering the above-mentioned information, it is reasonable to conclude that a substantial majority of both walnut growers and handlers would be considered small business entities according to current SBA definitions.

This final rule provides a defined payment schedule for required handler assessment payments, establishes interest and late payment charges on overdue handler assessments, and modifies the reporting requirements for walnut acquisitions. These changes were recommended by the Board to enhance the efficiency of the Board's administrative function.

The Board discussed alternatives to the recommendations contained in this rule, including different options for the reporting of walnut acquisitions, the timing of assessment payment installments, various late payment penalty rates, and the appropriate interest rate charged on unpaid assessments. The Board also considered making no changes and maintaining the Order's status quo. However, the Board recognized the financial and administrative inefficiencies inherent in the existing administrative provisions and believed that taking no action would have been imprudent. Further, the Board determined that the late penalty and the interest rate charge would serve to incentivize compliance with the Order's provisions without being excessive and burdensome.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, ''Vegetable and Specialty Crops.'' This final rule requires changes to the

Board's existing CWB Form #1. Further, this final action may result in additional report submissions from some handlers. However, the changes are minor and the currently approved burden for the form would only be minimally increased by these changes. The revised form has been submitted to OMB for approval.

This final rule may impose some additional reporting or recordkeeping requirements on either small or large California walnut handlers. However, the Board anticipates that the requirement to submit supplemental acquisition reports for walnuts that are acquired after the submission of the handler's initial CWB Form #1 report would only impact a small percentage of the total number of handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

A proposed rule concerning this action was published in the **Federal Register** on October 1, 2025 (90 FR 47248). Copies of the proposed rule were provided to all California walnut handlers. In addition, the proposal was made available through the internet by AMS and the Office of the Federal Register via *https://www.regulations.gov.* A 30-day comment period ending October 31, 2025, was provided to all interested persons to respond to the proposal. AMS received nine comments during the comment period. We address these comments below.

Of the comments received, five suggested modifications to either the payment schedule, late payment and interest charges, and/or grace period. The commenters did not self-identify as handlers or producers within the regulated production area. These commenters stated they understood the need to strengthen administrative requirements through the payment schedule and the late penalty and interest charges in order to incentive the timely collection of assessments and efficient operation of the Order. However, the comments expressed concern with the proposal, citing the potential economic impact the proposal would have on small businesses. Of the four remaining comments, two expressed support for the proposals, one recommended a more thorough burden analysis to demonstrate positive impacts on small producers, one did not address the merits of the proposal, and one raised concern about possible procedural deficiencies.

Commenters recommended the addition or extension of a grace period, a tiered penalty structure based on the handler size, lower penalty rates and interest charges, and/or a more flexible payment schedule. This rule includes a 60-day grace period before late penalties are assessed, which AMS and the Board view to be reasonable and appropriate to reduce financial burden, especially for small businesses. Additional time and the creation of a tiered penalty structure, as suggested by some commenters, would extend the grace period and delay payments further, potentially encouraging late payments. It may also result in different interest rates rather than a flat penalty fee of 1.5 percent, potentially raising fairness concerns among handlers and producers. In addition, payments being made at different intervals would increase administrative burden. The Board, which locally administers the Order, believes that applying the 60-day grace period and monthly penalty structure creates regulatory consistency across all handlers which it believes necessary to ensure timely and consistent payments for its efficient operation.

Prior to making its recommendation to amend the Order's administrative requirements, the Board met on two occasions to discuss the proposal's impact on industry handlers. The Board considered the regulatory impact on small businesses in formulating its recommendation. Ultimately, Board members representing small businesses unanimously supported the proposed changes, as evidenced by meeting minutes.

Moreover, AMS notes that this final rule aligns with other marketing orders that utilize late payment and interest charges as a standard business practice. AMS has reviewed the comments and ultimately concluded that the regulatory changes are appropriate, will enhance the efficient collection of assessments, and penalties will be administered proportionately, without bias, to all handlers regardless of size.

One comment raised concerns regarding the new reporting requirement and the extra paperwork burden that would be experienced by small businesses and one commenter suggested simplifying the acquisition report or offering technical assistance. While the action may impose some additional reporting and recordkeeping requirements on handlers who acquire walnuts after January 15, AMS anticipates that the change will have a minimal impact on burden, will only impact a limited number of handlers because acquiring additional walnuts is uncommon, will not impose an undue burden on small businesses specifically, and that modifying the reporting requirement is necessary for the efficient and equitable administration of the Order.

Lastly, one comment raised concerns about procedural deficiencies and lack of adherence to the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and Executive Order 12866 in the rulemaking process. Specifically, the commenter claims that AMS procedurally bypassed notice and comment, failed to present an analysis of the impacts on small businesses, and deprived interested parties a meaningful opportunity to comment. After reviewing the comment, AMS determined that all of the statutory and procedural requirements for rulemaking have been met regarding this action.

Contrary to the comment's assertions, AMS did not bypass notice and comment or invoke good cause. Interested persons had numerous opportunities to review pertinent information, present their views, and participate in the rulemaking process. AMS notes that in conducting all meetings publicly, the Board provided, rather than deprived, interested persons a meaningful opportunity to comment. In addition, AMS published a notice of proposed rulemaking in the **Federal Register** on October 1, 2025, that included a 30-day comment period, ending October 31, 2025.

The proposed rulemaking also included an Initial Regulatory Flexibility Analysis, pursuant to requirements set forth in the Regulatory Flexibility Act, that considered and detailed for the public's review the economic impact of this final rule on small entities. AMS has provided adequate opportunity for interested persons to consider the proposal and provide comments. This final rule follows the applicable procedures and is compliant with the Regulatory Flexibility Act and Administrative Procedure Act. The comment also asserted that the affected information collection was not clearly identified and that OMB approval is required. As stated in the proposed rule, this final rule reiterates the affected information collection as CWB Form #1 and that revised changes to the form are minor, do not significantly increase burden,

and that the form has been submitted to OMB. This final rule is compliant with information collection requirements under the Paperwork Reduction Act. Accordingly, AMS made no changes to the rule as proposed after review and consideration of all comments received.

Lastly, to address comments concerning Executive Order 12866, AMS reiterates that this final rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from the review process required by Executive Order 12866.

After consideration of all relevant material presented, including the information and recommendations submitted by the Board and other available information, AMS has determined that this final rule is consistent with and will effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 984 as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR Part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Add § 984.348 to subpart B to read as follows:

§ 984.348 Payment of assessments.

(a) Each handler shall pay assessments on walnut receipts reported by the handler pursuant to § 984.473(a) in three installments, invoiced by the Board, on January 31, April 30, and July 31 of each marketing year.

(b) Each handler shall pay assessments on walnut receipts reported by the handler pursuant to § 984.473(b), as requested by the Board, on demand.

■ 3. Add § 984.349 to subpart B to read as follows:

§ 984.349 Late payment and interest charges.

(a) The Board shall impose a late payment charge of ten percent (10%) on any handler whose assessment payment has not been received within sixty (60) days of the invoice date shown on the handler's assessment statement.

(b) Payments not received more than sixty (60) days after the invoice date shown on the handler's assessment statement shall be subject to a one and one-half percent (1.5%) interest charge per month. Interest shall be applied to the total outstanding assessment balance, including any late payment charge, at the end of each subsequent thirty (30) day period until final payment is made.

■ 4. Revise § 984.473 to read as follows:

§ 984.473 Report of walnut receipts.

(a) Each handler shall file a report of his or her walnut receipts from growers on or before January 15 of each marketing year on forms supplied by the Board.

(b) Each handler acquiring walnuts from growers after submission of their initial report of walnut receipts pursuant to paragraph (a) of this section shall file a revised report of walnut receipts by the 15th of the month following such receipt on forms supplied by the Board.

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2026–16723 Filed 8–14–26; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2025–N–1243]

Hematology and Pathology Devices; Reclassification of In Situ Hybridization Test Systems for Use With a Corresponding Approved Oncology Therapeutic Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final order reclassifying in situ hybridization (ISH) test systems indicated for use with a corresponding approved oncology therapeutic product (product codes NYQ, MVD, OWE, and PNK), all postamendments class III (premarket approval) devices, into class II (special controls), subject to premarket notification. FDA is also establishing a new device classification regulation, along with the special controls that are necessary to provide a reasonable assurance of safety and effectiveness of this device type.

DATES: This order is effective September 16, 2026. See further discussion in section IV, ''Implementation Strategy.''

FOR FURTHER INFORMATION CONTACT: Soma Ghosh, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3316, Silver Spring, MD 20993, 240–402–5333, *Soma.Ghosh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require approval of a premarket approval application (PMA), unless and until: (1) the Food and Drug Administration (FDA) reclassifies the device into class I or class II; or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of the procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and our implementing regulations (part 807, subpart E (21 CFR part 807, subpart E)).

A postamendments device that has been initially classified into class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.[1]

FDA relies upon ''valid scientific evidence,'' as stated in section 513(a)(3) of the FD&C Act and defined in 21 CFR

[1] See section 513 of the FD&C Act.

860.7(c)(2), in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies generally must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))). Section 520(h)(4) of the FD&C Act (21 U.S.C. 360j(h)(4)) provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include the descriptions of methods of manufacture and product composition and other trade secrets.[2]

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the requirements under section 510(k) of the FD&C Act if FDA determines that a premarket notification (510(k)) is not necessary to provide reasonable assurance of the safety and effectiveness of the device type.

On June 11, 2025, FDA published a proposed order[3] in the **Federal Register** (90 FR 24540) (''proposed order'') to reclassify in situ hybridization (ISH) test systems indicated for use with a corresponding approved oncology therapeutic product (product codes NYQ, MVD, OWE, and PNK)[4] (hereinafter referred to as oncology therapeutic ISH-based test systems) from class III to class II. FDA has considered the information available to the Agency, as described in the June 11, 2025, proposed order, and considered comments received from the public docket on the proposed order (as discussed in section II of this document), to determine that there is sufficient information to establish special controls to effectively mitigate the risks to health (updated as discussed in section II of this document). FDA has also determined based on this information that the special controls, together with general controls, provide a reasonable assurance of safety and effectiveness when applied to these devices.

Therefore, in accordance with section 513(f)(3) of the FD&C Act, FDA, on its own initiative, is issuing this final order to reclassify oncology therapeutic ISH-based test systems from class III to class II (special controls).[5] Absent the special controls identified in this final order, general controls applicable to the device type are insufficient to provide a reasonable assurance of safety and effectiveness. Specifically, general controls are insufficient to effectively mitigate the risks identified for this device type, such as the risk of false test results (*i.e.,* false positive and false negative test results), which may negatively influence treatment decisions for cancer patients—for example, by delaying access to an available and appropriate alternative therapy. FDA expects that the reclassification of these devices will enable more manufacturers to develop this type of device such that patients will benefit from increased access to oncology therapeutic ISH-based test systems for which there is a reasonable assurance of safety and effectiveness.

After the effective date of this order, for these class II devices, manufacturers may submit a premarket notification and obtain FDA clearance of the devices before marketing them, as opposed to having to submit a PMA and receive approval. This action will decrease regulatory burden on industry, as manufacturers will no longer have to submit a PMA for this type of device but can instead submit a 510(k) to the Agency for review prior to marketing their device. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately provides patients with more timely access to this type of device.

II. Comments on the Proposed Order and FDA Responses

A. Introduction

FDA received comments from fewer than 5 commenters on the proposed order published in the **Federal Register** on June 11, 2025. The comment period on the proposed order closed on August 11, 2025. The majority of the comments received by the close of the comment period came from members of the medical device industry. Some commenters provided multiple comments on one or more issues. All commenters provided support for the proposed reclassification with some comments also providing recommendations or proposed modifications for clarity.

We describe and respond to the comments in section II.B of this document. The order of the comments and our response to them is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received. Certain comments are grouped together under a single number because the subject matter is similar. Please note that in some cases we separated different issues discussed by the same commenter and designate them as distinct comments for purposes of our responses.

B. Description of Comments and FDA Response

(Comment 1) FDA received numerous comments supporting the proposed reclassification of oncology therapeutic ISH-based test systems, from class III to class II, subject to special controls. Citing, among other things, ISH as a long-established technology, commenters stated they believe that special controls could be established to provide reasonable assurance of the safety and effectiveness of these devices. In addition, commenters noted that the decreased regulatory burden resulting from the reclassification could increase development and availability of these tests, thus offering better diagnostic options for clinicians and improving patient access to diagnostics and therapies.

[2] Since the publication of the proposed order, data from one additional PMA and several PMA supplements have become available for consideration by FDA in accordance with section 520(h)(4) of the FD&C Act. FDA has determined that the data from the additional PMA and PMA supplements are cumulative of, and consistent with, the information addressed in the proposed order and do not raise any new or different questions regarding the safety and effectiveness of oncology therapeutic ISH-based test systems.

[3] FDA notes that the ''ACTION'' caption for the proposed order was styled as ''Proposed amendment; proposed order; request for comments,'' rather than ''Proposed order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of **Federal Register**'s (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

[4] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking of and easy reference to predicate device types. A medical device product code consists of a three-letter combination which associates a device's type with a product classification designated for the application. The three-digit classification product codes in CDRH's Product Classification Database carry no other significance. See FDA guidance titled ''Medical Device Classification Product Codes'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff*.

[5] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of **Federal Register**'s (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

(Response 1) FDA agrees with the comments supporting this reclassification. Based on the information the Agency considered and analyzed in proposing to reclassify these devices, as well as comments received in response to the proposed order, FDA has determined that reclassifying oncology therapeutic ISH-based test systems from class III (premarket approval) into class II (special controls) is appropriate. Specifically, based on the totality of information available, FDA has determined that general controls are insufficient to provide a reasonable assurance of safety and effectiveness for these devices and there is sufficient information to establish special controls for these devices that together with general controls will provide a reasonable assurance of safety and effectiveness. In addition, FDA also expects that the reclassification of these devices will enable more manufacturers to develop this type of device such that health care providers and patients will benefit from increased access to appropriately safe and effective tests.

(Comment 2) One commenter requested the Agency's guidance and further deliberation on these matters, either preceding or during a reclassification panel meeting.

(Response 2) FDA has determined that a classification panel is unnecessary to reclassify oncology therapeutic ISH-based test systems from class III to class II. Section 513(f)(3) of the FD&C Act provides that FDA may ask an appropriate panel to review information and make a recommendation before issuing an order reclassifying a postamendments device (see also 21 CFR 860.134(c)(2)). FDA is reclassifying these postamendments class III devices on its own initiative and does not believe a panel recommendation is needed to help determine whether these devices should be reclassified from class III to class II nor to identify appropriate special controls. FDA has determined, based on the information discussed in the preamble to the proposed order and FDA's consideration of public comments, that the standard in section 513(a)(1)(B) of the FD&C Act is met. Specifically, FDA has determined that general controls are insufficient to provide a reasonable assurance of safety and effectiveness, and there is sufficient information to establish special controls, which with general controls will provide a reasonable assurance of the safety and effectiveness when applied to these devices.

(Comment 3) One commenter expressed appreciation for the Agency's use of the least burdensome approach through discussion of predetermined change control plans (PCCPs) in the preamble to the proposed order. The commenter requested the Agency allow applicants to seek FDA's alignment on device-specific PCCPs via pre-submission rather than a pre-market notification and further requested that the Agency consider permitting PCCPs for a planned modification to already PMA-approved devices to include artificial intelligence (AI)/machine learning (ML) driven digital pathology (DP) algorithms intended to aid the end user or seek aid from the end user for end result generation, via PCCPs.

(Response 3) The new classification regulation at § 864.1890 (21 CFR 864.1890) applies to previously approved oncology therapeutic ISH-based test systems and new devices that are determined to be substantially equivalent. We note that, at the time of publication of this final order, FDA has not classified, cleared, approved, or granted authorization for any oncology therapeutic ISH-based test systems that incorporate DP devices, including AI/ML algorithm-assisted DP devices.

As described in the preamble of the proposed order, manufacturers may wish to use PCCPs as a way to implement future modifications to their devices without needing to submit a new 510(k) for each significant change or modification [6] while continuing to provide reasonable assurance of device safety and effectiveness. FDA reviews a PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP (see section 515C of the FD&C Act (21 U.S.C. 360e-4)). Thus, FDA's consideration of a device-specific PCCP, and the determination of whether the inclusion of a device modification, to include a modification to an AI/ML-enabled device via a PCCP is appropriate, will be based on the Agency's review and consideration of the information submitted at the time of a premarket submission. FDA encourages manufacturers to leverage the Q-Submission program to obtain FDA feedback on their approach to using a PCCP for a device prior to submitting a marketing submission. Additional information regarding the Q-Submission program can be found in FDA's final guidance document titled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 1). For additional information regarding marketing submissions that include a PCCP for AI/ML-enabled devices, see FDA's guidance, ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions'' (Ref. 2).

(Comment 4) One comment recommended the Agency reference and ''include the principles'' of FDA's guidance, ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices'' in this final order.

(Response 4) FDA appreciates this comment and acknowledges that the guidance ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices'' may be applicable under certain circumstances to oncology therapeutic ISH-based test systems (Ref. 3). When evaluating the applicability of this guidance to specific modifications to a particular test system, interested parties should follow the logic scheme and recommendations contained in the guidance.

(Comment 5) One commenter requested several changes to the proposed classification regulation. The commenter recommended revising the proposed codified text for § 864.1890 by adding a new paragraph titled ''Device Description and Principle of Operation,'' as § 864.1890(b). The suggested language would require, presumably in a submission to FDA and/or in the device labeling, detailed elements of a device's intended use/indication for use including specifications for the intended use population(s), biomarker lists, specimen type(s), system components, biomarker definitions as used in the therapeutic product trials and as detected by the test, along with the corresponding therapeutic product(s) or therapeutic product group, and a description of whether the device is qualitative, semi-quantitative, or quantitative. The commenter also proposed renumbering the identification provision as paragraph (a) and classification provision as paragraph (c).

The commenter also recommended adding a new labeling special control, to be incorporated as § 864.1890(c)(2)(i), which would require § 809.10 (21 CFR 809.10) compliant labeling and any product information and test output generated to include the intended use statement as outlined in the commenter's proposed § 864.1890(b).

(Response 5) While FDA agrees that labeling special controls, in addition to general controls, are needed to assure the safety and effectiveness of oncology therapeutic ISH-based test systems, FDA

[6] For the purpose of this final order reference to ''modification'' means a significant change or modification that would generally require a new premarket notification under § 807.81(a)(3).

disagrees that the commenter's proposed edits to § 864.1890 are necessary. FDA believes the labeling special controls proposed by the Agency, in combination with the applicable general controls, which include general in vitro diagnostic (IVD) product labeling requirements under § 809.10, are sufficient for the labeling of this device type.

FDA declines to adopt the proposed revisions at § 864.1890(b) to the codified text. Much of this information is already required to be submitted to FDA under existing general controls. For example, § 809.10(b)(2) requires the type of procedure to be included in labeling (*e.g.,* qualitative or quantitative) and § 807.87(e) requires submission of the device's proposed labeling as part of a 510(k). FDA does not believe that an additional requirement mandating submission of all of this information is necessary for all devices in this device type. Moreover, and as discussed further below, FDA does not believe all of this information needs to be included in the device's intended use/indications for use statement found in the device's labeling to provide reasonable assurance of the safety and effectiveness of these devices. Accordingly, FDA is not adding the proposed paragraph to § 864.1890, nor is FDA renumbering the identification and classification paragraphs as proposed.

FDA also declines to incorporate the commenter's proposed edits to the labeling special control. The suggested revisions would require labeling to include an intended use statement referencing the commenter's proposed § 864.1890(b), which FDA is not adopting for the reasons described in the previous paragraph. Moreover, the commenter's suggested requirements duplicate or overlap with existing regulatory requirements under § 809.10 and part 801 (21 CFR part 801), as well as the labeling elements already encompassed by the Agency's proposed special controls. The Agency's proposed special controls, along with applicable statutory and regulatory requirements, address all of the necessary intended use statements and operational descriptions (*e.g.,* summary and explanation of the test) that are to be included in labeling, without the need for the additional codified requirements. FDA believes the special controls, as finalized, along with general controls, will ensure the device's risks to health are appropriately mitigated and provide a reasonable assurance of the safety and effectiveness of oncology therapeutic ISH-based test systems.

(Comment 6) One comment acknowledged the suitability of the analytical performance tests outlined in the proposed order but recommended that FDA consider incorporating surrogate samples for use in the precision/reproducibility data generation, where the sample type can be supported as representative. This would apply to situations where sufficient clinical specimens for the intended use specimen type(s) are unavailable for analytical validation testing. The comment stated that such an inclusion would facilitate manufacturers' ability to conduct adequate verification testing by using surrogate samples that are morphologically comparable to the intended-use clinical specimens.

(Response 6) Based on the information FDA considered and analyzed in proposing to reclassify these devices, as well as comments received in response to the proposed order, FDA acknowledges that certain exceptional clinical circumstances may warrant consideration of alternative approaches to the use of clinical specimens for the purpose of analytical validation testing (*e.g.,* rare cancer(s) or tumor type(s) where obtaining sufficient clinical specimens presents a significant challenge). However, FDA maintains that precision studies represent a fundamental device performance requirement that is essential for demonstrating analytical performance and ensuring consistent and reliable device function. Upon further consideration, FDA has decided to modify the special control related to this comment (see § 864.1890(b)(1)(v)) to consider surrogate samples that adequately represent the intended use specimen type(s) and intended use biomarker(s), as appropriate, as determined by FDA, to supplement clinical specimens. For example, FDA will determine the appropriateness of surrogate samples based on clinical and scientific data and/or justification available to the Agency.

In addition to the above modification, FDA, based in part on the comments received, has also removed the special control requiring device performance data demonstrating appropriate reagent stability. Upon further review of the information the Agency considered and analyzed in proposing to reclassify these devices, such as postmarket safety data from medical device reports and recalls, as well as comments received on the proposed special controls, FDA believes that a special control requiring reagent stability data is not necessary and that general controls, such as premarket notification (510(k)) requirements and quality system requirements set forth under part 820 (21 CFR part 820) are sufficient to ensure that reagents are appropriately assessed and labeled such that this special control is not necessary. As such, the Agency is removing proposed § 864.1890(b)(1)(viii).

(Comment 7) One comment recommended FDA revise the ''Identification'' language of proposed § 864.1890 to include the term ''companion.''

(Response 7) FDA disagrees with the recommended edit and is finalizing the identification language in this final order without change. The comment did not provide context to support the suggested revision, and FDA continues to believe that the identification, as proposed, provides an appropriate level of clarity regarding the type of device intended to fall within the scope of § 864.1890.

(Comment 8) One comment expressed a desire to work with the Agency to address nuanced clinical performance adequacy scenarios as potentially applicable to future devices either via a pre-submission route or alternative mechanism.

(Response 8) FDA agrees that questions of this nature may be appropriate topics to discuss with the Agency through the Q-Submission program. Prior to submission, a sponsor may seek FDA input on specific questions regarding review topics relevant to a planned marketing submission by utilizing our Q-Submission program. Through the Q-Submission program FDA may provide input on device-specific requirements and recommendations intended to support a marketing submission. Additional information regarding the Q-Submission program can be found in FDA's final guidance document titled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 1).

Sponsors may also review information on FDA's Center for Devices and Radiological Health's (CDRH) website regarding previously approved oncology therapeutic ISH-based test systems, such as Summary of Safety and Effectiveness Data (SSED) documents available in FDA's Premarket Approval Database,[7] which detail the clinical evidence, risks, and benefits for medical devices. Additionally, sponsors may consider reviewing CDRH's 510(k) Decision Summaries, found in FDA's 510(k) Premarket Notification Database,[8] which summarize the information that informed the Agency's substantial

[7] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.*

[8] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.*

equivalence decision and that may help inform interested parties regarding FDA's thinking on the types of performance the Agency might expect for this type of device. Sponsors also should refer to the special controls codified at § 864.1890, established as part of this final order, which set forth requirements that are necessary to provide a reasonable assurance of safety and effectiveness for these devices. Comments related to a sponsor's study- or device-specific questions are outside the scope of this final order.

(Comment 9) One comment requested that FDA evaluate other devices and therapies with comparable risk profiles to determine whether reclassification may be appropriate, with the goal of broadening availability of such devices. The comment also requested that FDA review and update the special controls for oncology therapeutic ISH-based test systems on a regular basis and ensure that clinical data supporting the development and implementation of the special controls is transparent and readily available to interested parties.

(Response 9) The FDA periodically reviews the classification of devices to ensure they are being regulated in the appropriate class (class III, II, I) with the necessary level of regulatory controls. CDRH has previously undertaken reclassification efforts as part of the Center's systematic approach, including the 2014–2015 Strategic Priorities,[9] and as part of CDRH's regular due diligence in considering the specific classification for a particular device type. Additionally, in 2024, CDRH announced its intent to initiate the reclassification process for most high risk IVD devices, reflecting this ongoing, systematic approach to ensuring appropriate classification.[10] FDA intends to continue evaluating the classification of devices to ensure they are subject to the appropriate level of regulatory controls.

Further, FDA acknowledges the comment's request that the Agency regularly review and update the special controls and ensure transparency. For class II devices, special controls are established to provide reasonable assurance of safety and effectiveness for the device type and are developed based on the totality of available scientific evidence at the time of classification or reclassification. As new information becomes available, including advances in scientific knowledge and changes in device technology, FDA may evaluate whether such developments and device modifications give rise to new benefit-risk considerations such that new or different special controls, in addition to general controls, are needed to assure the safety and effectiveness for the device type.

With respect to transparency, FDA strives to make publicly available the scientific basis for its regulatory decisions, consistent with applicable statutes and regulations. In general, the clinical and scientific information that forms the basis of the special controls is included in the public docket associated with the classification or reclassification action, to the extent permitted by law. FDA, therefore, believes that the current regulatory framework provides an appropriate mechanism for ensuring the relevance of special controls and the availability of supporting information. No changes to the final order have been made in response to this comment.

(Comment 10) One comment proposed edits to Table 1. Risks to Health and Mitigation Measures in the proposed order. The comment proposed additional mitigation measures to each of the three identified risks to health to include, for example, the addition of ''*Device Description and Principle of Operation*'' and ''*Implementation of Controls, procedures and user training requirements.*''

(Response 10) As discussed in response to comment 5, FDA disagrees that such line edits or clarifications are needed to the mitigations identified in the proposed order. The mitigation measures proposed to be added to table 1 correspond to this commenter's proposed additions to the codified, as described in comment 5. As noted in response to comment 5, the language proposed by the commenter is generally already covered for oncology therapeutic ISH-based test systems by the regulatory requirements for IVDs under part 801 and § 809.10, as well as the Agency's proposed special controls. FDA believes that the special controls set forth in the proposed order with the changes identified in this final order (see comment 5 and the Agency's response), together with general controls, are sufficient to effectively mitigate the risks to health identified in section V of the proposed order and are necessary to provide a reasonable assurance of the safety and effectiveness of oncology therapeutic ISH-based test systems. For these reasons, we decline to incorporate the proposed edits.

With regards to the commenter's recommendation to include ''*Implementation of Controls, procedures and user training requirements*'' in table 1 of the proposed order, FDA also disagrees that this is necessary. FDA believes that the commenter's proposed requirement is already encompassed within the Agency's proposed special controls. Specifically, this proposed recommendation falls within certain design verification and validation activities required by the special controls under § 864.1890(b)(1)(i) which indicates that ''[s]*pecification for risk mitigation elements intended to mitigate risks associated with testing and results interpretation, including controls, procedures, and user training requirements, as appropriate.*''

(Comment 11) One comment requested clarification on how FDA's determination that devices under the relevant oncology therapeutic ISH-based test system product codes share similar purposes, designs, functions, and risk profiles would affect their use as predicate devices under the 510(k) pathway. The commenter also sought general guidance on how substantial equivalence would be evaluated in cases where a device's intended use or labeling is expanded, such as to include a new oncology therapeutic product, clinical indication, or clinical cut-off.

(Response 11) FDA acknowledges the commenter's request for clarification regarding the implications of this reclassification on the use of these devices as predicates under the 510(k) pathway. While the Agency has determined that devices within the relevant product codes share similar purposes, designs, functions, and overall risk profiles for purposes of reclassification, this determination does not alter the statutory and regulatory requirements applicable to demonstrating substantial equivalence. For a new device to be considered substantially equivalent to a predicate device, the new device must have the same intended use as the predicate device and the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness than the predicate device. Additional information can be found in FDA's final guidance ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' (Ref. 4).

In accordance with section 513(i) of the FD&C Act and part 807, substantial equivalence determinations are made on a case-by-case basis and depend on the specific intended use and technological characteristics of the device under review. Any oncology therapeutic ISH-based test system with a new intended use or technological characteristics that raise different questions of safety and

[9] See 81 FR 52445.

[10] See *https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-intent-initiate-reclassification-process-most-high-risk-ivds.*

effectiveness compared to legally marketed devices would generally not be found to be substantially equivalent. However, devices could be used as predicate devices to support a substantial equivalence determination when a device has a new clinical cut-off or a new indication for use that includes a new therapeutic product if adequate data and information are provided to demonstrate the new indication(s) for use fall within the intended use of the predicate device and any technological differences do not raise different questions of safety and effectiveness. If a manufacturer has a question regarding a specific device for which they intend to seek marketing authorization, the manufacturer may choose to utilize the Q-Submission Program to seek feedback on the appropriate regulatory pathway for modified devices. Additional information regarding the Q-Submission program can be found in FDA's final guidance document titled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 1).

(Comment 12) One comment requested that the Agency clarify that devices already on the market would be automatically reclassified into class II without the need for any additional premarket notification or submission, and that only future devices, or currently marketed devices with significant modifications, would be required to submit a premarket notification.

(Response 12) FDA appreciates the need to provide clarification on the implementation of this final order. To provide such clarification and assist in the efficient implementation of this final order, the Agency has added an implementation strategy in section IV of this final order. Among other things, section IV clarifies that upon its effective date the final order reclassifies devices that are oncology therapeutic ISH-based test systems as described within the scope of the proposed order and adopted as part of this final order, from class III (premarket approval) into class II (special controls). Oncology therapeutic ISH-based test systems with prior PMA approval may continue to be marketed per the previous marketing authorization and would not require an additional marketing application. For changes or modifications that could significantly affect the safety or effectiveness of such devices or a major change or modification in the intended use of such devices (see § 807.81(a)(3)), FDA expects that manufacturers will submit a 510(k) for the modified device.

(Comment 13) One comment encouraged FDA to issue a detailed guidance regarding the special controls described in the proposed order at the same time as the publication of this final order in the **Federal Register**.

(Response 13) At this time, FDA does not intend to issue a guidance document regarding compliance with the special controls identified in this final order. For the reasons discussed in the proposed order, the Agency believes that the special controls, as stated in § 864.1890(b), provide sufficiently clear and appropriate requirements, at a level of detail necessary to reasonably assure the safety and effectiveness of this device type. Should FDA determine in the future that further information is warranted, the Agency may consider issuing guidance. The Agency also believes information available to sponsors through other resources will be helpful in preparing 510(k)s for submission and complying with special controls. For example, sponsors may review information on CDRH's website regarding previously approved oncology therapeutic ISH-based test systems such as SSED documents available in FDA's Premarket Approval Database, which detail the clinical evidence, risks, and benefits for approved devices. In addition, the performance data and related valid scientific evidence included in 510(k)s reviewed by FDA may be a helpful resource. Once available, sponsors may consider reviewing the 510(k) Decision Summaries in FDA's 510(k) Premarket Notification Database to inform the types of performance the Agency expects for this type of device.

III. The Final Order

In this final order, FDA is adopting relevant findings, including the reasoning that supports those findings, from the June 11, 2025, proposed order. FDA has made revisions in this final order based, in part, on the comments received (see section II). FDA is issuing this final order to reclassify oncology therapeutic ISH-based test systems from class III into class II under a new device classification regulation with the name In Situ Hybridization Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product, and to establish special controls by revising 21 CFR part 864 (adding § 864.1890).

Further, in this final order, FDA has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, along with general controls, provide a reasonable assurance of the safety and effectiveness for oncology therapeutic ISH-based test systems. As described in section II of this document, FDA has made revisions to the special controls as previously described in the proposed order. Based, in part, on comments regarding the proposed order, FDA has revised the design verification and validation special controls to add to the existing proposed § 864.1890(b)(1)(v) requirement the consideration of surrogate samples that adequately represent the intended use specimen type(s) and intended use biomarker(s), as appropriate, as determined by FDA, to supplement clinical specimens. Additionally, FDA has removed the proposed § 864.1890(b)(1)(viii) requiring device performance data demonstrating reagent stability.

Based on the information discussed in the preambles to the proposed order and this final order, including the comments received for the proposed order, FDA concludes that special controls, in addition to general controls, provide a reasonable assurance of the safety and effectiveness of oncology therapeutic ISH-based test systems. In this final order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, along with general controls, provide a reasonable assurance of the safety and effectiveness of these devices. In addition, in this final order, to provide additional clarification and to efficiently implement this order, the Agency has added an implementation strategy in section IV.

Under the FD&C Act, 510(k) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m).[11] FDA has not made this determination for oncology therapeutic ISH-based test systems and, therefore, this class II device type is not exempt from 510(k) requirements. Thus, under sections 510(k) and 513(f) of the FD&C Act, persons who intend to market this device type must submit a 510(k) containing information on the

[11] In considering whether to exempt class II devices from premarket notification, FDA considers whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA generally considers the factors initially identified in 63 FR 3142 (January 21, 1998) and further explained in FDA's guidance ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff,* to determine whether premarket notification is necessary for class II devices. FDA also considers that even when exempting devices from the 510(k) requirements, these devices would still be subject to certain limitations on exemptions, for example, the general limitations set forth in 21 CFR 864.9.

oncology therapeutic ISH-based test system that they intend to market and must obtain FDA clearance of the device prior to marketing it.

Under this final order, oncology therapeutic ISH-based test systems are prescription use IVD devices and as such, these tests must satisfy prescription labeling requirements for IVD products (see § 809.10(a)(4) and (b)(5)(ii)). This device type is subject to the submission and device clearance requirements of sections 510(k) and 513 of the FD&C Act and of part 807, subpart E, of FDA's regulations.

IV. Implementation Strategy

This final order is effective 30 days after the date of its publication in the **Federal Register**.

For oncology therapeutic ISH-based test systems that have not been offered for sale prior to the effective date of the final order, manufacturers must obtain 510(k) clearance before marketing the device (and for subsequent modifications to the device, as appropriate).

For oncology therapeutic ISH-based test systems that have been offered for sale prior to the effective date of the final order and have prior PMA approval, such devices may continue to be marketed under the previously issued PMA approval and do not require an additional marketing authorization.

For devices that have been legally marketed via PMA before the effective date of this final order, FDA expects that manufacturers will submit a 510(k) premarket notification when making a change or modification that could significantly affect the safety or effectiveness of the device or a major change or modification in the intended use of the device. See § 807.81(a)(3).

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final administrative order refers to previously approved collections of information found in FDA regulations. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 (Investigational Device Exemptions) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E (Premarket Approval of Medical Devices) have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E (Premarket Notification Procedures) have been approved under OMB control number 0910–0120; and the collections of information in parts 801 and 809 (Device Labeling) have been approved under OMB control number 0910–0485.

VII. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3) of the FD&C Act, we are codifying in this final order the classification of In Situ Hybridization Test Systems for Use with a Corresponding Approved Oncology Therapeutic Product in the new § 864.1890, under which these oncology therapeutic ISH-based test systems are reclassified from class III into class II.

VIII. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and Food and Drug Administration Staff,'' May 29, 2025. (Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.*)
2. FDA, ''Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions; Guidance for Industry and Food and Drug Administration Staff,'' August 18, 2025. (Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.*)
3. FDA, ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff,'' August 17, 2022. (Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/replacement-reagent-and-instrument-family-policy-in-vitro-diagnostic-devices.*)
4. FDA, ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]; Guidance for Industry and Food and Drug Administration Staff,'' July 28, 2014. (Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.*)

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 864.1890 to subpart B to read as follows:

§ 864.1890 In situ hybridization test systems for use with a corresponding approved oncology therapeutic product.

(a) *Identification.* In situ hybridization (ISH) test systems indicated for use with a corresponding approved oncology therapeutic product are identified as prescription in vitro diagnostic devices consisting of nucleic acid probes intended for the qualitative or quantitative detection of specific nucleic acid sequences in human clinical specimens to provide information related to the use of a corresponding approved oncology therapeutic product as described in the corresponding approved oncology therapeutic product labeling.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) Specification for risk mitigation elements intended to mitigate risks

associated with testing and results interpretation, including controls, procedures, and user training requirements, as appropriate.

(ii) Specification of the criteria for test result interpretation and reporting, including device cut-off(s) (*i.e.,* clinical threshold(s) or the medical decision point(s) between positive and negative results) or other relevant criteria that distinguishes positive and negative or quantitative results. This information must include the rationale for the chosen cut-off(s) to include the upper reference of normal, or other relevant criteria and results supporting validation of the cut-off(s) evaluating borderline samples around the clinical threshold(s). Scoring criteria for all applicable signals must be included.

(iii) Device performance data demonstrating appropriate analytical sensitivity from studies using interphase nuclei from intended use specimen type(s) that are considered karyotypically normal, or through an alternative approach, as determined to be appropriate by FDA (*e.g.,* probe sensitivity and probe limits).

(iv) Device performance data demonstrating appropriate analytical specificity of the device for the intended use specimen type(s), as determined to be appropriate by FDA (*e.g.,* probe specificity, interference study, cross-reactivity and cross contamination testing).

(v) Device performance data demonstrating appropriate precision and reproducibility of the device using clinical specimens representing the intended use specimen type(s) and intended use biomarker(s) from the intended use population and investigating major sources of variability (*e.g.,* multiple reagent lots, operators, instruments over multiple days, and inter- and intra-reader precision). Surrogate samples that adequately represent the intended use specimen type(s) and intended use biomarker(s) may be appropriate, as determined by FDA, to supplement clinical specimens. If the device will be used at more than one site, data must demonstrate adequate reproducibility across multiple intended use sites. Additionally, precision and reproducibility of the device must be evaluated with specimens near the clinical decision threshold(s) and near the limits of reportable range. Additionally, device performance data demonstrating appropriate precision must be included from studies evaluating the different signals and associated cut-offs and controls, as determined to be appropriate by FDA. Furthermore, precision of the device must be evaluated per specimen and in aggregate.

(vi) Device performance data demonstrating appropriate device robustness, as determined to be appropriate by FDA. The study must assess the tolerance ranges for various critical test and specimen parameters, as applicable.

(vii) Device performance data demonstrating linearity of quantitative results using samples covering the device measuring range, as applicable.

(viii) Device performance data demonstrating appropriate specimen stability based on the intended use specimen type(s) of the device, as applicable.

(ix) Clinical data generated using well-characterized clinical specimens representative of the intended use population demonstrating appropriate clinical performance of the device for its intended use, as determined to be appropriate by FDA.

(2) Labeling must include:

(i) An appropriate summary, as determined by FDA, of the performance studies performed and the results of those studies, including those that relate to all design verification and validation special controls.

(ii) A limiting statement, as appropriate, that explains that the test results are intended to be interpreted by a qualified or appropriately trained reader in conjunction with other diagnostic laboratory test results and/or pathology test results, relevant clinical information, and proper controls.

(iii) Language indicating that the test system is indicated for use with a corresponding FDA-approved oncology therapeutic product and device labeling must be consistent with the information set forth in the corresponding FDA-approved oncology therapeutic product labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16727 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2024–0007; T.D. TTB–206; Ref: Notice No. 235]

RIN 1513–AD08

Establishment of the Columbia Hills Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the 29,387-acre ''Columbia Hills'' American viticultural area (AVA) in Klickitat County, Washington. The newly established AVA is located entirely within the existing Columbia Valley viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: This final rule is effective September 16, 2026.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at *https://www.regulations.gov/docket/TTB-2024-0007.*

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury (Secretary) to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated certain administrative and enforcement authorities to the TTB Administrator through Treasury Order 120–01.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission to TTB of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and, once approved, a name and a delineated boundary codified in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and allows any interested party to petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions to establish or modify AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA;
- If the proposed AVA is to be established within, or overlapping, an existing AVA, an explanation that both identifies the attributes of the proposed AVA that are consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct from the existing AVA and therefore appropriate for separate recognition;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Columbia Hills Petition

TTB received a petition to establish the ''Columbia Hills'' AVA submitted on behalf of the owner of Cascade Cliffs Vineyard and Winery, which is located within the proposed AVA. The proposed Columbia Hills AVA is located in Klickitat County, Washington, and is entirely within the established Columbia Valley AVA (27 CFR 9.74). Within the proposed AVA, there are approximately 338 acres of vineyards owned by 19 different property owners, as well as 4 wineries. The distinguishing features of the proposed Columbia Hills are its topography, soils, and climate.

The proposed AVA is situated on the southern slopes of the Columbia Hills, a 35-mile-long ridgeline that parallels the north side of the Columbia River between Rowena Gap and the mouth of Rock Creek in Klickitat County, Washington. Erosion of the generally flat-lying layers of bedrock by ice-age flooding created a series of south-facing stepped terraces within the proposed AVA. Large, gently-sloped gravel bars deposited by ice-age floods also exist within the proposed AVA. The petition states that these gently-sloped terraces and gravel bars provide excellent locations for vineyards within the otherwise steeply sloped valley of the Columbia River.

The soils of the proposed Columbia Hills AVA are divided into two main soil map units—the Cheviot—Horseflat—Rockly—Kiona unit, which is described as ''well-drained soils that formed in colluvium and residuum derived from basalt mixed with loess;'' and the Ewall-Dallesport-Rock Outcrop unit, which consists of wind-deposited sand that was draped over the bedrock and gravel bars that were left behind when the ice-age floods ceased. The soils of the proposed AVA are well drained to excessively well drained and are typically much coarser than the loess-based soils that are common elsewhere in the Columbia River basin. The petition states that the coarse soils warm more quickly than finer soils and encourage vines to root deeply.

According to the petition, 80 percent of the land in the proposed Columbia Hills AVA is within a mile of the Columbia River, which acts as a thermal reservoir to moderate the climate near its shores. Due to its proximity to the river, the proposed AVA generally has warmer growing season temperatures than the surrounding regions, particularly during the early morning hours. Average growing season temperatures within the proposed AVA range from 63.9 to 67.7 degrees Fahrenheit (F), with average growing season maximum temperatures between 74.5 and 80.2 degrees F and average growing season minimum temperatures between 53 and 55.3 degrees F.

The average number of frost-free days within the proposed AVA ranges between 194 and 254 days. The average number of growing degree days (GDDs) [1] ranges from 3,091 to 3,588. Average annual rainfall amounts within the proposed AVA are generally between 10 and 20 inches. The petition states that the warm climate of the proposed AVA aids and accelerates the ripening of grapes and allows for the cultivation of warmer climate grape varietals such as Grenache and Mourvedre.

To the north of the proposed AVA, the topography is much steeper, higher, and less impacted by ice-age flooding than the proposed AVA. Soils are generally deep and derived from loess. Growing season average temperatures are lower, ranging from 57 to 59.5 degrees F, as are average growing season maximum and minimum temperatures, which range from 72 to 77 degrees F and 42 to 43 degrees F, respectively. Average annual GDD accumulations to the north of the proposed AVA are also lower, ranging from 1,834 to 2,309 GDDs. The average frost-free period to the north ranges from 142 to 164 days.

To the east of the proposed Columbia Hills AVA is the established The Burn of Columbia Valley AVA (27 CFR 9.276), which is relatively flat and has higher elevations that were less impacted by ice-age floods. The soils are primarily from the Van Nostern—Morrow—Bakeoven soil unit and contain large amounts of loess. Annual precipitation rates average less than 10 inches.

South of the proposed AVA, elevations are generally lower and the slopes have a northerly aspect. Soils are generally deep and derived from loess.

[1] *See* Albert J. Winkler et al., *General Viticulture* (Berkeley: University of California Press, 2nd ed.), pages 61–64 (1974). In the Winkler climate classification system, annual heat accumulation during the growing season, measured in annual GDDs, defines climatic regions. One GDD accumulates for each degree Fahrenheit (F) that a day's mean temperature is above 50 degrees F, the minimum temperature required for grapevine growth.

Temperatures are lower than within the proposed AVA, with average growing season temperatures ranging from 58 to 59.7 degrees F. Average annual maximum and minimum growing season temperatures range from 70 to 75 degrees F and 44 to 46 degrees F, respectively. The average frost-free period ranges from 163 to 174 days, and annual GDD accumulations range from 2,006 to 2,255 GDDs.

West of the proposed Columbia Hills AVA is the established Columbia Gorge AVA (27 CFR 9.178), which has higher elevations and a more diverse topography. Soils within the established Columbia Gorge AVA are also more diverse than within the proposed AVA due to large variations in bedrock, elevation, and slope angles. Temperatures are lower to the west of the proposed AVA, with average growing season temperatures ranging from 58.7 to 62 degrees F. Average GDD accumulations range from 2,107 to 2,647 GDDs.

Notice of Proposed Rulemaking and Comments Received

TTB published Notice No. 235 in the **Federal Register** on December 5, 2024 (89 FR 96623), proposing to establish the Columbia Hills AVA. In the notice, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features of the proposed AVA. The notice also included the information from the petition comparing the distinguishing features of the proposed AVA to the surrounding areas. For a detailed description of the evidence and for a detailed comparison of the proposed AVA to the surrounding areas, see Notice No. 235.

In Notice No. 235, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. In addition, given the proposed Columbia Hills AVA's location within the Columbia Valley AVA, TTB solicited comments on whether the evidence submitted in the petition sufficiently differentiates it from the established AVA. TTB also requested comments on whether the features of the proposed AVA are so distinguishable from the established AVA that the proposed AVA should no longer be part of the established AVA. The comment period closed February 3, 2025.

TTB received five comments in response to Notice No. 235, four of which specifically support the proposed AVA. One comment from a representative of V75 Vineyard (comment 4) describes the area as having a unique terroir distinct from other grape growing areas in the northwest. Another representative of V75 Vineyard (comment 2) describes the winds, growing degree days, and geology as unique features that support distinguishing this area within the larger Columbia Valley AVA. This commenter also notes the appropriateness of the AVA name for this region. The supporting comments from V75 Vineyard representatives (comments 2, 4, and 5) also express the view that establishing the proposed AVA will provide economic benefits to the region, helping support and market the region's vineyards and wines. A separate comment (comment 3) describes the proposed AVA as ''one of the most interesting grape-growing/viticultural areas identified in years.''

The remaining comment (comment 1) expressed neither support nor opposition to the proposed AVA and just asked whether the proposed ''Columbia Hills'' name might be confused with the established Columbia Valley AVA. TTB notes that, as described more fully in the Notice No. 235, the petition provided evidence that the area of the proposed AVA is known by the name ''Columbia Hills'', which is reflected in the Columbia Hills Natural Area Preserve and Columbia Hills Historical State Park. TTB did not receive any comments in response to Notice No. 235 questioning the sufficiency of the name evidence. As noted below in the section ''Impact on Current Wine Labels,'' because the Columbia Hills AVA is situated within and maintains features consistent with the Columbia Valley AVA, vintners will be able to use ''Columbia Hills,'' ''Columbia Valley,'' or both as appellations of origin for wines made primarily from grapes grown within the Columbia Hills AVA if the wines meet the eligibility requirements for these appellations. As with the establishment of any AVA, the extent to which wine consumers recognize the name of the AVA and associate the name with certain features of the wine depends upon the efforts of vineyard owners and winemakers in the region, which are factors beyond the establishment of the AVA.

TTB Determination

After careful review of the petition and the comments received in response to Notice No. 235, TTB finds that the evidence provided by the petitioner supports establishing the Columbia Hills AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and parts 4 and 9 of the TTB regulations, TTB establishes the ''Columbia Hills'' AVA in Klickitat County, Washington, effective 30 days from the publication date of this document.

TTB has also determined that the Columbia Hills AVA will remain part of the established Columbia Valley AVA. As discussed in Notice No. 235, the Columbia Hills AVA shares some broad characteristics with the established AVA. For example, the proposed AVA and the Columbia Valley AVA both have growing seasons longer than 150 days, limited annual rainfall amounts, and GDD accumulations generally over 2,000. Unlike the surrounding Columbia Valley AVA, however, the proposed Columbia Hills AVA is not a large, treeless basin. Instead, the proposed AVA is a region of hillslopes and flood-carved terraces within a deeply incised river valley.

Boundary Description

See the narrative description of the boundary of the Columbia Hills AVA in the regulatory text published at the end of this final rule.

Maps

The petitioners provided the required maps, and they are listed below in the regulatory text. The Columbia Hills AVA boundary may also be viewed on the AVA Map Explorer on the TTB website, at *https://www.ttb.gov/regulated-commodities/beverage-alcohol/wine/ava-map-explorer.*

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

With the establishment of the Columbia Hills AVA, its name,

''Columbia Hills,'' will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the regulation clarifies this point. Consequently, wine bottlers using the name ''Columbia Hills'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the AVA name as an appellation of origin.

The establishment of the Columbia Hills AVA will not affect the existing Columbia Valley AVA, and any bottlers using ''Columbia Valley'' as an appellation of origin or in a brand name for wines made from grapes grown within the Columbia Valley AVA will not be affected by the establishment of this new AVA. The establishment of the Columbia Hills AVA will allow vintners to use ''Columbia Hills,'' ''Columbia Valley,'' or both as appellations of origin for wines made primarily from grapes grown within the Columbia Hills AVA if the wines meet the eligibility requirements for these appellations.

Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866, as amended. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this final rule.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Add § 9.301 to read as follows:

§ 9.301 Columbia Hills.

(a) *Name.* The name of the viticultural area described in this section is ''Columbia Hills''. For purposes of part 4 of this chapter, ''Columbia Hills'' is a term of viticultural significance.

(b) *Approved maps.* The two United States Geological Survey (USGS) 1:100,000 scale topographic maps used to determine the boundary of the viticultural area are as follows:

(1) Hood River OR–WA, 1982; and

(2) Goldendale, WA–OR, 1980.

(c) *Boundary.* The Columbia Hills viticultural area is located in Klickitat County, Washington. The boundary of the Columbia Hills viticultural area is as described as follows:

(1) The beginning point is on the Hood River map at the intersection of the northern shoreline of the Columbia River and an unnamed creek due east of the marked ''Cold Spring.'' From the beginning point, proceed northerly along the unnamed creek to its intersection with the 300-meter elevation contour; then

(2) Proceed east along the 300-meter elevation contour to the eastern boundary of the Hood River map; then

(3) Proceed north along the map boundary for approximately 400 feet; then

(4) Proceed east onto the 320-meter elevation contour on the Goldendale map and continue east along the 320-meter elevation contour to its intersection with the boundary between Range 18 East and Range 19 East, south of Sand Spring Canyon; then

(5) Proceed southeast in a straight line for 9,000 feet (1.7 miles) to the intersection of the boundary between sections 31 and 32, T3N/R19E and the northern shoreline of the Columbia River; then

(6) Proceed west along the northern shoreline of the Columbia River, returning to the beginning point.

Signed: August 11, 2026.

Mary G. Ryan,

Administrator.

Approved: August 12, 2026.

Kevin M. Salinger,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2026–16701 Filed 8–14–26; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–1058]

RIN 1625–AA00

Safety Zone; Fox River, Green Bay, WI

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on the Fox River, in Green Bay, WI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with an overwater fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Lake Michigan, or their designated representative.

DATES: This rule is effective on September 5, 2026, from 9 p.m. to 9:45 p.m.

ADDRESSES: To view available documents go to *https://www.regulations.gov* and search for USCG–2026–1058.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MSTC Dylan Caikowski, Sector Lake Michigan, Waterways Management Division, U.S. Coast Guard; telephone (571) 608–0739, or email *D09-SMB-SecLakeMichigan-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from land adjacent to the Fox River in Green Bay, WI. The Captain of the Port (COTP) Sector Lake Michigan has determined that potential hazards associated with fireworks are a safety concern for anyone within 500 feet of the fireworks display.

Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

Because of these potential hazards, the Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of this event on July 29, 2026, but we must establish this safety zone by September 5, 2026, to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a temporary safety zone on September 5, 2026, from 9 p.m. until 9:45 p.m. The safety zone will cover all navigable waters of the Fox River within 500 feet of the fireworks launch location in approximate GPS position 44°31.25′ N, 088°00.778′ W. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port, Sector Lake Michigan or a designated representative.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analysis based on a number of these statutes and Executive orders.

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act's flexibility analysis provisions do not apply here.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), if this rule will affect your small business, organization, or governmental jurisdiction and you have questions, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

B. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

C. Federalism and Indian Tribal Governments

We have analyzed this rule under Executive Order 13132, Federalism, and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in that Order.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

D. Unfunded Mandates Reform Act

As required by The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Coast Guard certifies that this rule will not result in an annual expenditure of $100,000,000 or more (adjusted for inflation) by a State, local, or tribal government, in the aggregate, or by the private sector.

E. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This rule is a safety zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; DHS Delegation No. 00170.1, Revision No. 01.4.

■ 2. Add § 165.T09–1058 to read as follows:

§ 165.T09–1058 Safety Zone; Fox River, Green Bay, WI.

(a) *Location.* The following area is a safety zone: all navigable waters of the Fox River within 500 feet of the fireworks launch location in approximate GPS position 44°31.25′ N, 088° 00.778′ W. These coordinates are based on the World Geodetic System (WGS 84).

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Lake Michigan (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF–FM channel 16 or by telephone at (414) 747–7182. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 9 p.m. to 9:45 p.m. on September 5, 2026.

Rhianna N. Macon,

Captain, U.S. Coast Guard, Captain of the Port Sector Lake Michigan.

[FR Doc. 2026–16757 Filed 8–14–26; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0743; FRL 13377–01–OCSPP]

Calcium Carbonate; Exemption From the Requirement of a Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of calcium carbonate (CAS # 471–34–1), in or on all food commodities when used in accordance with label directions and good agricultural practices. Columbia River Carbonates, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of calcium carbonate in or on all food commodities, in accordance with the terms of the exemption.

DATES: This regulation is effective August 17, 2026. Objections and requests for hearings must be received on or before October 16, 2026, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0743, is available at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Shannon Borges, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1606; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is EPA's authority for taking this action?

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' FFDCA section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2022–0743 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 16, 2026.

EPA's Administrative Law Judges Division (ALJD), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* ''Order Urging Electronic Filing and Service,'' dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf.* Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the ALJD electronically, a person should utilize the ALJD e-filing system at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf.*

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 23, 2022 (87 FR 58047) (FRL–9410–05–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F9018) by Columbia River Carbonates,

300 North Pekin Road, Woodland, Washington 98674. The petitioner requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of calcium carbonate.

The notice of filing referenced a summary of the petition prepared by Columbia River Carbonates, which is available in the docket at *https://www.regulations.gov.* There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing a tolerance exemption, as explained in Unit III.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' 21 U.S.C. 346a(c)(2)(A)(i). Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' *Id.* at 346a(c)(2)(A)(ii). This includes exposure through drinking water and in residential settings, but does not include occupational exposure.

Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C) and (D). FFDCA section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . . '' It provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA supports the choice of a different factor.

Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for calcium carbonate, including exposure resulting from the tolerance exemption established by this action.

A full explanation of the data upon which the EPA relied and its risk assessment based on those data can be found within the document entitled, ''HH Assessment Calcium Carbonate.'' This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

A. Toxicological Profile and Endpoints

Calcium carbonate is of low acute toxicity. Calcium carbonate is of low acute oral toxicity (Toxicity Category III), of low acute dermal toxicity (Toxicity Category III) and inhalation toxicity (Toxicity Category IV). It is not an eye irritant (Toxicity Category IV), not a dermal irritant (Toxicity Category IV) and is not a dermal sensitizer in mice. A non-occupational and occupational short- and intermediate-term (1 day to 6 months) inhalation endpoint was found. The endpoint was derived from the 90-day inhalation toxicity study in rats. The no observed adverse effect level (NOAEL) of 0.123 mg/L and lowest observed adverse effect concentration (LOAEC) of 0.212 mg/L for portal of entry effects are based on increased bronchoalveolar lavage (BAL) derived enzymes changes (ALP and LDH) and increased neutrophil and protein levels in females. It was noted that the LOAEC was selected conservatively, and likely reflects an inflection point for the effects observed at the highest dose tested, due to the lack of measurements in the percent viable cells after the recovery period for the three middle doses and lack of weight information in the other two lung regions. There were no systemic effects up to the highest dose tested (0.399 mg/L). The level of concern (LOC) for short- and intermediate-term inhalation exposure is 30 (3X for interspecies extrapolation and 10X for intraspecies variation). The standard interspecies extrapolation uncertainty factor can be reduced from 10X to 3X due to the HEC calculation accounting for pharmacokinetic interspecies differences and not pharmacodynamic, interspecies differences. The total UF of 30X for occupational inhalation exposure scenarios includes: 3X for interspecies extrapolation, and 10X for intraspecies variability (LOC=30).

B. FQPA Safety Factor for Infants and Children

EPA concluded that an FQPA safety factor is not required at this time as the calcium carbonate toxicology database is complete and adequate to characterize potential pre- and post-natal toxicity to infants and children, there is no indication of increased quantitative or qualitative susceptibility in the developmental or reproduction toxicity studies, and no dietary endpoints have been identified.

C. Exposure Assessment

In accordance with the FFDCA, EPA must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In evaluating dietary exposure to calcium carbonate from pesticide chemical residues in food or feed, EPA considered exposure under the petitioned-for tolerance exemption. Given that no toxicological endpoints were identified, EPA conducted a qualitative dietary exposure and risk assessment. EPA's dietary exposure assessment also includes exposure to pesticide residues in drinking water. Finally, as required under the FFDCA, EPA assessed the potential for ''residential exposure,'' which refers to non-occupational, non-dietary exposure. EPA did not conduct a quantitative aggregate exposure assessment as no endpoints were selected for oral and dermal exposures. While an inhalation endpoint was selected, the exposures cannot be combined as no endpoints were selected for oral and dermal exposures.

D. Cumulative Effects

Based on the lack of toxicity in the available data, calcium carbonate and its metabolites are not expected to share a common mechanism of toxicity with other chemicals. For the purposes of this action, therefore, EPA has assumed that calcium carbonate does not have a common mechanism of toxicity with other substances.

E. EPA's Safety Determination

EPA determines whether chronic dietary pesticide exposure is safe by comparing estimated aggregate food and drinking water exposure to the chronic population adjusted dose. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists.

Based on the data summarized in the calcium carbonate Human Health Risk Assessment, EPA has concluded that calcium carbonate does not pose any risks of concern to the U.S. population, including any subpopulations, based on aggregate exposure to calcium carbonate, for any exposure scenario. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general U.S. population, or to infants and children, from aggregate exposure to calcium carbonate residues.

F. Analytical Enforcement Methodology

An analytical method is not required for calcium carbonate because the EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

IV. Conclusion

Based upon its evaluation in the Human Health Risk Assessment, the EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of calcium carbonate. Therefore, an exemption from the requirement of a tolerance is established for residues of calcium carbonate in or on all food commodities.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .'' (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific review documents, located in the applicable docket at *https://www.regulations.gov.*

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is exempt from review under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 11, 2026.

Elizabeth Vizard,

Acting Director, Office of Pesticide Programs.

For the reasons set forth in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1423 to subpart D to read as follows:

§ 180.1423 Calcium carbonate; Exemption from the Requirement of a Tolerance.

An exemption from the requirement of a tolerance is established for residues of calcium carbonate in or on all raw agricultural commodities when used in accordance with label directions and good agricultural practices.

[FR Doc. 2026–16720 Filed 8–14–26; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 91, No. 157
Monday, August 17, 2026

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Administration

7 CFR Parts 272, 274, and 277

[FNS–2026–0595]

RIN 0584–AF22

Supplemental Nutrition Assistance Program: Changes in Federal-State Administrative Cost Sharing; Extension of Comment Period

AGENCY: Food and Nutrition Administration (FNA), USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The U.S. Department of Agriculture's (USDA) Food and Nutrition Administration (FNA) is extending the public comment period on the proposed rule, ''Supplemental Nutrition Assistance Program: Changes in Federal-State Administrative Cost Sharing,'' which was published in the **Federal Register** on June 24, 2026. This action extends the public comment period from August 24, 2026, to September 8, 2026, to give the public additional time to review the proposed rule.

DATES: The comment period for the proposed rule published June 24, 2026, at 91 FR 37837, is extended. To be assured of consideration, comments on this proposed rule must be received by FNA on or before September 8, 2026.

ADDRESSES: FNA invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

—*Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

—*Mail:* Send comments to Maribelle Balbes, Food and Nutrition Administration, USDA, 1320 Braddock Place, Alexandria, VA 22314, *SM.FN.SNAPSAB@usda.gov.*

—*Email:* Send comments to *SM.FN.SNAPSAB@usda.gov.* Include Docket ID Number FNA–2026–0034 and rule title in the subject line of the message.

—All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Maribelle Balbes, FNA, 1320 Braddock Place, Alexandria, VA 22314, 703–605–4272, and *SM.FN.SNAPSAB@usda.gov.*

SUPPLEMENTARY INFORMATION: In response to section 10106 of Public Law 119–21, the One Big Beautiful Bill Act of 2025, this proposed rule would amend the Supplemental Nutrition Assistance Program (SNAP) regulations to codify the reduction of the amount of the Federal Government's share of annual SNAP State administrative costs from 50 percent to 25 percent, effective beginning in fiscal year 2027. The Department published the proposed rule in the **Federal Register** on June 24, 2026, at 91 FR 37837. This action extends the public comment period from August 24, 2026, to September 8, 2026, to give the public additional time to review the proposed rule and supporting documentation.

Eve Stoody,

Deputy Administrator of Nutrition Research and Regulations, Food and Nutrition Administration.

[FR Doc. 2026–16760 Filed 8–14–26; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–8781; Project Identifier MCAI–2024–00182–E]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) Model Trent XWB–75, XWB–79, XWB–79B, and XWB–84 engines. This proposed AD was prompted by reports of differential oil pressure measurements that were lower than expected on in-service engines. This proposed AD would require modification of the engine with an improved front bearing housing oil feed tube assembly. This proposed AD would also prohibit the installation of an affected front bearing housing oil feed tube assembly on any engine. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by October 1, 2026.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–8781; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this proposed AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section,

Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7146; email: *barbara.caufield@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under **ADDRESSES**. Include ''Docket No. FAA–2026–8781; Project Identifier MCAI–2024–00182–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Barbara Caufield, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0070, dated March 14, 2024 (EASA AD 2024–0070) (also referred to as the MCAI), to correct an unsafe condition on RRD Model Trent XWB–75, XWB–79, XWB–79B, and XWB–84 engines. The MCAI states that occurrences have been reported of in-service engines measuring differential oil pressures that were lower than expected. A manufacturer investigation identified a need to restrict excess oil supply to the front bearing housing bearing chamber because oil pressure could drop below the amber limit during operation at the extremes of the flight envelope. To address this potential unsafe condition, RRD developed a modification that introduced an improved oil tube assembly that re-distributes the oil flow between all bearing chambers and gearboxes, thereby increasing the overall differential oil pressure within the oil feed system. RRD also published service material with instructions for replacement of affected front bearing housing oil feed tube assemblies with the improved modification assemblies. The FAA is proposing this AD to prevent oil pressure from dropping below the safe operating range. This condition, if not addressed, could result in front bearing housing bearing chamber firing, which could lead to an engine in-flight shutdown (IFSD) or dual IFSD with consequent reduced control or loss of control of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–8781.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0070, which specifies procedures for modification of the engine with an improved front bearing housing oil feed tube assembly. EASA AD 2024–0070 also prohibits the installation of an affected front bearing housing oil feed tube assembly on any engine. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the civil aviation authority (CAA) of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the MCAI, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some CAA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0070 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0070 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0070 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0070. Material required by EASA AD 2024–0070 for compliance will be available at *regulations.gov* under Docket No. FAA–2026–8781 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 80 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification of front bearing housing oil feed tube assembly.	3.5 work-hours × $85 per hour = $297.50	$6,375	$6,672.50	$533,800

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Rolls-Royce Deutschland Ltd & Co KG: Docket No. FAA–2026–8781; Project Identifier MCAI–2024–00182–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by October 1, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Rolls-Royce Deutschland Ltd & Co KG Model Trent XWB–75, XWB–79, XWB–79B and XWB–84 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7931, Engine Oil Pressure.

(e) Unsafe Condition

This AD was prompted by reports of differential oil pressures that were lower than expected on in-service engines. The FAA is issuing this AD to prevent oil pressure from dropping below the safe operating range. The unsafe condition, if not addressed, could result in front bearing housing bearing chamber firing, which could lead to an engine in-flight shutdown (IFSD) or dual IFSD with consequent reduced control or loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) EASA AD 2024–0070, dated March 14, 2024 (EASA AD 2024–0070).

(h) Exceptions to EASA AD 2024–0070

(1) Where EASA AD 2024–0070 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where the service material referenced in EASA AD 2024–0070 specifies to discard certain parts, this AD requires those parts be removed from service.

(3) This AD does not adopt the ''Remarks'' paragraph of EASA AD 2024–0070.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0070 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0070, dated March 14, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on

the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on August 12, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–16705 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–9901; Airspace Docket No. 26–ASW–13]

RIN 2120–AA66

Revocation of Class E Airspace; Santa Elena, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke the Class E airspace at Diamond ''O'' Ranch Airport, Santa Elena, TX. The FAA is proposing this action due to the instrument procedures being cancelled and the decommissioning of the Santa Elena radio beacon (RBN).

DATES: Comments must be received on or before October 1, 2026.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2026–9901 and Airspace Docket No. 26–ASW–13 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W58–213, West Building, 5th Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11K, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Raul Garza Jr., Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5874.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would remove the Class E airspace at the affected airport because it is no longer needed to support IFR operations.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice (DOT/ALL–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace relevant to this action is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11K, dated August 4, 2025, and effective September 15, 2025. These updates would be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 that would remove the Class E airspace extending upward from 700 ft. above the surface at Diamond ''O'' Ranch Airport, Santa Elena, TX due

to the instrument procedures being cancelled and the decommissioning of the Santa Elena RBN.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Order 2100.6B, ''Policies and Procedures for Rulemakings'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these proposed amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

ASW TX E5 Santa Elena, TX [Remove]

* * * * *

Issued in Fort Worth, Texas, August 13, 2026.

Jerry J. Creecy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2026–16774 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–9835; Airspace Docket No. 26–AGL–19]

RIN 2120–AA66

Establishment of Class E Airspace; DeKalb, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Northwestern Memorial Healthcare Heliport, DeKalb, IL. The FAA is proposing this action to support new instrument procedures and instrument flight rule (IFR) operations.

DATES: Comments must be received on or before October 1, 2026.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2026–9835 and Airspace Docket No. 26–AGL–19 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W58–213, West Building, 5th Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11K, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Raul Garza Jr., Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5874.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending upward from 700 feet above the surface at Northwestern Memorial Healthcare Heliport, DeKalb, IL, to support IFR operations at this airport.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice (DOT/ALL–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operation). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11K, dated August 4, 2025, and effective September 15, 2025. These updates would be published subsequently in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 that would establish Class E airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Northwestern Memorial Healthcare Heliport, DeKalb, IL.

This action is the result of instrument procedures being developed for this airport to support IFR operations.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Order 2100.6B, ''Policies and Procedures for Rulemakings'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these proposed amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

AGL IL E5 DeKalb, IL [Establish]

Northwestern Memorial Healthcare Heliport, IL
(Lat. 41°57′38″ N., long. 88°43′18″ W.)
That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Northwestern Memorial Healthcare Heliport.

* * * * *

Issued in Fort Worth, Texas, on August 13, 2026.

Jerry J. Creecy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2026–16750 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870, 876, and 878

[Docket No. FDA–2025–N–6224]

Medical Devices; Classification of Accessories Distinct From Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: As required by the FDA Reauthorization Act of 2017 (FDARA), the Food and Drug Administration (FDA or Agency) has identified a list of accessories for which the Agency believes general controls alone are sufficient to provide reasonable assurance of safety and effectiveness, making them appropriate for class I classification. FDA is publishing this document proposing to classify these accessories into class I and distinct from other devices, as well as seeking public comment in accordance with procedures established by FDARA. This document does not represent FDA's final determination with respect to the proposed accessories listed in this document.

DATES: Either electronic or written comments on the notification must be submitted by October 16, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–N–6224 for ''Medical Devices; Classification of Accessories Distinct from Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993–0002, 301–796–5678.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) sets forth a process to classify certain medical devices, *i.e.,* accessories, separate from the parent device or system of devices with which the accessory is intended to be used. FDA refers to this process as distinct classification, and it originates from section 707 of FDARA, which was signed into law on August 18, 2017 (131 Stat. 1060–62, Pub. L. 115–52). Under section 513(f)(6)(D)(i) of the FD&C Act as amended by FDARA (21 U.S.C. 360c(f)(6)(D)(i)), FDA periodically proposes accessories that may be suitable for distinct classification into class I and seeks public comment on the proposal. This notification is a periodic proposal pursuant to section 513(f)(6)(D)(i) of the FD&C Act, and FDA is seeking feedback on this proposal through public comment. This notification follows a request for public input regarding which accessories to consider proposing for distinct classification that FDA posted on its website on December 5, 2025, to develop this document.[1]

II. Legal Authority

The accessories subject to this proposal are devices regulated under the FD&C Act. Specifically, section 201(h) of the FD&C Act defines a ''device'' to include, among other articles, an ''accessory'' (see 21 U.S.C. 321(h)). An accessory is a kind of device, and all articles that meet the definition of ''device'' are regulated under the FD&C Act. FDA has described our current thinking on which devices FDA would generally consider to be accessories in the guidance document, ''Medical Device Accessories—Describing Accessories and Classification Pathways''(''Accessories Guidance'').[2] That guidance, based on sections 201(h) and 513(f)(6) of the FD&C Act, defines an accessory as a ''finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.''

FDA regulates devices according to classes that reflect the regulatory controls necessary to provide reasonable assurance of their safety and effectiveness. Section 513 of the FD&C Act defines three classes of devices, which are class I (general controls), class II (special controls), and class III (premarket approval). Because accessories may have marketing

[1] Available at *https://www.fda.gov/medical-devices/classify-your-medical-device/cdrh-seeks-public-comment-identifying-accessories-suitable-distinct-classification-class-i-devices.* A copy is also available in the public docket. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

[2] Available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.*

authorization as part of a submission for another device with which they are intended to be used, often called the parent device or system of devices, an accessory may be subject to more than general controls on account of the parent device or system of devices. However, for some such accessories, general controls alone may suffice to provide reasonable assurance of safety and effectiveness when the accessory is considered distinct from the parent device or system of devices.

General controls, under section 513(h)(1) of the FD&C Act, are the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 of the FD&C Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j). These controls include, but are not limited to, provisions related to adulteration and misbranding, registration and listing, records and reports on devices, and good manufacturing practices. The provisions for good manufacturing practices under 21 CFR part 820, the Quality Management System Regulation, include requirements for design and development controls for the manufacture of certain devices. However, requirements for design and development controls generally do not apply to class I devices except those identified in § 820.10(c)(2) (21 CFR 820.10(c)(2)) and those automated with computer software.

FDA is publishing this document pursuant to the legal authorities discussed in this notification and providing the public with the opportunity to comment on the proposals. Once the comment period ends, FDA will consider the comments and publish in the **Federal Register** a final action distinctly classifying suitable accessories into class I, if any.

III. Factors for Consideration

The classification of each accessory will be based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used (see section 513(f)(6)(A) of the FD&C Act).

In general, FDA considers an accessory to be eligible for classification into class I distinct from another device if the accessory: (1) is not for use in supporting or sustaining human life, or of substantial importance in preventing impairment to human health (see 21 CFR 860.3, defining ''life-supporting or life-sustaining device,'' among other terms); (2) does not present a potential unreasonable risk of illness or injury; and (3) general controls alone would be sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Note that by regulation, design and development controls apply to class I devices only if the devices are automated with computer software or are listed under § 820.10(c)(2). Thus, if an accessory is not automated with computer software but would require design controls to provide reasonable assurance of safety and effectiveness, FDA does not consider it eligible for distinct classification through this process.

Similarly, ''device-specific accessories'' are accessories designed for use with a specific parent device and/or system of devices, based upon unique dimensions, geometry, and/or deployment. In these cases, design specifications are critical to the proper use of the accessory in supporting, supplementing, and/or augmenting the performance of the parent device and/or the specific system. For such device-specific accessories, design and development controls are an important element of ensuring appropriate compatibility between the accessory and parent and/or system, and as such, device-specific accessories are not generally eligible for distinct classification through this process. In the **Federal Register** of August 17, 2018, FDA proposed this rationale for device-specific orthopedic instruments (83 FR 41023, 41025–26), which we then adopted in the **Federal Register** of April 12, 2019 (84 FR 14865, 14869). The same principle and definition apply to this proposal.

You may wish to propose additional accessories as suitable for distinct classification into class I using the factors described above where the accessories are otherwise eligible for classification under section 513(f)(6)(D)(i) of the FD&C Act. Should you wish to propose additional accessories, your comment should identify each accessory's product code and/or classification regulation, and it should briefly explain why you think general controls alone will provide reasonable assurance of safety and effectiveness for the accessory if distinctly classified.[3] Conversely, should you disagree with any of the proposed accessories for class I, your comments should briefly explain why additional regulatory controls, such as premarket review through a 510(k) submission or premarket approval (PMA), are necessary to provide reasonable assurance of safety and effectiveness.

IV. Proposed List of Accessories for Distinct Classification Into Class I

FDA is proposing the following accessories, which have been granted marketing authorization as part of a premarket submission (*i.e.,* 510(k), De Novo classification request, or PMA) for another device with which they are intended to be used, as suitable for distinct classification into class I (see table 1). When FDA publishes the final list of accessories, after considering comments submitted for this proposed list and the factors in section II, FDA will consider those accessories classified into class I, distinct from other devices, through such action.

For each distinct classification that is finalized as proposed, FDA would place a classification regulation for each of these accessories in 21 CFR part 870, 876, or 878, as appropriate. Each of these accessories would be class I, exempt from the premarket notification procedures in 21 CFR part 807, subject to the applicable limitations of exemption (*i.e.,* 21 CFR 870.9, 876.9, or 878.9). FDA intends to make conforming changes to existing classification regulations for consistency and clarity, as appropriate.

[3] FDA's Product Classification Database for medical devices is online at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.*

TABLE 1—PROPOSED ACCESSORIES FOR CLASSIFICATION INTO CLASS I AND DISTINCT FROM OTHER DEVICES

Current classification regulation (21 CFR)	Device type (existing product code)	Proposed device type identification
	Current Status of Accessory	
870.1130	Noninvasive blood pressure measurement system accessories (DXN).	A tube connecting the blood pressure cuffs to the noninvasive blood pressure measurement system.
870.3610	Electrocardiogram cable (DXY and OSR).	Implantable pacemaker pulse electrocardiogram cable accessories are cables used to transmit electrical signals between a pacing device and cardiac pacing leads or to connect the implantable pacemaker pulse generator system to compatible external equipment. They are not intended to power the implant or transmit energy to the implant.
870.4100	Extracorporeal membrane oxygenation accessories (QJZ and QNR).	A non-electrical device that has no contact with blood and that is used in an extracorporeal membrane oxygenation circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line. Examples include but are not limited to an oxygenator mounting bracket or system-priming equipment. It is not intended to be used in transport environments.
870.5300	Auxiliary power supply (alternating current or direct current) for low-energy direct-current defibrillator (MPD).	An accessory used to charge the defibrillator batteries when the defibrillator is not in use.
876.5130	Urological catheter plug (KNY).	Sterile plug used with a urological catheter to seal the distal end of the catheter to prevent contamination of the catheter and/or leakage of urine from the catheter.
878.4400	Detachable suction sleeve (GEI).	Detachable plastic attachment at the distal end of a smoke evacuating monopolar pencil that channels surgical smoke away from the surgical site. It is a single-use and sterile device.
878.4740 878.4750	Power charger accessory to a battery-powered surgical instrument (GAG and GDW).	An accessory used to supply an electrical charge to the battery.

In addition, FDA received comments in response to the December 2025 request posted on our website suggesting that FDA distinctly classify reprocessing aids or tools, as well as percutaneous catheterization accessories. However, the suggestions did not identify product codes or classification regulations. Further, FDA has not separately identified such devices suitable for distinct classification. Information submitted in response to this notification that describes devices by referring to specific product codes may facilitate the identification and potential distinct classification into class I for such accessories.

V. Paperwork Reduction Act of 1995

While this document contains no new collection of information, it does refer to previously approved collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
"De Novo Classification Process (Evaluation of Automatic Class III Designation)".	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR).	0910–0073
"Medical Device Accessories—Describing Accessories and Classification Pathways for New Accessory Types.".	Medical Device Accessories	0910–0823

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16729 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2026–N–8249]

Gastroenterology-Urology Devices; Reclassification of Diagnostic Endoscopic Light Source Systems To Be Renamed Cystoscopic Systems Intended as an Aid for Detection of Bladder Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify diagnostic endoscopic light source systems (product code OAY), which are postamendments class III devices, from class III (premarket approval) into class II (special controls), subject to premarket notification. FDA is also proposing a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer,'' along with special controls that FDA believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

DATES: Either electronic or written comments on the proposed order must be submitted by October 16, 2026. Please see Section X of this document for the proposed effective date when the new requirements would apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
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Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–8249 for ''Gastroenterology-Urology Devices; Reclassification of Diagnostic Endoscopic Light Source Systems To Be Renamed Cystoscopic Systems Intended as an Aid for Detection of Bladder Cancer.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf* .

Docket: For access to the docket to read background documents, the plain language summary of the proposed order of not more than 100 words consistent with the ''Providing Accountability Through Transparency Act,'' or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Esther Kaplan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2604, Silver Spring, MD 20993, 301–796–1863, *Esther.Kaplan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C

Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions FDA (the Agency or we) deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976 (generally referred to as ''postamendments devices'') are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA action. Those devices remain in class III and require approval of a premarket approval application (PMA), unless and until: (1) FDA reclassifies the device into class I or II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of the premarket notification procedures in section 510(k) of the FD&C Act and part 807, subpart E, of FDA's regulations (21 CFR part 807, subpart E).

A postamendments device that has initially been classified into class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.[1]

FDA relies on ''valid scientific evidence,'' as stated in section 513(a)(3) of the FD&C Act and defined in 21 CFR 860.7(c)(2), in the classification process to determine the level of regulation for devices.[2] In general, to be considered in the reclassification process, the ''valid scientific evidence'' on which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information; *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include the descriptions of methods of manufacture and product composition and other trade secrets.

In accordance with section 513(f)(3) of the FD&C Act, the Agency is issuing this proposed order to reclassify postamendments class III diagnostic endoscopic light source systems intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy as an adjunct to white light cystoscopy for the detection of known or suspected bladder cancer, including carcinoma in situ, or in patients undergoing surveillance cystoscopy for bladder cancer (product code OAY),[3] hereinafter referred to as cystoscopic systems intended as an aid for detection of bladder cancer, into class II (special controls), subject to premarket notification, under a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer.''

Based on the PMA data available to FDA in accordance with section 520(h)(4) of the FD&C Act,[4] [5] published peer-reviewed literature, data and information from a public meeting of the Oncologic Drugs Advisory Committee (ODAC) held on December 17, 2009, to discuss NDA 022555 for CYSVIEW (hexaminolevulinate hydrochloride) for Intravesical Solution [6] (CYSVIEW (hexaminolevulinate hydrochloride)) for use with the Karl Storz Photodynamic Diagnostic D-Light C System (PDD System) (P050027), a cystoscopic system intended as an aid for detection of bladder cancer, and data available to the Agency demonstrating a lack of significant postmarket safety signals, FDA believes there is sufficient information to reclassify cystoscopic systems intended as an aid for detection of bladder cancer from class III (premarket approval) into class II (special controls).

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[1] See generally section 513 of the FD&C Act.

[2] See generally *id.*

[3] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking of and easy reference to predicate device types. CDRH and a subset of Center for Biologics Evaluation and Research regulated medical device product codes consist of a three-letter combination that associates a device's type with a product classification designated for the application. There is no definitive meaning for the three-digit classification product codes in CDRH's Product Classification Database. See FDA guidance titled ''Medical Device Classification Product Codes,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff.*

[4] In proposing to reclassify, on its own initiative, cystoscopic systems intended as an aid for the detection of bladder cancer from class III to class II, FDA is relying on data from the relevant PMA available to FDA in accordance with the six-year rule (see section 520(h)(4) of the FD&C Act) (see also, FDA's guidance titled ''Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997—Guidance for Industry and for FDA Reviewers''), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-section-216-food-and-drug-administration-modernization-act-1997-guidance-industry-and-fda.* This data was from a PMA approved after November 28, 1990, and before July 24, 2020, for this specific proposed reclassification as noted in section II of this proposed order. See also FDA's premarket approval database, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.*

[5] For the purpose of this proposed order, PMA data considered in accordance with section 520(h)(4) includes only that data which was submitted to and therefore considered by FDA at the time the PMA was reviewed and approval was issued.

[6] At the time of the ODAC meeting, the proposed trade name for the cross-labeled drug was HEXVIX (hexaminolevulinate hydrochloride) Kit.

FDA believes the standard in section 513(a)(1)(B) of the FD&C Act is met as general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of these devices, and there is sufficient information to establish special controls, which, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of these devices.[7] Therefore, FDA is proposing to establish a new device classification regulation, ''Cystoscopic system intended as an aid for detection of bladder cancer,'' and classify this device type into class II along with the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

Under the FD&C Act, premarket notification (510(k)) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[8] FDA has not made this determination for cystoscopic systems intended as an aid for detection of bladder cancer, and therefore, FDA is not proposing that this class II device type be exempt from 510(k) requirements. If this proposed order is finalized, persons who intend to market this type of device will have to submit to FDA a premarket notification under section 510(k) of the FD&C Act and receive clearance prior to marketing the device.

[7] FDA notes that the ''ACTION'' caption for this proposed order is styled as ''Proposed amendment; proposed order; request for comments,'' rather than ''Proposed order.'' Beginning in December 2019, this editorial change was made to indicate that the document, if finalized, will amend the Code of Federal Regulations. The change was made in accordance with the Office of the Federal Register's (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

[8] In considering whether to exempt class II devices from premarket notification, FDA considers whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA generally considers the factors initially identified in the January 21, 1998, **Federal Register** notice (63 FR 3142) and further explained in FDA's guidance issued on February 19, 1998, titled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff,* in determining whether premarket notification is necessary for class II devices. FDA also considers that even when exempting devices from the 510(k) requirements, these devices would still be subject to certain limitations on exemptions, for example, the general limitations set forth in 21 CFR 876.9.

II. Regulatory History of the Device

In accordance with section 513(f)(1) of the FD&C Act, cystoscopic systems intended as an aid for detection of bladder cancer were automatically classified into class III because they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, have not been reclassified into class I or class II, and have not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently classified or reclassified into class II or class I. Therefore, they are subject to the PMA requirements under section 515 of the FD&C Act (21 U.S.C. 360e).

On May 28, 2010, FDA approved an original PMA for the PDD System (P050027) (Ref. 1), which is the first approved cystoscopic system intended as an aid for detection of bladder cancer. The PDD System, when used in combination with the approved optical imaging drug CYSVIEW (hexaminolevulinate hydrochloride) (New Drug Application (NDA) 022555), was approved with an indication for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of non-muscle invasive papillary cancer of the bladder in patients suspected or known to have the lesion on the basis of a prior cystoscopy (Ref. 1). The device is only to be used as an adjunct to white light cystoscopy (Ref. 2) and, therefore, is not intended to be used as the sole or definitive basis for diagnosis.

Approval of the PMA for the PDD System occurred on the same day as the approval of the NDA for CYSVIEW (hexaminolevulinate hydrochloride), consistent with recommendations made by the ODAC. On December 17, 2009, the ODAC met to discuss the benefit/risk assessment for CYSVIEW [9] (hexaminolevulinate hydrochloride), when used with the PDD System, for photodynamic blue light cystoscopy performed as an adjunct to white light cystoscopy in the detection of non-muscle invasive papillary cancer of the bladder in patients with known or suspected bladder cancer (Ref. 3). Discussion by the ODAC members included considerations applicable to the PDD System (*e.g.,* the risk of false positives) as part of the combined use of the two products. The ODAC was presented with data that included results from a prospective, controlled clinical trial of adult subjects with known or suspected bladder cancer, as well as data from several supportive studies. The majority of ODAC members found that the data established a favorable diagnostic benefit-risk assessment for CYSVIEW (hexaminolevulinate hydrochloride) when used in combination with the PDD System for the detection of non-muscle invasive papillary cancer of the bladder in patients with known or suspected bladder cancer. Although several ODAC members expressed concerns about potential repetitive use of CYSVIEW (hexaminolevulinate hydrochloride), these concerns related to use of the drug and not specifically the PDD System. In a September 3, 2010, **Federal Register** notice (75 FR 54154), FDA announced the PMA approval order and the availability of the Summary of Safety and Effectiveness Data (SSED) for the device.

FDA's approval of the PDD System included a postmarket study commitment for a prospective, randomized, controlled clinical study to assess the safety and efficacy of CYSVIEW (hexaminolevulinate hydrochloride) in the detection of carcinoma in situ of the bladder (Ref. 1).[10] On February 15, 2018, FDA approved a PMA supplement to the PDD System (P050027/S011), supported by clinical data from the postmarket study results, which, among other things, added an additional subsystem that included a flexible video cystoscope and expanded the indications for use for the device to include use in combination with CYSVIEW (hexaminolevulinate hydrochloride) for detection of carcinoma in situ of the bladder and in patients undergoing surveillance cystoscopy for bladder cancer.[11] The approval of this PMA supplement was consistent with changes to the labeling for CYSVIEW (hexaminolevulinate hydrochloride) approved on the same day (NDA 22555/S–005) (Ref. 4).

As of the date of issuance of this proposed order, fewer than 6 years have passed since FDA's approval of certain other PMA supplements for the PDD System. Therefore, in accordance with the ''six-year rule'' described in section 520(h)(4) of the FD&C Act, no information from these documents has been used in support of this proposed

[9] See FN 6.

[10] Postmarket study requirements also included a prospective, randomized, controlled clinical study to assess the safety and efficacy of CYSVIEW (hexaminolevulinate hydrochloride) for repetitive use.

[11] Additional information regarding this PMA supplement is discussed in a petition for reclassification submitted by the manufacturer of the PDD System on October 21, 2022, under Docket Number FDA–2022–P–2644.

order to reclassify cystoscopic systems intended as an aid for detection of bladder cancer into class II. In addition, since the first approval order for a cystoscopic system intended as an aid for detection of bladder cancer, FDA has received no other original PMAs for this device type.

On April 29, 2015, FDA published a notice in the **Federal Register** (80 FR 23798) titled ''Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection.'' This notice announced the Center for Devices and Radiological Health's progress on its 2014–2015 strategic priority, ''Strike the Right Balance Between Premarket and Postmarket Data Collection'' (Ref. 5). As part of that strategic priority, FDA was at that time conducting a retrospective review of all PMA product codes with active PMAs approved prior to 2010 to determine whether, in light of FDA's then-current understanding of the technology, there may be sufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness for these devices, together with general controls, supporting reclassification of these devices from class III to class II. FDA solicited comments on certain product codes that had been identified at that time, including devices in product code OAY, as candidates for reclassification (Ref. 6). FDA received no comments on the notice about the potential reclassification of devices in product code OAY.

In October 2022, FDA received a petition from the manufacturer of the PDD System requesting that FDA reclassify devices under product code OAY from class III to class II (the Reclassification Petition) (Docket No. FDA–2022–P–2644). In February 2024, the petitioner submitted a potential draft special control guidance document for devices under product code OAY for FDA to consider. FDA also heard from health care practitioners, patients, medical device manufacturers, a patient advocacy organization, and the holder of the NDA for CYSVIEW (hexaminolevulinate hydrochloride) in connection with the Reclassification Petition, who were in favor of reclassifying devices under product code OAY from class III to class II.[12] On March 27, 2026, FDA denied the Reclassification Petition, as FDA did not agree that the information provided and the special controls proposed by the petitioner supported reclassification from class III to class II.

As discussed in this proposed order, FDA is now proposing, on its own initiative, to reclassify cystoscopic systems intended as an aid for detection of bladder cancer from class III to class II. FDA has considered the information available to the Agency and believes that there is sufficient information available to establish special controls and that the special controls proposed in section VII of this document, together with general controls, would provide a reasonable assurance of the safety and effectiveness of devices under product code OAY.

A review of data from FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which contains Medical Device Reports (MDRs) of adverse events, indicates that as of April 30, 2026, there have been 11 unique MDRs associated with product code OAY. Most of the adverse events were related to thermal injury from contact with the light cable. One adverse event was related to user injury, a cut, from a damaged device. Two MDRs reported that the blue light mode stopped working after the first use.

Based on a search of FDA's Medical Device Recalls database using product code OAY, as of June 15, 2026, there has been one recall involving a cystoscopic system intended as an aid for detection of bladder cancer. The recall was initiated by the device manufacturer on August 16, 2012, and was reported to be due to the system's instruction manuals containing a labeling error. The correction applied to the three component manuals indicated for use within the device. To address the labeling error, a Safety Alert letter was sent to all customers to inform them that there was a labeling error, including instructions on how to correct the error. The recall was classified as a class II[13] recall and was terminated by FDA on May 8, 2013.[14] FDA is not aware of any injuries related to this recall. These facts, coupled with the low number of MDRs, indicate a lack of significant postmarket safety signals for this device type. FDA believes the special controls proposed herein, in addition to general controls, can effectively mitigate the risks to health identified in this document to provide a reasonable assurance of the safety and effectiveness of cystoscopic systems intended as an aid for detection of bladder cancer.

III. Device Description

A cystoscopic system intended as an aid for detection of bladder cancer is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. A cystoscopic system intended as an aid for detection of bladder cancer is a prescription device intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of bladder cancer, including carcinoma in situ, in patients suspected or known to have the lesion on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for bladder cancer. The device is not intended as the sole or definitive basis for diagnosis. The device system includes a cystoscope and accessories, including a light source, camera system, fluid light cables, and software. The device can be used in white light or blue light modes. The blue light mode is used to view tissue fluorescence, either via the eyepiece on the scope or on a video monitor, after application of an approved optical imaging agent. The optical imaging agent reacts with the bladder lesions to provide visualization under blue light through the cystoscope. As discussed in section VI of this document, tissue fluorescence observation under blue light offers enhanced detection of potential bladder cancer compared to tissue observation under white light.

FDA is proposing to reclassify cystoscopic systems intended as an aid for detection of bladder cancer from class III (premarket approval) to class II (special controls) and to establish a new name for the device type as described within the classification regulations. FDA proposes to revise 21 CFR part 876 to create a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer.'' The Agency believes that this name and the identification language included in this proposed order more accurately describes this device type.

IV. Proposed Reclassification and Summary of Reasons for Reclassification

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify cystoscopic systems intended as an aid for detection of bladder cancer, which are postamendments devices, from class III into class II, subject to section 510(k) of the FD&C Act.

FDA believes that there is sufficient data and information available to FDA

[12] See Docket No. FDA–2022–P–2644 available at: *https://www.regulations.gov/docket/FDA-2022-P-2644*.

[13] Class I, II, and III recalls are defined in 21 CFR 7.3(m).

[14] For details about termination of a recall, see 21 CFR 7.55.

through the data and information provided in the original PMA (P050027) and one PMA supplement (P050027/S011) for the PDD System that may be considered under section 520(h)(4) of the FD&C Act, the ODAC materials, published peer-reviewed literature, and FDA's publicly available MAUDE and Medical Device Recalls databases to establish special controls (Refs. 3 and 7 to 14). More specifically, in evaluating these data sources, FDA has identified the risks to health for inclusion in the overall risk assessment for a cystoscopic system intended as an aid for detection of bladder cancer and is proposing special controls that include mitigation measures for each of the risks to health identified in section V. FDA believes that these special controls, together with general controls, would effectively mitigate the risks to health identified in section V and are necessary to provide a reasonable assurance of safety and effectiveness of these devices. FDA does not believe that the general controls applicable to the devices are sufficient to effectively mitigate the risks to health identified for these devices, such as the risk of additional biopsies from false positive results or delayed diagnosis due to false negative results and, therefore, does not believe that the general controls applicable to the devices are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

FDA is proposing to revise 21 CFR part 876 to create a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer.'' Under this proposed order, if finalized, cystoscopic systems intended as an aid for detection of bladder cancer will be identified as prescription devices. If the proposed order is finalized, these devices will be subject to the prescription labeling requirements for devices (see 21 CFR 801.109).

Under the FD&C Act, 510(k) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[15] FDA has not made this determination for cystoscopic systems intended as an aid for detection of bladder cancer, and therefore FDA is not proposing that these proposed class II devices be exempt from 510(k) requirements. If this proposed order is finalized, persons who intend to market a cystoscopic system intended as an aid for detection of bladder cancer will need to submit a 510(k) to FDA and receive clearance prior to marketing the device.

This proposed order, if finalized, will decrease regulatory burden on industry, as manufacturers will no longer have to submit a PMA for this type of device but can instead submit a 510(k) to the Agency for review prior to marketing their device. The 510(k) pathway is less burdensome and generally more cost-effective for industry and FDA than the PMA pathway, the most stringent type of device marketing pathway. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately may provide more timely patient access for this type of device. FDA expects that the reclassification of these devices would enable more manufacturers to develop this type of device such that patients would benefit from increased access to appropriately safe and effective devices used adjunctively to detect bladder cancer.

Additionally, manufacturers may wish to use predetermined change control plans (PCCPs) as a way to implement future modifications to their devices without needing to submit a new 510(k) for each significant change or modification [16] while continuing to provide a reasonable assurance of device safety and effectiveness.[17] FDA reviews a PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification to the device as described in the PCCP. When used appropriately, PCCPs authorized by FDA are expected to be least burdensome for manufacturers and FDA.[18]

[15] See *supra* note 8.

[16] For the purpose of this proposed order, reference to ''modification'' means a significant change or modification that would generally require a new premarket notification under 21 CFR 807.81(a)(3).

[17] Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Public Law 117–328 (FDORA), enacted on December 29, 2022, added section 515C ''Predetermined Change Control Plans for Devices'' to the FD&C Act (21 U.S.C. 360e–4). Section 515C has provisions regarding PCCPs for devices requiring premarket approval or premarket notification. Under section 515C, supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA.

[18] Sections 513 and 515 of the FD&C Act. See also, FDA's guidance titled ''The Least Burdensome Provisions: Concept and Principles,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

V. Risks to Health

FDA is providing a substantive summary of the valid scientific evidence concerning the public health benefits of the use of cystoscopic systems intended as an aid for detection of bladder cancer and the risks to health of these devices (see further discussion of the special controls being proposed to mitigate these risks in section VII of this proposed order). FDA considered data from the original PMA for the PDD System (P050027) and one PMA supplement (P050027/S011) available to FDA under section 520(h)(4) of the FD&C Act, input from the ODAC, published peer-reviewed literature, and postmarket information regarding cystoscopic systems intended as an aid for detection of bladder cancer.

In 2025, the number of new cases of bladder cancer is estimated to have been 84,870, or 4.2 percent of all estimated new cancer cases. The number of deaths in the United States in 2025 from bladder cancer is estimated to have been 17,420, equating to 2.8 percent of all estimated cancer deaths (Ref. 15). Currently, a combination of methods is used for diagnosis of bladder cancer because no single available procedure detects all malignancies. The use of cystoscopic systems intended as an aid for detection of bladder cancer provides a benefit to the public health by improving visualization and identification of malignant lesions of the bladder not detected by white light cystoscopy alone (see discussion in section VI of this document). Use of the device in combination with an approved optical imaging agent can provide a source of adjunctive information when triaging patient care for bladder cancer.

Based on FDA's review of the data and information described in this section and section VI of this document, the Agency has identified the following risks to health associated with the use of cystoscopic systems intended as an aid for detection of bladder cancer:

- *False positive or false negative results*—False negative results could result in complications such as incorrect or delayed diagnoses and delays in biopsy decisions and bladder cancer treatment, which may allow an undetected condition to worsen and potentially increase morbidity and mortality. False positive results may result in complications such as incorrect treatment management of the patient, including unnecessary additional invasive biopsy procedures and more frequent screenings, as well as the potential administration of inappropriate treatments and/or the

delay of appropriate treatments, with possible adverse effects.

- *Device failure/malfunction*—Device failure or malfunction could result in the absence or delay of device output, or incorrect device output, which could lead to inaccurate patient assessment. Inaccurate results may result in the same complications associated with false negative or false positive results as discussed in this section.
- *Electrical, mechanical, thermal, or light-related injury*—While in operation, the device may discharge electricity that could shock the user or patient. Electrical discharge or exposure to device-generated heat may cause thermal injury or discomfort. Moving parts may cause mechanical injury. For devices that utilize energy (*e.g.,* light) to provide adjunctive diagnostic information, accidental eye exposure to the energy source could cause eye injury or high levels of light output could cause photochemical or photothermal tissue damage to the mucosal lining.
- *Interference with other devices*—Individuals with electrically powered implants could experience an adverse interaction with the device due to electromagnetic interference or radiofrequency interference.
- *Infection/Cross contamination*—If reusable components are not adequately reprocessed between uses, the device may introduce pathogenic organisms to patients and cause an infection.
- *Adverse tissue reaction*—A patient could experience skin irritation and/or allergic reaction associated with the use and operation of the device via the use of non-biocompatible materials in patient-contacting devices.

VI. Summary of Data Upon Which the Reclassification Is Based

The safety and effectiveness of this device type have become well established since the initial approval in 2010 of the first cystoscopic system intended as an aid for detection of bladder cancer. FDA believes that cystoscopic systems intended as an aid for detection of bladder cancer, which are used with an approved optical imaging agent and intended as an adjunct to white light cystoscopy for the detection of known or suspected bladder cancer, should be reclassified from class III (premarket approval) into class II (special controls) on the basis that special controls, in addition to general controls, can be established to mitigate the risks to health identified in section V, and there is sufficient information to establish such special controls which, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of these devices. The proposed special controls are identified by FDA in section VII of this proposed order.

Taking into account the available evidence, including the health benefits of the use of these devices and the nature and known incidence of the risks to health of the devices, FDA, on its own initiative, is proposing to reclassify these postamendments class III devices into class II. FDA has considered and analyzed the following information to support this proposed reclassification: (1) data from the original PMA (P050027) and one PMA supplement (P050027/S011) for the PDD System, including information available in the SSED and device labeling, available to FDA in accordance with section 520(h)(4) of the FD&C Act, (2) input from the ODAC for CYSVIEW (hexaminolevulinate hydrochloride) when used in combination with the PDD System, (3) published peer-reviewed literature, and (4) MDR and recall data from the Agency's publicly available MAUDE and Medical Device Recalls databases. The available evidence demonstrates that there are public health benefits derived from the use of cystoscopic systems intended as an aid for detection of bladder cancer by improving visualization and identification of malignant lesions of the bladder not detected by white light cystoscopy alone. In addition, the nature of the associated risks to health are known, and special controls can be established to sufficiently mitigate these risks.

The data considered by the Agency included the results of non-clinical testing of the PDD System, which demonstrated that the device had acceptable optical performance, electrical safety, electromagnetic compatibility, and reprocessing methods (Ref. 7). The data also included the results of a pivotal clinical trial supporting the use of the PDD System with CYSVIEW (hexaminolevulinate hydrochloride) for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy, for the detection of non-muscle invasive papillary cancer of the bladder in patients suspected or known to have the lesion on the basis of a prior cystoscopy, which met its primary effectiveness endpoints by exceeding the prespecified 10 percent threshold for patients who had a Ta or T1 lesion detected only with blue light (Ref. 7). FDA also considered data from postmarket clinical trial results supporting the expanded indications of the PDD System for carcinoma in situ and surveillance cystoscopy, which confirmed the increased efficacy of using photodynamic blue light cystoscopy with CYSVIEW (hexaminolevulinate hydrochloride) over white light cystoscopy in detecting non-muscle invasive bladder cancer, including carcinoma in situ (Ref. 8).

The data also included safety data from six studies conducted during clinical development of CYSVIEW (hexaminolevulinate hydrochloride) used in combination with the PDD System, as summarized in the PDD System SSED (Ref. 7). Adverse events included bladder spasm, dysuria, hematuria, bladder pain, procedural pain, urethral pain, urinary retention, headache, erythema, and pruritus (Refs. 7 and 8). These are common complications in patients undergoing cystoscopy procedures, which generally include administration of a general anesthetic, cystoscopy, and biopsy. In addition, concerns raised by the ODAC during its review of CYSVIEW (hexaminolevulinate hydrochloride) when used in combination with the PDD System included concerns about false positives that may lead to unnecessary biopsies, which were relevant to the device, in addition to concerns generally associated with use of the drug (*e.g.,* hypersensitivity, anaphylactic reaction) (Ref. 3).

FDA performed a literature search of published peer-reviewed literature to evaluate the safety and effectiveness of FDA-approved cystoscopic systems intended as an aid for detection of bladder cancer using the optical imaging agent hexaminolevulinate hydrochloride. The most frequent adverse events reported in patients who underwent photodynamic blue light cystoscopy procedures were hematuria, dysuria, bladder spasm, urinary retention, and bladder pain (Refs. 8 to 10).

The literature search results also included studies comparing photodynamic blue light cystoscopy following white light cystoscopy to white light cystoscopy alone in detecting bladder cancer to determine if the use of photodynamic blue light cystoscopy increases the risk of false positive/negatives over existing white light technologies. These comparisons involved assessments of diagnostic accuracy to mitigate the risk of false positives and false negatives. Diagnostic accuracy was assessed via sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Effectiveness outcomes, including recurrence and residual disease, were also assessed in the comparison where data was available.

In comparisons of photodynamic blue light cystoscopy following white light cystoscopy versus white light

cystoscopy alone, the addition of blue light often showed higher rates of tumor detection (Refs. 8 and 10). Photodynamic blue light cystoscopy had improved sensitivity and NPV compared to white light cystoscopy, while white light cystoscopy had improved specificity compared to photodynamic blue light cystoscopy, and PPV was similar between white and blue light cystoscopy (Refs. 11 to 14). The literature did not indicate a significant difference in the proportion of patients experiencing an adverse event between those that underwent photodynamic blue light cystoscopy as an adjunct to white light cystoscopy and those that underwent white light cystoscopy alone (Ref. 9).

FDA did not identify new risks or safety and effectiveness concerns from the published literature that differed from the Agency's findings from the PMA data, ODAC materials, and postmarket safety data.

A search of FDA's publicly available MAUDE database revealed 11 MDRs for product code OAY as of April 30, 2026. These MDRs were reported to be related to user injury from a damaged device, thermal injury or damage from contact with an overheated light cable, and failure of the blue light mode to work after the device's first use.

Finally, a search of FDA's publicly available Medical Device Recalls database for product code OAY through January 5, 2026, revealed one product recall, a class II recall, related to a labeling error that was addressed by the manufacturer. The recall was terminated on May 8, 2013. The lack of other recalls, coupled with the low number of reported adverse events, indicate no significant postmarket safety signals for this device type (see further discussion of the MDR and recall data in section II of this proposed order).

Based on the Agency's review of the information described in this proposed order, FDA has determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for cystoscopic systems intended as an aid for detection of bladder cancer and that sufficient information exists to establish such special controls. Therefore, FDA, on its own initiative, is proposing to reclassify these postamendments devices from class III (premarket approval) into class II (special controls), subject to 510(k) requirements.

VII. Proposed Special Controls

FDA believes that cystoscopic systems intended as an aid for detection of bladder cancer can be reclassified into class II with the establishment of special controls. FDA believes that the following proposed special controls would mitigate each of the risks to health described in section V and that these special controls, in addition to general controls, would provide a reasonable assurance of safety and effectiveness for cystoscopic systems intended as an aid for detection of bladder cancer. Table 1 demonstrates how FDA believes each risk to health described in section V would be mitigated by the proposed special controls.

To mitigate the risk of false positive and false negative results, FDA believes that clinical data as well as non-clinical performance testing and certain labeling are needed as special controls. Clinical data are needed to demonstrate that the device can provide accurate detection of bladder cancer with appropriate sensitivity and specificity when used with the approved optical imaging agent(s) specified in the device labeling, as a determination of the likelihood of obtaining a false positive or false negative result needs to be confirmed through clinical biopsy samples in patients with known or suspected bladder cancer. This evaluation cannot be replicated in a non-clinical model, and non-clinical performance testing and labeling would not adequately mitigate this risk.

However, in addition to clinical data, non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must verify and validate filter specifications and functional characteristics, including spectrum and intensity of the illumination source, spectrum of any excitation or emission filters, excitation power and power density, and the optical performance of the cystoscopic system. This non-clinical performance testing would allow flexibility to evaluate appropriate performance based on the characteristics of the subject device without establishing a specific testing requirement that may not be applicable to a particular cystoscopic system intended as an aid for detection of bladder cancer.

In addition, special controls that require in the labeling a summary of clinical data available for the device, a warning that the device should not be used as the only or definitive basis for diagnosis, a statement describing the compatible approved optical imaging agent or agents with the cystoscope, and a detailed summary of the device technical parameters would further mitigate this risk.

The risk of device failure or malfunction can be mitigated by special controls requiring the non-clinical performance testing described above and software verification, validation, and hazard analysis. This risk would be further mitigated by special controls that require the device labeling to include statements related to any device-specific hazards (*e.g.,* foreseeable situations in which the device is likely to fail or not to operate at its expected performance level) and a warning to the user to assess the device for damage prior to use and instructions on determining whether the device has reached the end of its use-life.

The risk of electrical, mechanical, thermal, or light-related hazards leading to patient or user injury or discomfort can be mitigated by special controls that require (1) performance testing that demonstrates electrical, mechanical, thermal, and optical safety; (2) software verification, validation, and hazard analysis; and (3) device labeling that includes instructions on appropriate usage and maintenance of the device, including servicing.

The risk that the device may interfere with other devices due to radiofrequency or electromagnetic interference can be mitigated by a special control requiring performance testing that demonstrates electromagnetic compatibility and device labeling that includes relevant electromagnetic compatibility testing results.

The risks of infection and cross contamination for patient-contacting components can be mitigated by special controls requiring sterilization and reprocessing validation for device components intended to be sterilized by the user prior to use, shelf-life testing, and labeling that includes validated methods and instructions for sterilization and/or reprocessing of any reusable components and an expiration date for any components provided sterile.

The risk of adverse tissue reaction for patient-contacting devices can be mitigated by special controls that require elements of the device that may contact the patient to be demonstrated to be biocompatible and labeling that includes instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR CYSTOSCOPIC SYSTEMS INTENDED AS AN AID FOR DETECTION OF BLADDER CANCER

Identified risks to health	Mitigation measures
False positive or false negative results.	Clinical data Non-clinical performance testing. Labeling.
Device failure or malfunction.	Non-clinical performance testing Software verification, validation, and hazard analysis. Labeling.
Electrical, mechanical, thermal, or light-related injury.	Electrical, mechanical, thermal, and optical safety testing Software verification, validation, and hazard analysis. Labeling.
Interference with other devices.	Electromagnetic compatibility testing. Labeling.
Infection and cross contamination.	Sterilization/reprocessing validation. Shelf-life testing Labeling.
Adverse tissue reaction.	Biocompatibility evaluation. Labeling.

If this proposed order is finalized, cystoscopic systems intended as an aid for detection of bladder cancer will be identified as prescription devices. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5 if the conditions of 21 CFR 801.109 are met.

If this proposed order is finalized, cystoscopic systems intended as an aid for detection of bladder cancer will be reclassified into class II (special controls) and will be subject to premarket notification requirements under section 510(k) of the FD&C Act. As discussed in this proposed order, the intent is for the reclassification to be codified in the new classification regulation 21 CFR 876.1560. If finalized, firms will be required to comply with the particular mitigation measures set forth in the special controls. FDA believes that adherence to the special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of cystoscopic systems intended as an aid for detection of bladder cancer.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

While this proposed order contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E (Premarket Notification Procedures) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485, and the collections of information in 21 CFR part 814 (Premarket Approval of Medical Devices) have been approved under OMB control number 0910–0231.

X. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective 30 days after the date of its publication in the **Federal Register**.

XI. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3) of the FD&C Act, in the proposed order, we are proposing to codify ''Cystoscopic system intended as an aid for detection of bladder cancer'' in the new 21 CFR 876.1560, under which these cystoscopic systems intended as an aid for detection of bladder cancer would be reclassified from class III into class II.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. FDA, PMA No. P050027, Approval Order (May 28, 2010). Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050027.*
* 2. PMA No. P050027, Approved Labeling at p. 7. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050027.*
* 3. FDA, December 17, 2009, Meeting of the Oncologic Drugs Advisory Committee, Transcript. Available at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/oncologic-drugs-advisory-committee.*
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List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.1560 to subpart B to read as follows:

§ 876.1560 Cystoscopic system intended as an aid for detection of bladder cancer.

(a) *Identification.* A cystoscopic system intended as an aid for detection of bladder cancer is a prescription device, which includes a cystoscope and accessories, intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy as an adjunct to white light cystoscopy for the detection of known or suspected bladder cancer, including carcinoma in situ, or in patients undergoing surveillance cystoscopy for bladder cancer. The device is not intended to be the sole or definitive basis for diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must confirm accurate detection of bladder cancer when used with the approved optical imaging agent(s) specified in the device labeling based on output from the device including an assessment of appropriate sensitivity and specificity.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and must verify and validate filter specifications and functional characteristics including the following:

(i) Spectrum and intensity of the illumination source;

(ii) Spectrum of any excitation or emission filters;

(iii) Excitation power and power density; and

(iv) Optical performance of the cystoscopic system.

(3) Performance testing must demonstrate electromagnetic compatibility and electrical, mechanical, thermal, and optical safety of the device.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must demonstrate the sterility of the device or device components intended to be provided sterile.

(7) Performance data must validate the reprocessing instructions for reusable components of the device.

(8) Performance data must support the shelf life of the device or device components intended to be provided sterile by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(9) Labeling must include the following:

(i) A detailed summary of the device technical parameters.

(ii) An expiration date for the device or device components provided sterile.

(iii) Summary of clinical data available for the device.

(iv) A warning that the device should not be used as the only or definitive basis for diagnosis.

(v) A statement describing the approved optical imaging agent(s) that are compatible for use with the cystoscope and supported by the clinical data described in (b)(1).

(vi) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and reprocessing, as applicable, of any reusable components.

(vii) Statements related to any device specific hazards (*e.g.,* foreseeable situations in which the device is likely to fail or not to operate at its expected performance level).

(viii) A warning to assess the device for damage prior to use and instructions on determining whether the device has reached the end of its use-life.

(ix) Instructions on appropriate usage and maintenance of the device, including relevant electromagnetic compatibility testing results and servicing.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16728 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–109082–25]

RIN 1545–BR58

Proposed Removal of a Reporting Requirement for Trusts Whose Charitable Contribution Deductions Are Solely for Contributions Made by Passthrough Entities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would amend existing regulations that require certain trusts to report all charitable contributions and amounts permanently set aside for a charitable purpose on Form 1041–A, *U.S. Information Return Trust Accumulation of Charitable Amounts.* The proposed regulations would remove the reporting requirement for these trusts with respect to taxable years in which the trust's only claimed charitable contribution deduction results from charitable

contributions made by a passthrough entity in which the trust owns an interest. The proposed regulations would also modify the existing regulations to clarify that split-interest trusts satisfy their filing obligations by filing Form 5227, *Split-Interest Trust Information Return,* rather than Form 1041–A. The proposed regulations would affect certain trusts that are required to report all charitable contributions and amounts permanently set aside for a charitable purpose.

DATES: Written or electronic comments and requests for a public hearing must be received by October 16, 2026.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–109082–25) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG–109082–25), Room 5503, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, contact Ganesh Gangasingh or David D. Lee of the Office of Associate Chief Counsel (Passthroughs, Trusts, and Estates), (202) 317–6007 (not a toll-free number); concerning submissions of comments and/or requests for a public hearing, Publications and Regulations Section at (202) 317–6901 (not a toll-free number) or by email at *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Authority

This document contains a proposed amendment to the Income Tax Regulations (26 CFR part 1) under section 6034 of the Internal Revenue Code (Code) relating to the return filing requirements of certain trusts. Section 6034(a) contains an express delegation of authority to the Secretary of the Treasury or the Secretary's delegate (Secretary) to require every trust described in section 4947(a)(2) to furnish the information prescribed by forms or regulations with respect to the taxable year. Section 6034(b) contains an express delegation of authority to the Secretary to require a trust not described in section 4947(a)(1) or (2) of the Code but claiming a deduction under section 642(c) of the Code for the taxable year to furnish the information prescribed by forms or regulations with respect to that taxable year.

These proposed regulations also are issued under the express delegation of authority under section 7805(a) of the Code, which authorizes the Secretary to ''prescribe all needful rules and regulations for the enforcement of [the Code], including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.''

Background

In the case of an estate or trust (other than a ''simple trust'' meeting the specifications of sections 651 and 652 of the Code), section 642(c)(1) generally allows as a deduction in computing its taxable income (in lieu of the deduction allowed by section 170(a) of the Code, relating to the deduction for charitable contributions and gifts) any amount of the trust's gross income, without limitation, which pursuant to the terms of the trust's governing instrument is, during the taxable year, paid for a purpose specified in section 170(c) (determined without regard to section 170(c)(2)(A), which denies deductions for contributions to foreign charities). In addition, if a charitable contribution is paid at any time during the calendar year immediately following the close of such taxable year, then the trustee or administrator may elect, at such time and in such manner as the Secretary prescribes by regulations, to treat such contribution as having been paid during such taxable year.

Section 642(c)(2) also permits such a deduction in computing taxable income for a decedent's estate, and for a trust (other than a simple trust) that is required by its governing instrument to set aside amounts for such charitable purposes, but this provision generally applies only if the estate was established by a will executed, or the trust was created, on or before October 10, 1969, and certain other requirements are met. Such an estate or trust may deduct amounts in computing taxable income that are not paid until a later calendar year.

The predecessor provision to section 6034 under the Internal Revenue Code of 1939 was enacted in the Revenue Act of 1950, Public Law 81–814, 64 Stat. 906 (1950), as part of a larger package of substantive and procedural requirements imposed upon charities and related organizations. With regard to trusts claiming the income tax charitable deduction under the predecessor provision to section 642(c), Congress was concerned that deductions were being claimed for amounts accumulated in the trust that might not actually be paid to charity for an extended period.[1]

Section 6034(a) provides that every trust described in section 4947(a)(2)[2] (split-interest trust) must furnish such information with respect to the taxable year as the Secretary may by forms or regulations require. Section 1201(b)(1) of the Pension Protection Act of 2006, Public Law 109–280, 1201(b)(1), 120 Stat. 780, 1066 (2006), broadly amended section 6034 to allow the IRS to make changes to information reporting requirements for trusts described in section 4947(a)(2). In response, the IRS revised Form 5227, *Split-Interest Trust Information Return.* Form 5227 replaced Form 1041–A, *U.S. Information Return Trust Accumulation of Charitable Amounts,* for trusts described in section 4947(a)(2) for taxable years beginning on or after January 1, 2007. Revised Form 5227 incorporated information previously reported on Form 1041–A, specifically information relating to distributions of principal for charitable purposes and accumulated income set aside for charitable purposes and income distributions for charitable purposes.

With regard to all other trusts that claim a charitable deduction under section 642(c) for the taxable year, section 6034(b)(1) generally requires the trust to furnish such information with respect to the taxable year as the Secretary may by forms or regulations prescribe, including (A) the amount of the deduction taken under section 642(c) within such year, (B) the amount paid out within such year that represents amounts for which deductions under section 642(c) were taken in prior years, (C) the amount for which such deductions were taken in prior years but that has not been paid out at the beginning of such year, (D) the cumulative amount paid out of principal in the current and prior years for the purposes described in section 642(c), (E) the total income of the trust within such year and the expenses attributable thereto, and (F) a balance sheet showing the assets, liabilities, and

[1] S. Rept. No. 2375, 81st Cong., 2d Sess. at 34, 35 (1950); H.R. Rept. No. 81–2319, 81st Cong., 2d Sess. at 40 (1950).

[2] Section 4947(a)(2) describes a category of trusts, not tax-exempt under section 501(a) of the Code, with both charitable and non-charitable beneficiaries for which a charitable deduction was allowed at creation or funding, which are subject to some of the same excise tax rules as private foundations.

net worth of the trust as of the beginning of such year.

Section 6034(b)(2) provides that the reporting requirements under section 6034(b)(1) do not apply to a trust for any taxable year if either (A) all the trust's net income for such year is required to be distributed currently to the trust beneficiaries, or (B) the trust is a charitable trust described in section 4947(a)(1).[3] This reporting, in addition to the trust's annual income tax return, makes it easier for the IRS to determine whether a charitable deduction claimed under section 642(c) relates to funds that have actually been paid and whether a deduction has been claimed more than once for the same charitable contribution. The current revision of Form 1041–A (Sept. 2018), after the initial section identifying the trust and trustee, includes four parts that together account for the six categories of information required to be furnished under section 6034(b)(1)(A) through (F).

Section 1.6034–1(a) generally follows the statutory provisions of section 6034(b), requiring that the categories of information specified in the statute be reported on Form 1041–A. Section 1.6034–1(a) also provides that every trust described in section 4947(a)(2) must file a Form 1041–A, unless an exception applies.[4] Section 1.6034–1(b) excepts two categories of trusts from the requirement of filing Form 1041–A: (1) simple trusts, and (2) trusts described in 4947(a)(1). Section 1.6034–1(c) provides that Form 1041–A is to be filed on or before the 15th day of the fourth month following the close of the trust's taxable year, with the Internal Revenue officer designated by the form instructions, and that an extension may be permitted under § 1.6081–1. Section 1.6034–1(d) includes cross-references to section 6104 (regarding public access to the information on Form 1041–A), section 6652(d) (now section 6652(c)) of the Code (regarding penalties), and sections 7203, 7206, and 7207 of the Code (regarding criminal penalties).[5]

Section 6104 provides for public disclosure of tax information for certain tax-exempt organizations and trusts. Under section 6104(b), this includes the information required to be furnished by section 6034.

Section 6652(c)(2) imposes penalties on a trust and/or the persons required to file returns for the trust for failure to file a return required under section 6034. Section 6652(c)(2)(A) provides that the failure to file penalty generally is $10 per day up to a maximum of $5,000 per return.

Explanation of Provisions

I. Reason for Proposed Regulations

Some deductions under section 642(c) are for a trust's distribution of its own income for purposes specified in section 170(c), but other deductions under section 642(c) can be for charitable contributions made by a passthrough entity in which the trust has an interest. A trust holding a partnership interest would take its distributive share of any of the partnership's charitable contributions by operation of section 702 of the Code, which requires, in determining a partner's income tax, that each partner take into account separately the partner's distributive share of the partnership's items, including charitable contributions (as defined in section 170(c)). Similarly, by operation of section 1366 of the Code, trusts that hold S corporation stock would take into account their pro rata share of the S corporation's items of, among other things, deduction or credit, the separate treatment of which could affect the liability for tax of any shareholder. In either case, it would be the underlying passthrough entity, not the trust, that makes the contribution giving rise to a deduction under section 642(c). The ability for trusts to take into account charitable contributions from passthroughs is addressed in Revenue Ruling 2004–5, 2004–1 C.B. 295 (concerning trusts holding partnership interests) and § 1.641(c)–1(d)(2)(ii) (concerning trusts holding stock in S corporations). In each case, a trust's share of the charitable deduction being passed through from the partnership or S corporation is reported to the IRS on the Schedule K–1 issued to the trust in connection with the entity's own annual return.

Commenters have requested that the Form 1041–A filing requirement be eliminated for each trust whose section 642(c) deductions consist solely of the trust's allocable share of a contribution made by a partnership or S corporation in which the trust holds an interest. Such trusts are not accumulating any income that may be distributed to charity in the future. Instead, these charitable deductions are based solely on the current contributions of a passthrough entity made directly to a charity and are not from any prior year's accumulation of income by the trusts. The trusts themselves never received the amounts that were given to charity and never made any direct charitable contributions. Under these circumstances, the commenters argue, the requirement to file Form 1041–A places an unnecessary burden on those trustees who may not be aware of this filing requirement and who may not have the necessary information to fill out the form.

II. Summary of Proposed Regulations

The Treasury Department and IRS believe that an administrative exception should be created for trusts whose section 642(c) deductions consist solely of the trust's allocable share of a contribution made by a partnership or S corporation in which the trust holds an interest, because these trusts do not fall within the purpose of the information reporting requirement of section 6034(b). The Treasury Department and the IRS propose to remove the section 6034 reporting requirements for trusts whose charitable deduction is exclusively the result of contributions made by a passthrough entity in which the trust directly or indirectly holds an interest.

Additionally, there is a discrepancy between § 1.6034–1 and published instructions for Form 5227 (revised Dec. 2025). Section 1.6034–1 requires every trust described in section 4947(a)(2) to file a Form 1041–A, unless an exception applies. The published instructions for Form 5227, revised after the Pension Protection Act of 2006, state that Form 5227 replaces Form 1041–A for split-interest trusts (after noting that § 1.6034–1 references Form 1041–A). The Treasury Department and the IRS therefore propose updates to § 1.6034–1 to reflect that split-interest trusts must file Form 5227 (or a successor form) rather than Form 1041–A. Proposed § 1.6034–1(a) would clarify the filing requirements by providing that trusts described in section 4947(a)(2) must file a Form 5227 (or a successor form) for each taxable year and that every other trust claiming a charitable or other deduction under section 642(c) for the taxable year must file a Form 1041–A (or a successor form) for each taxable year.

The proposed regulations would create an additional exception under § 1.6034–1(b) for trusts whose section 642(c) deduction for a given taxable year arises solely as a result of the operation of section 702 or section 1366, representing a charitable contribution made at the level of a passthrough entity

[3] Section 4947(a)(1) describes certain trusts, not tax-exempt under section 501(a), but all of the unexpired interests in which are devoted to charitable purposes.

[4] As explained below, § 1.6034–1(a) does not reflect the fact that Form 5227 replaced Form 1041–A for trusts described in section 4947(a)(2) for taxable years beginning on or after January 1, 2007.

[5] Sections 7203, 7206, and 7207 do not specifically refer to section 6034 or Form 1041–A, but provide general criminal penalties for, respectively, willful failures to file returns, fraud or false statements, and fraudulent returns.

in which the trust directly or indirectly holds an interest. Proposed § 1.6034–1(b)(3) would provide that any trust that falls within the exception for a taxable year will not be required to furnish the amount of such deduction on Form 1041–A (or a successor form) for that year.

Proposed Applicability Date

The proposed regulations are proposed to apply to taxable years of trusts ending on or after the date these regulations are published as final regulations in the **Federal Register**. An entity described in proposed § 1.6034–1(b)(3) or a trust described in section 4947(a)(2) may rely on the proposed regulations for taxable years ending before that date.

Special Analyses

I. Regulatory Planning and Review

The Office of Management and Budget's Office of Information and Regulatory Analysis has determined that this proposed regulation is not significant and is not subject to review under section 6(b) of Executive Order 12866. Therefore, a regulatory impact assessment is not required.

The Executive Order 14192 designation for this rule is expected to be deregulatory.

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) generally requires that a Federal agency obtain the approval of the Office of Management and Budget (OMB) before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number. The burdens associated with the collections of information in these proposed regulations are included in Form 5227 and its instructions and approved under OMB control numbers 1545–0047 and 1545–0092 in accordance with PRA procedures under 5 CFR 1320.10.

II. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that the proposed regulations would not have a significant economic impact on a substantial number of small entities. This rule primarily affects trusts, which are not small entities for purposes of the Regulatory Flexibility Act. Although it is anticipated that there may be an incremental economic impact on trustees and advisors that are small entities, including entities that provide tax and legal services that assist individuals and trusts in preparing tax returns, any impact would not be significant and would not affect a substantial number of small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

III. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandate Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million (updated annually for inflation). These proposed regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments or by the private sector in excess of that threshold.

IV. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These proposed regulations do not have federalism implications and do not impose substantial, direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

V. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments) prohibits an agency from publishing any rule that has Tribal implications if the rule either imposes substantial, direct compliance costs on Indian Tribal governments, and is not required by statute, or preempts Tribal law, unless the agency meets the consultation and funding requirements of section 5 of the Executive order. This proposed rule does not have substantial direct effects on one or more federally recognized Indian tribes and does not impose substantial direct compliance costs on Indian Tribal governments within the meaning of the Executive order.

Comments and Requests for a Public Hearing

Pursuant to the Administrative Procedure Act at 5 U.S.C. 553(b)(4), a plain language summary of these proposed regulations is available on the rulemaking docket at *https://www.regulations.gov.*

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All comments submitted will be made available at *https://www.regulations.gov* or upon request.

A public hearing will be scheduled if requested in writing by any person that timely submits electronic or written comments. Requests for a public hearing are also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Statement of Availability of IRS Documents

IRS notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Drafting Information

The principal authors of these proposed regulations are Ganesh Gangasingh and David Lee, Office of the Associate Chief Counsel (Passthroughs, Trusts, and Estates). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

■ **Par. 2.** Section 1.6034–1 is amended by:
■ 1. Revising the section heading.
■ 2. Revising paragraph (a) introductory text.
■ 3. In paragraph (b)(1), adding the language ''(or a successor form)'' after ''Form 1041–A'' in the first sentence.
■ 4. Adding the language ''(or a successor form)'' at the end of paragraph (b)(2).
■ 5. Adding paragraph (b)(3).
■ 6. Revising paragraphs (c) and (d).
■ 7. Adding paragraph (e).

The additions and revisions read as follows:

§ 1.6034–1 Information returns required of trusts described in section 4947(a) or claiming charitable or other deductions under section 642(c).

(a) *In general.* Except as provided in paragraph (b) of this section, every trust described in section 4947(a)(2) of the Internal Revenue Code (Code) (including trusts described in section 664 of the Code) must file a return of information on Form 5227 (or a successor form) for each taxable year, unless all transfers in trust occurred before May 27, 1969, or no deduction was allowed under section 4947(a)(2) for any transfer after that date to a trust created before that date. In addition, except as provided in paragraph (b) of this section, every other trust claiming a charitable or other deduction under section 642(c) for the taxable year must file a return of information on Form 1041–A (or a successor form) for such taxable year. The return must set forth the name and address of the trust and the following information concerning the trust in such detail as is prescribed by the form or in the instructions issued with respect to such form:

* * * * *

(b) * * *

(3) *Trusts claiming section 642(c) deductions resulting from amounts paid by a passthrough entity.* A trust is not required to file a Form 1041–A (or a successor form) if the trust's only claimed deductions under section 642(c) of the Code are attributable to contributions taken into account by the trust under section 702(a)(4) of the Code, section 1366(a)(1) of the Code, or both, for amounts of gross income paid for a purpose specified in section 170(c) of the Code.

(c) *Time and place for filing return.* The return on Form 1041–A or on Form 5227 (or a successor to either form) must be filed on or before the 15th day of the 4th month following the close of the taxable year of the trust, with the Internal Revenue officer designated by the instructions applicable to such form. For extensions of time for filing returns under this section, *see* § 1.6081–1.

(d) *Other provisions.* For publicity of information on Form 1041–A or on Form 5227 (or a successor to either form), see section 6104 of the Code and the regulations thereunder in part 301 of this chapter. For provisions relating to penalties for failure to file a return required by this section, see section 6652(d) of the Code. For the criminal penalties for a willful failure to file a return and filing a false or fraudulent return, see sections 7203, 7206, and 7207 of the Code.

(e) *Applicability date.* This section applies to taxable years ending on or after [date of publication of final regulations in the **Federal Register**].

Frank J. Bisignano,

Chief Executive Officer.

[FR Doc. 2026–16769 Filed 8–14–26; 8:45 am]

BILLING CODE 4831–GV–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 174 and 180

[EPA–HQ–OPP–2026–0332; FRL–13201–05–OCSPP]

Receipt of Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities—May 2026

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of and solicits public comment on initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities. The Agency is providing this notice in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA uses the month and year in the title to identify when the Agency compiled the petitions identified in this notice of filing. Unit II. of this document identifies certain petitions received in 2025 and 2026 that are currently being evaluated by EPA, along with information about each petition, including who submitted the petition and the requested action.

DATES: Comments must be received on or before September 16, 2026.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition (PP) of interest identified in Unit II. of this document, online at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting on and visiting the docket, along with more information about dockets generally, are available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Each application summary in Unit II. specifies a contact division. The appropriate division contacts are identified as follows:

- RD (Registration Division) (Mail Code 7505T); Charles Smith; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What is the Agency's authority for taking this action?

EPA regulations for residues of pesticide chemicals in or on various food commodities are established under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), requires EPA to publish a notice of receipt of these petitions in the **Federal Register** and provide an opportunity for public comment on the requests.

C. What action is the Agency taking?

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the receipt of pesticide petitions filed under FFDCA section 408 that request the establishment or modification of regulations for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comments on the requests before responding to the petitioner. Pursuant to 40 CFR 180.7(f), a summary of the petition identified in this document, prepared by the petitioner, is included in a docket. EPA has determined that the pesticide petitions described in this document contain data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2), and 40 CFR 180.7(b); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be

warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Based upon review of the data supporting these petitions and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA may establish a final tolerance or tolerance exemption that ''may vary from that sought by the petitioner.'' For example, EPA may determine that it is appropriate to vary the commodity name for consistency with EPA's Food and Feed Commodity Vocabulary, which is located here *https://www.epa.gov/pesticide-tolerances/food-and-feed-commodity-vocabulary,* or vary the tolerance level based on available data, harmonization interests, or the trailing zeros policy. In addition, when evaluating a petition's requests for a tolerance or exemption, EPA will consider how use of the pesticide on a crop for which a tolerance is requested may result in residues in or on commodities related to that requested commodity (*e.g.,* whether use on sugar beets for which a tolerance was requested on sugar beet root also requires a tolerance on sugar beet tops or whether use on a cereal grain for which a grain tolerance was requested also requires a tolerance on related animal feed commodities derived from that cereal grain). Public commenters should consider the possibility of such revisions in preparing comments on these petitions.

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. In addition to one complete version of the comment that includes CBI, a copy of the comment without CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov//commenting-epa-dockets.*

II. Petitions Received

This unit provides the following information about the petitions:

- The Pesticide Petition (PP) Identification (IN) number;
- EPA docket ID number for the petition;
- Information about the petition (*i.e.,* name of the petitioner, name of the pesticide chemical residue and the commodities for which a tolerance or exemption is sought);
- The analytical method available to detect and measure the pesticide chemical residue or the petitioner's statement about why such a method is not needed; and
- The division to contact for that petition.

Additional information on the petitions may be obtained through the petition summaries that were prepared by the petitioners pursuant to 21 U.S.C. 346a(d)(2)(A)(i)(I) and 40 CFR 180.7(b)(1), which are included in the docket for the petition as identified in this unit.

- *PP 5F9204.* (EPA–HQ–OPP–2025–3061). Control Solutions, Inc. 5903 Genoa Red Bluff Pasadena, TX 77507, requests to amend the tolerance(s) in 40 CFR 180.564 for residues of the insecticide indoxacarb in or on milk at 0.50 parts per million (ppm); cattle, fat at 1.9 ppm; meat at 0.11 ppm; by products at 0.08 ppm. Animal residue enforcement method is used to measure and evaluate the chemical indoxacarb. *Contact:* RD.
- *PP 5F9167.* (EPA–HQ–OPP–2025–3060). Albaugh North America Limited, EPA Company Number 81598, 4900 Stockyard Expressway, St. Joseph, MO 64504, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide glufosinate-P-ammonium ((2S)-2-amino-4-(hydroxymethylphosphinyl) butanoic acid ammonium salt), including its metabolites and degradates, in or on berries, blueberry at 0.15 ppm; berries, raspberry at 0.15 ppm; canola, rapeseed at 0.4 ppm; cattle, fat at 0.4 ppm; cattle, meat byproducts at 6 ppm; cattle, meat, at 0.15 ppm; citrus, orange at 0.15 ppm; corn, field forage at 4 ppm; corn, field, grain at 0.2 ppm; corn, field, stover at 6 ppm; corn, sweet, ears/grain at 0.3 ppm; corn, sweet, forage at 1.5 ppm; corn, sweet, stover at 6 ppm; cotton seed subgroup 20C at 15 ppm; cotton, gin byproducts at 30 ppm; grapes at 0.05 ppm; milk at 0.15 ppm; olives at 0.5 ppm; pome fruit, apple at 0.25 ppm; pome fruit, pear at 0.25 ppm; potato, tubers at 1.6 ppm; poultry, fat at 0.15 ppm; poultry, meat at 0.15 ppm; poultry, meat byproducts at 0.6 ppm; soybean, forage at 10 ppm; soybean, hay (not established); soybean, seed at 2 ppm; stone fruit, cheery tart at 0.3 ppm; stone fruit, cherry sweet at 0.3 ppm; stone fruit, peach at 0.3 ppm; stone fruit, plum at 0.3 ppm; sugar beets, leaves at 1.5 ppm; sugar beets, molasses at 5 ppm; sugar beets, roots at 1.5 ppm; sugar beets, tops at 0.9 ppm; tree nut, almond hulls at 0.5 ppm; tree nut, almond nutmeat at 0.5 ppm; tree nut, pecan at 0.5 ppm; and indirect or inadvertent residues of glufosinate on barley, hay at 0.4 ppm; barley, straw at 0.4 ppm; buckwheat, fodder at 0.4 ppm; buckwheat, forage at 0.4 ppm; oat, forage at 0.4 ppm; oat, hay at 0.4 ppm; oat, straw at 0.4 ppm; rye, forage at 0.4 ppm; rye, straw at 0.4 ppm; teosinte at 0.4 ppm; triticale at 0.4 ppm; wheat, forage at 0.4 ppm; wheat, hay at 0.4 ppm; and wheat, straw at 0.4 ppm; and indirect or inadvertent residues of glufosinate-P-ammonium on barley, hay at 0.4 ppm; barley, straw at 0.4 ppm; buckwheat, fodder at 0.4 ppm; buckwheat, forage at 0.4 ppm; oat, forage at 0.4 ppm; oat, hay at 0.4 ppm; oat, straw at 0.4 ppm; rye, forage at 0.4 ppm; rye, straw at 0.4 ppm; teosinte at 0.4 ppm; triticale at 0.4 ppm; wheat, forage at 0.4 ppm; wheat, hay at 0.4 ppm; and wheat, straw at 0.4 ppm. Independently validated analytical methods that have been submitted are used to measure and evaluate the chemical glufosinate-P-ammonium. *Contact:* RD.
- *PP 5F9194.* (EPA–HQ–OPP–2025–3291). BASF Agricultural Solutions US LLC, 2 TW Alexander Drive, Research Triangle Park, NC 27713, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide topramezone, [3-(4,5-Dihydro-isoxazol-3-yl)-4-methanesulfonyl-2-methylphenyl] -(5-hydroxyl-1-methyl-1H-pyrazol-4-yl) methanone, including its metabolite M670H05 in or on rapeseed subgroup 20A at 0.01 ppm. Liquid Chromatography-MS/MS is used to measure and evaluate the chemical topramezone. *Contact:* RD.
- *PP 6F9235.* (EPA–HQ–OPP–2026–3169). Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide florylpicoxamid in or on almond, hulls at 15 ppm; apple, wet pomace at 2 ppm; avocado at 0.5 ppm; barley, bran at 0.20 ppm; barley, grain at 0.05 ppm; barley, hay at 2.0 ppm; barley, straw at 0.90 ppm; beet, sugar, dried pulp at 0.40 ppm; beet, sugar, roots at 0.05 ppm; berry, low growing, subgroup 13–07G at 2 ppm; broccoli at 3 ppm; bushberry, subgroup 13–07B at 2 ppm; fruit, pome, group 11–10 at 0.8 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 3 ppm; fruit, stone, group 12–12 at 2 ppm; grape, raisin at 7 ppm; herb fresh leaves subgroup 25A at 90 ppm; hop, dried cones at 30 ppm; leaves of root and

tuber vegetables, group 2 at 30 ppm; nut, tree, group 14–12 at 0.08 ppm; onion, bulb, subgroup 3–07A at 0.09 ppm; onion, green, subgroup 3–07B at 6 ppm; potato, wet peel at 0.03 ppm; rapeseed subgroup 20A at 0.04 ppm; vegetable, cucurbit, group 9 at 0.3 ppm; vegetable, fruiting, group 8–10 at 1.5 ppm; vegetable, leafy, group 4–16 at 40 ppm; vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E at 0.02 ppm; vegetable, legume, pulse, pea, dried shelled, subgroup 6–22F at 0.02 ppm; vegetable, legume, forage and hay, except soybean, subgroup 7–22A at 8.0 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.3 ppm; vegetable, tuberous and corm, subgroup 1C at 0.02 ppm; wheat, aspirated grain fractions at 0.10 ppm; wheat, bran at 0.05 ppm; wheat, forage at2.0 ppm; wheat, grain at 0.02 ppm; wheat, hay at 4.0 ppm; wheat, straw at 0.30 ppm; and in or on the raw agricultural commodity cattle, fat at 0.05 ppm; cattle, liver at 0.07 ppm; cattle, meat byproducts, except liver at 0.02 ppm; goat, fat at 0.05 ppm; goat, liver at 0.07 ppm; goat, meat byproduct, except liver at 0.02 ppm; horse, fat at 0.05 ppm; horse, liver at 0.07 ppm; horse, meat byproduct, except liver at 0.02 ppm. An independently validated multi-residue analytical method is used to measure and evaluate the chemical florylpicoxamid and its metabolite (X12485649). *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: August 11, 2026.

Elizabeth Vizard,

Acting Director, Office of Pesticide Programs.

[FR Doc. 2026–16724 Filed 8–14–26; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 91, No. 157

Monday, August 17, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday, August 21, 2026, 10:00 a.m. EST.

ADDRESSES: Meeting to take place virtually and is open to the public. The meeting will be livestreamed on the Commission's YouTube page: *https://www.youtube.com/user/USCCR/videos.*

FOR FURTHER INFORMATION CONTACT: Joe Kim: 202–499–0263; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Government in Sunshine Act (5 U.S.C. 552b), the Commission on Civil Rights is holding a meeting to discuss the Commission's business for the month of August. This business meeting is open to the public. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, August 21, 2026, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
A. Discussion and Vote on Fiscal Year 2027 Report Topics:
- *Fiscal Year 2027 Statutory Enforcement Report:* Beyond the Border: The State of Civil Rights Under Federal Immigration Enforcement in America's Communities
- *Fiscal Year 2027 Briefing Report:* Protecting and Promoting the Civil Rights of Aging and Disabled Persons in Senior and Long-Term Care Facilities and Managed Care

B. Management and Operations
- Staff Director's Report

III. Adjourn Meeting

Dated: August 13, 2026.

Hyung Kim,

USCCR Public Affairs Specialist.

[FR Doc. 2026–16743 Filed 8–13–26; 11:15 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–101–2026]

Foreign-Trade Zone (FTZ) 176, Notification of Proposed Production Activity; Coilcraft, Inc.; (Ferrous Iron Pre-Fabrication Material); Princeton, Illinois

Coilcraft, Inc. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Princeton, Illinois, within FTZ 176. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on August 11, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished product is ferrous iron pre-fabrication material (duty free).

The proposed foreign-status material/component is ferrous iron raw materials (duty free).

The request indicates that certain materials/components are subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is September 28, 2026.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Brian Warnes at *brian.warnes@trade.gov.*

Dated: August 13, 2026.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2026–16752 Filed 8–14–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–967]

Aluminum Extrusions From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2024–2025

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that the 18 companies under review of the antidumping duty (AD) order on aluminum extrusions from the People's Republic of China (China), covering the period of review (POR) May 1, 2024, through April 30, 2025, are not eligible to receive a separate rate and are, therefore, part of the China-wide entity.

DATES: Applicable August 17, 2026.

FOR FURTHER INFORMATION CONTACT: Robert Hedberg, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482- 0955.

SUPPLEMENTARY INFORMATION:

Background

On April 14, 2026, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited interested parties to comment.[1] On June 5, 2026, Commerce notified U.S. Customs and

[1] *See Aluminum Extrusions from the People's Republic of China: Preliminary Results and Rescission, in Part, of Antidumping Duty Administrative Review; 2024–2025,* 91 FR 19109 (April 14, 2026) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum (PDM).

Border Protection (CBP) that evasion of antidumping duties may be occurring on imports of subject merchandise.[2] No interested party submitted comments on the *Preliminary Results,* which are herein adopted as the final results of review. Additionally, because the final results remain unchanged from the *Preliminary Results,* no decision memorandum accompanies this notice. Commerce conducted this administrative review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [3]

The products covered by the *Order* are aluminum extrusions from China. For a complete description of the scope of this *Order, see* the Preliminary Decision Memorandum.

The China-Wide Entity

Commerce considers all companies for which a review was requested, and which did not demonstrate separate-rate eligibility, to be part of the China-wide entity. As stated above, the 18 companies under review are not eligible for a separate rate and are, thus, part of the China-wide entity because they did not provide the requisite documentation to establish separate rate eligibility.

Because no party requested a review of the China-wide entity, and Commerce no longer considers the China-wide entity as an exporter conditionally subject to administrative reviews,[4] we did not conduct a review of the China-wide entity. Thus, the weighted-average dumping margin for the China-wide entity rate (*i.e.,* 86.01 percent) is not subject to change.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce did not calculate any dumping margins in this review, there are no calculations to disclose.

Assessment Rate

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Because we determine that certain companies under review did not demonstrate separate rate eligibility and are part of the China-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 86.01 percent to all entries of subject merchandise during the POR that were exported by companies listed in the Appendix to this notice.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) for previously examined China and non-China exporters not listed in the Appendix that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (2) for all China exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity (*i.e.,* 86.01 percent); and (3) for all non-China exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the China exporter that supplied that non-China exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(1).

Dated: August 12, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Companies Determined To Be Part of the China-Wide Entity

1. Anji Chang Hong Chain Manufacturing Co., Ltd.
2. Assa Abloy (Zhongshan) Security Technology
3. Assa Abloy Entrance Systems Suzhou
4. Assa Abloy Global Solutions (Shanghai)
5. Citic Dicastal Co., Ltd.
6. Damco China Limited Ningbo Branch
7. Ewellix Motion Technologies (Pinghu)
8. Green & Light Automotive Components
9. Hebei Jinshi Industrial Metal Co., Ltd.
10. Ningbo Yesheng Precision Technical
11. Pxi Auto Components (Suzhou) Co., Ltd.
12. SAIC Volkswagen Automotive Co., Ltd
13. Shanghai Zesheng Automotive Technology Co., Ltd.
14. Synergy Architectural Hardware Limited
15. Techno Precision (Shen Zhen) Co., Ltd.
16. Xiamen Xianghao Trading Co., Ltd.
17. Zhongnan Aluminum Wheel
18. ZZF Fence Technology Co., Ltd.

[FR Doc. 2026–16753 Filed 8–14–26; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See* Commerce's Letter, ''CBP Evasion Notification,'' dated June 5, 2026.

[3] *See Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order,* 76 FR 30650 (May 26, 2011) (*Order*).

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF932]

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Meeting of the South Atlantic Fishery Management Council.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the Habitat and Ecosystem Committee; the Southeast Data, Assessment and Review Catch Advice and Data Committee; and the Snapper Grouper Committee. The meeting week will also include a formal public comment session and closed and open meetings of the Full Council.

DATES: The Council meeting will be held from 8:30 a.m. on Monday, September 14, 2026, until 12 p.m. on Friday, September 18, 2026.

ADDRESSES: *Meeting address:* The meeting will be held at the Drury Plaza Hotel North Charleston, 2934 West Montague, North Charleston, SC 29418; phone (843) 938–1503. The meeting will also be available via webinar. See **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Myra Brouwer, Deputy Director for Management, SAFMC; phone (843) 302–8436 or toll free (866) SAFMC–10; FAX (843) 769–4520; email: *myra.brouwer@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including agendas, overviews, and briefing book materials will be posted on the Council's website at: *https://safmc.net/council-meetings/.* Webinar registration links for the meeting will also be available from the Council's website.

Public comment: Public comment on agenda items may be submitted through the Council's online comment form available from the Council's website. Written comments will be accepted from August 28, 2026, until September 18, 2026. These comments are accessible to the public, part of the Administrative Record of the meeting, and immediately available for Council consideration. A formal public comment session will also be held during the Council meeting.

The items of discussion in the individual meeting agendas are as follows

Council Session I, Monday, September 14, 2026, 8:30 a.m. Until 12 p.m. (Closed Session):

The Council will meet in closed session to receive a litigation brief, if needed, review proposed changes to the advisory panel policy to clarify term limits, consider establishing chair and vice chair positions for the Citizen Science Operations Advisory Panel (AP), hold a discussion related to membership in the Executive Committee, review the Award of Excellence criteria, and make appointments to APs and Southeast Data, Assessment, and Review (SEDAR) workshop observers.

Council Session I, Monday, September 14, 2026, 1:30 p.m. Until 5 p.m

Newly appointed Council members will be sworn in and the 2025 Law Enforcement Officer of the Year Award will be presented. The Council will receive the following reports: a litigation brief, state agencies, Council liaisons, and the Shrimp Workgroup. The Council will also receive an update on Executive Order 14276. The National Marine Fisheries Service (NMFS) Southeast Regional Office (SERO) and Southeast Fisheries Science Center (SEFSC) will provide updates to the Council, including a presentation on discards in South Atlantic fisheries and the Observer Program. The Council will also receive a presentation on landings of unmanaged species and an update on the Resilient Fisheries projects. A presentation to review information on the scoping process for potential Atlantic Large Whale Take Reduction Plan modifications will also be delivered. Lastly, the Council will receive updates on managed species outside its jurisdiction.

Habitat and Ecosystem Committee, Tuesday, September 15, 2026, 8:30 a.m. Until 10:30 a.m

The Committee will receive a presentation on the Ecosystem Information Review project and a report from the Habitat and Ecosystem AP.

SEDAR Catch Advice and Data Committee, Tuesday, September 15, 2026, 10:45 a.m. Until 3:30 p.m

The Committee will receive a report from the SEDAR Steering Committee, review assessment updates and the SEDAR schedule, and conduct the stock risk rating for hogfish, black grouper, and gag. The Committee will review terms of reference for red grouper, snowy grouper, and vermilion snapper. The Committee will review and approve an outline and timeline for the Standardized Bycatch Reduction Methodology review and receive an update on the Southeast Reef Fish Survey and the Southeast Area Monitoring and Assessment Program.

Snapper Grouper Committee, Tuesday, September 15, 2026, 3:45 p.m. Until 5 p.m., Wednesday, September 16, 2026, 8:30 a.m. Until 3:45 p.m., and Thursday, September 17, 2026, 8:30 a.m. Until 2:30 p.m

The Committee will receive updates from the NMFS on amendments undergoing rulemaking and Exempted Fishing Permit applications. The Committee will continue discussion of Amendment 61 to the Snapper Grouper Fishery Management Plan to evaluate the composition of the Snapper Grouper Fishery Management Unit.

The Committee will discuss Amendment 44 to the Snapper Grouper Fishery Management Plan addressing jurisdictional and sector allocations of yellowtail snapper and mutton snapper, and Regulatory Amendment 39 to the Snapper Grouper Fishery Management Plan addressing sunsetting of Spawning Special Management Zones. The Committee will consider approving these two amendments for public hearings. The Committee will continue discussing Amendment 60 to the Snapper Grouper Fishery Management Plan addressing commercial management measures and receive a presentation on Vessel Monitoring Systems (VMS) and notification requirements. The Committee will review comments from public hearings held over the summer and approve all actions in the amendment. A public hearing on Amendment 60 will also be held, and comment will be accepted during the public comment period.

Wednesday, September 16, 2026, 4 p.m.—Public comment will be accepted from individuals attending the meeting in person and via webinar on all items on the Council's meeting agenda. The Council Chair will determine the amount of time provided to each commenter based on the number of individuals wishing to comment.

The Committee will continue discussing Regulatory Amendment 38 to the Snapper Grouper Fishery Management Plan, which addresses vessel limits for headboats, and will receive an update on the Snapper Grouper Management Strategy Evaluation (MSE) and the Wreckfish MSE. The Committee will provide comments and draft conclusions and recommendations for the Wreckfish Individual Transferable Quota Program Review. Lastly, the Committee will receive a report from the Blueline Tilefish Joint Sub-Committee and

review and approve topics for the fall meeting of the Snapper Grouper AP.

Council Session II, Thursday, September 17, 2:45 p.m. Until 5 p.m

The Council will hold elections for Chair and Vice Chair. The Council will then discuss a comprehensive amendment to address commercial trip limit sale and revise the abbreviated framework process. The Council will discuss potential modifications to the requirements for sea turtle release gear, management of cownose rays, and review and approve topics for the fall meeting of the Mackerel Cobia AP.

Council Session II, Friday, September 18, 8;30 a.m. Until 12 p.m

The Council will review its workplan, reports from the committees that met during the week and the June 2026 report from the Executive Committee, review upcoming meetings, and discuss any other business as needed.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 12, 2026.

Anna Michelle Harrison,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–16703 Filed 8–14–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF936]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Ferndale Pier Maintenance Activities in Ferndale, Washington

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of renewal incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued a renewal incidental harassment authorization (IHA) to Petrogas Pacific, LLC (Petrogas) to harass marine mammals incidental to Ferndale Pier Maintenance Activities in Ferndale, Washington.

DATES: This renewal IHA is valid from August 13, 2026, through July 31, 2027.

ADDRESSES: Electronic copies of the original application, renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Robert Pauline, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are promulgated or, if the taking is limited to harassment, an IHA is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as ''mitigation measures''). NMFS must also prescribe requirements pertaining to monitoring and reporting of such takings. The definition of key terms such as ''take,'' ''harassment,'' and ''negligible impact'' can be found in the MMPA and NMFS's implementing regulations (see 16 U.S.C 1362; 50 CFR 216.103).

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances.

Specifically, on a case-by-case basis, NMFS may issue a one-time 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when: (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned; or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice would not be completed by the time the initial IHA expires and a renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA). The request for renewal must include the following:
  - An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial

IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

○ A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

• Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals.*

History of Request

On September 4, 2024, NMFS issued an IHA to Petrogas to take marine mammals incidental to Ferndale Pier Maintenance Activities in Ferndale, Washington (89 FR 73381, September 10, 2024), effective from August 1, 2025, through July 31, 2026. On May 15, 2026, NMFS received an application from Petrogas for the renewal of that initial IHA. As described in the application for renewal IHA, the activities for which incidental take is requested are nearly identical to those covered in the initial authorization but will not be completed prior to its expiration

As required, the applicant also provided a preliminary monitoring report (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities*) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted. The notice of the proposed renewal IHA was published on July 13, 2026 (91 FR 42944).

Description of the Specified Activities and Anticipated Impacts

The purpose of this construction project is to remove the existing timber Pier in Ferndale, Washington, that has served as a loading facility since 1965 and replace it with a new structure that meets current industry best practices. As described in detail in the notices for the initial 2025 IHA (89 FR 73381, September 10, 2024; 89 FR 47903, June 4, 2024) planned in-water construction activities included impact and vibratory installation of 9 permanent 30-inch steel pipe piles and removal of 69 existing 16-inch timber piles by vibratory hammer over 17 days. These 69 timber piles were not removed under the initial IHA. During the 2025 construction season, only 10 days of in-water construction were required to install the nine 30-inch steel piles by impact and vibratory installation between August 1, 2025, and October 31, 2025.

A minor change to the activities conducted by Petrogas was described in the renewal letter. We refer to the documents related to the previously issued IHA and describe any new or changed information here. These previous documents include the **Federal Register** notice of the issuance of the initial IHA (89 FR 73381, September 10, 2024), and the **Federal Register** notice of the proposed IHA (89 FR 47903, June 4, 2024) and all associated references and documents. The descriptions and analyses contained in those documents remain accurate apart from the minor modifications described herein. We also refer the reader to the previous Petrogas application and final monitoring report for the 2025 construction activities, which can be found at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.*

Petrogas made a minor, unanticipated design change to the project. Nine permanent 30-inch steel piles were installed by vibratory and impact driving for the replacement North Mooring Dolphin (NMD) as planned under the initial IHA. However, an additional nine temporary 30-inch steel piles were installed by vibratory driving only around the old NMD to build a temporary work platform. One of these temporary 30-inch piles was removed under the initial IHA. The remaining 8 30-inch temporary piles and the existing 69 16-inch timber piles will be removed during the upcoming season by vibratory driving. Work is anticipated to require 5 days of in-water work.

Detailed Description of the Activity

A detailed description of the construction activities for which take is authorized here may be found in the Notices of the Proposed (89 FR 47903, June 4, 2024) and Final IHA (89 FR 73381, September 10, 2024) for the initial authorization. The renewal IHA is effective for a period not exceeding 1 year from the date of expiration of the initial IHA (July 31, 2027). The location and timing are identical to those described in the previous notices.

As noted above, Petrogas was forced to make a design change under the initial IHA. Petrogas initially planned to remove the large concrete cap of the NMD with a crane and place it on a barge. Since the cap weighed approximately 500 tons (453.6 metric tons), a very large crane was needed. Petrogas was not able to procure a crane large enough for this task, so an alternative plan was developed late in the planning, permitting and preparation process. The safest available plan was to build a temporary work platform around the NMD using eight temporary 30-inch steel piles for support and then cut the pile cap into smaller, manageable pieces. Note that an additional, temporary 30-inch pile was lightly placed to hold the pile form for installing the other eight temporary piles at the appropriate design angles. This single pile was removed under the initial IHA.

Under the initial IHA it was assumed that up to 1.5 30-inch steel piles would be installed via vibratory driver each day and 20 16-inch timber piles would be removed via vibratory driver each day. The renewal IHA assumes that the 8 temporary 30-inch steel piles and 20 16-timber piles would be removed via vibratory driver each day.

The mitigation and monitoring requirements as described in the initial IHA and the marine mammal monitoring plan were followed throughout the first year of work including during vibratory installation of the temporary steel 30-inch steel piles. The temporary pile drive time per day in the initial IHA is equivalent to those in the renewal for 16-inch timber piles (40 minutes), while the temporary drive time per day for vibratory driving of the 30-inch piles is 10 minutes greater per day for the renewal IHA (40 vs. 30 minutes). However, vibratory removal of 30-inch steel piles would be done in a single day under the renewal IHA compared to up to 5 days under the initial IHA. Vibratory removal of the existing 16-inch timber piles would take 4 days under either scenario. This assumes that Petrogas is able to work

uninterrupted at maximum capacity every day. Since this may not be possible due to a range of factors (*e.g.,* weather, turbidity above a regulatory threshold), Petrogas may require additional in-water workdays. This renewal IHA is effective from August 13, 2026, through July 31, 2027.

TABLE 1—PRODUCTION RATES FOR VIBRATORY PILE DRIVING AND REMOVAL ACTIVITIES INCLUDED IN THE INITIAL IHA AND PETROGAS' PLANNED REVISIONS FOR THE RENEWAL

	Initial IHA 2025		Renewal 2026	
	Permanent and temporary pile installation: vibratory 30-inch steel	Temporary pile removal: vibratory 16-inch timber	Temporary pile removal: vibratory 30-inch steel	Temporary pile removal: vibratory 16-inch timber
Number of piles	*18	69	8	69
Maximum piles per day	1.5	20	8	20
Minutes per pile	20	2	5	2
Minutes per day	30	40	40	40
Number of days	12	4	1	4

*Nine additional piles added due to inability to secure crane. One temporary pile removed in 2025.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for take is authorized, including information on abundance, status, distribution, and hearing, may be found in the Notices of the Proposed (89 FR 47903, June 4, 2024) and Final IHA (89 FR 73381, September 10, 2024) for the initial authorization. With the exception of harbor seals, NMFS has reviewed the monitoring data from the initial IHA, current stock assessment reports, information on relevant unusual mortality events, and other scientific literature, and determined there is no new information that affects which species or stocks have the potential to be affected or the pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the initial IHA. According to Pearson *et al.* (2024), the stock abundance of the Northern Inland Waters stock of harbor seal is now 15,898 animals (changed from 16,451) and the minimum population is 14,505 animals (changed from 15,462). The potential biological removal and mortality/serious injury values are undetermined.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which incidental take is authorized here may be found in the Notice of the Proposed IHA (89 FR 47903, June 4, 2024) for the initial authorization. NMFS has reviewed the monitoring data from the initial IHA, current stock assessment reports, information on relevant unusual mortality events, and other scientific literature, and determined that there is no new information that affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods used to estimate take for the specified activity are found in the Notices of the Proposed (89 FR 47903, June 4, 2024) and Final IHA (89 FR 73381, September 10, 2024) for the initial authorization. The source levels and marine mammal occurrence data applicable to this renewal authorization remain unchanged from the previously issued initial IHA (89 FR 73381, September 10, 2024).

Petrogas and NMFS reanalyzed the Level A harassment zones for vibratory pile installation and removal activities to reflect Petrogas' planned minor changes (table 1) as well as the 2024 Updated Technical Guidance as the initial analysis was based on the 2018 Technical Guidance (89 FR 73381, September 10, 2024). Results are shown in table 2.

For both the initial IHA and proposed IHA renewal, Petrogas and NMFS quantitatively assessed potential exposure of marine mammals to noise levels from pile driving over the NMFS threshold guidance using the following equation to provide an estimate of potential exposures within estimated harassment zones:

$$\textit{Exposure estimate} = N \times \textit{Level B harassment zone (km}^2\textit{)} \times \textit{maximum days of pile driving}$$

Where:

N = density estimate (animals per km²) used for each species.

TABLE 2—LEVEL A AND LEVEL B HARASSMENT ISOPLETHS FROM VIBRATORY DRIVING USING THE 2024 TECHNICAL GUIDANCE

[Level A harassment isopleths based on 2018 guidance, used in the 2024 IHA analysis, are presented in parentheses]

Pile size/type	Level A isopleths—pinnipeds (m)		Level A isopleths—cetaceans (m)			Level B isopleths (m)/area (km²)
	Harbor seal	Sea lions	LF	HF [1]	VHF [2]	
16-inch Timber Piles	10.6 (3.7)	3.6 (0.3)	8.2 (6.1)	3.2 (0.5)	6.7 (9)	6,309.6 (62.5)
30-inch steel	6.7 (1.9)	2.2 (0.1)	5.2 (3.2)	2 (0.3)	4.2 (4.7)	3,981 (24.9)

[1] Species that were considered Mid-Frequency cetaceans under the NMFS 2018 Technical Guidance are now considered High Frequency cetaceans under the NMFS 2024 Technical Guidance.

[2] Species that were considered High-Frequency cetaceans under the NMFS 2018 Technical Guidance are now considered Very High Frequency cetaceans under the NMFS 2024 Technical Guidance.

Level A harassment isopleths increased slightly for all hearing groups except for very high frequency cetaceans (categorized as high frequency cetaceans prior to application of the 2024 Technical Guidance). These changes do not impact NMFS' analysis related to the potential for Level A harassment, which is unlikely to occur.

Petrogas would continue to implement shutdown zones that are equivalent to the Level A harassment zones during all vibratory pile removal activities for all hearing groups, as described in the initial 2025 IHA (89 FR 73381, September 10, 2024). The same occurrence assumptions that were used to estimate take for the 2024 IHA and described in the associated proposed FRN (89 FR 47903, June 4, 2024) are applied here. The daily duration of vibratory removal of 30-inch piles has increased from 30 to 40 minutes while the estimated total number of in-water workdays has decreased from 17 to 5.

The calculated take by Level B harassment based on species density for Steller sea lions and California sea lions was one and six respectively. Petrogas has requested an increase to 10 Steller sea lion takes and 30 California sea lion takes by Level B harassment. While there are no haul-out sites nearby, there are haul-out sites in the greater Strait of Georgia, and animals of these species are known to travel significant distances in search for prey, possibly into the marine waters of the adjacent Cherry Point Aquatic Reserve. The initial IHA had also increased authorized take of sea lions above the calculated estimated take values. The marine mammal monitoring report submitted by Petrogas recorded a single sea lion observation which occurred when there was no driving activity underway. A total of 41 harbor porpoises and 22 harbor seals were observed with 7 porpoise and 9 seal takes by Level B harassment.

NMFS' authorized take for the renewal IHA are indicated in table 3. No take by Level A harassment is authorized.

TABLE 3—AUTHORIZED TAKE OF MARINE MAMMALS BY LEVEL A AND LEVEL B HARASSMENT BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Common name	Stock	Stock abundance	Level A	Level B	Take as percentage of stock
Harbor porpoise	Washington Inland Waters	11,233		594	5.29
Steller sea lion	Eastern U.S.	36,308		10	0.03
California sea lion	U.S.	257,606		30	0.01
Harbor seal	Washington Northern Inland	15,898		209	1.31

Description of Mitigation, Monitoring and Reporting Measures

The required mitigation, monitoring, and reporting measures included as requirements in this authorization are nearly identical to those included in the **Federal Register** notice announcing the issuance of the initial 2025 IHA (89 FR 73381, September 10, 2024) and the discussion of the least practicable adverse impact included in that document and the Notice of the proposed IHA (89 FR 47903, June 4, 2024) remains accurate. The only changes are removal of the mitigation requirements for use of bubble curtains as well as soft start since no impact driving would occur under this renewal IHA. The following measures are required under this renewal:

(a) Petrogas must employ Protected Species Observers (PSO) and establish monitoring locations. The Holder must monitor the project area to the maximum extent possible based on the required number of PSOs, required monitoring locations, and environmental conditions.

(b) Monitoring must take place from 30 minutes prior to initiation of pile driving activity (*i.e.,* pre-start clearance monitoring) through 30 minutes post-completion of pile driving activity.

(c) Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the lead PSO to determine that the shutdown zones are clear of marine mammals. Pile driving may commence following 30 minutes of observation when the determination is made that the shutdown zones are clear of marine mammals.

(d) If a marine mammal is observed entering or within the shutdown zones (table 4), pile driving activity must be delayed or halted.

(e) If pile driving is delayed or halted due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily exited and been visually confirmed beyond the shutdown zone, or 15 minutes have passed without re-detection of the animal.

(f) Specific measures for avoiding take of killer whales and humpback whales:

(i) Prior to the start of pile driving activities each day, Petrogas must contact the ORCA network to obtain the latest sightings information for Southern Resident killer whale (SRKW) and humpback whales.

(ii) Petrogas must delay or halt pile driving activities if SRKW, unidentified killer whale (*i.e.,* transient) or humpback whales are sighted within the vicinity of the project area and are approaching the Level B harassment zones during in-water activities.

(iii) If a SRKW, unidentified killer whale, or humpback whale enters the Level B harassment zone undetected, in-water pile driving must be suspended immediately upon detection and must not resume until the animal exits the Level B harassment zone or 15 minutes have passed without re-detection of the animal.

(g) Pile driving activity must be halted (as described in condition 4(d) of initial IHA) upon observation of either a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met, entering or within the harassment zone.

(h) Construction supervisors and crews, PSOs, and relevant Petrogas staff must avoid direct physical interaction with marine mammals during construction activity. If a marine mammal comes within 10 meters of such activity, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions, as necessary to avoid direct physical interaction.

The required shutdown and monitoring zones shown in table 4 are identical to those included as part of the initial IHA.

TABLE 4—SHUTDOWN AND MONITORING ZONES (m)

Pile size/type	Shutdown zone			Level B harassment monitoring zone
	VHF	Phocid	Otariid	
16-inch timber Vibratory	10	10	10	6,310
30-inch steel Vibratory	10	10	10	3,990

Comments and Responses

A notice of NMFS' proposal to issue a renewal IHA to Petrogas was published in the **Federal Register** on July 13, 2026 (91 FR 42944). That notice either described, or referenced descriptions of, Petrogas' activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, estimated amount and manner of take, and proposed mitigation, monitoring and reporting measures. NMFS received no public comments.

Determinations

The planned action is identical to that of the initial authorization in terms of effects. The minor change of vibratory removal of an additional eight temporary 30-inch steel installed under the initial IHA does not modify our findings. The same marine mammals are affected, and the potential effects and estimated take are a subset of the initial IHA. Mitigation and monitoring requirements remain the same as the initial authorization apart from removing bubble curtain and soft-start measures since no impact driving is planned. While the population abundance of Northern Inland Waters stock of harbor seal has decreased slightly (now 15,898 animals changed from 16,451) there has been no effect on our findings.

With a subset of estimated take, the extensive analysis, as well as the associated findings included in the prior documents remain applicable. We found that the previous IHA had a negligible impact, and with the issuance of a renewal, the taking would be small relative to population size.

NMFS has concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Petrogas' activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are included.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our action (*i.e.,* the issuance of a renewal IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental take authorizations with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS determined that the issuance of the initial IHA qualified to be categorically excluded from further NEPA review. NMFS has determined that the application of this categorical exclusion remains appropriate for this renewal IHA.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Renewal

NMFS has issued a renewal IHA to Petrogas for the take of marine mammals incidental to conducting Ferndale Pier Maintenance Activities in Ferndale, Washington effective from the date of issuance through July 31, 2027.

Dated: August 13, 2026.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2026–16758 Filed 8–14–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE886]

Notice of Intent To Prepare an Environmental Analysis Assessing Potential Modifications to the Atlantic Large Whale Take Reduction Plan To Reduce Mortality and Serious Injury of Large Whales in Commercial Trap/Pot and Gillnet Fisheries Along the U.S. East Coast

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to prepare an environmental impact statement; request for comments.

SUMMARY: NMFS intends to prepare an environmental analysis in accordance with the National Environmental Policy Act (NEPA) to analyze the impacts of alternatives to amend the Atlantic Large Whale Take Reduction Plan (Plan) if determined to be necessary to reduce mortalities and serious injuries of North Atlantic right whales (*Eubalaena*

glacialis) and other large whales caused by entanglement in commercial trap/pot and gillnet fisheries along the U.S. East Coast. This notice of intent informs the public of an upcoming scoping period to solicit input on potential efforts to reduce the risk of entanglement to right, humpback *(Megaptera novaeangliae),* and fin whales *(Balaenoptera physalus)* in U.S. East Coast commercial trap/pot and gillnet fishing gear while stabilizing the economic viability of the U.S. commercial fishing industry, protecting coastal community heritage, and minimizing regulatory burdens to meet statutory requirements under the Marine Mammal Protection Act (MMPA) and other laws as well as administration priorities. A complete list of fisheries regulated by the Plan is included below. This Notice of Intent (NOI) initiates the scoping process, an early and open step designed to determine the scope of issues to be addressed in depth within the environmental analysis. This document is not a notice of proposed rulemaking.

DATES: Comments must be received by October 16, 2026.

Public Hearing: A recorded presentation will be provided online and a virtual public scoping meeting will be scheduled. Additionally, presentations for the Atlantic States Marine Fisheries Commission and New England, Mid-Atlantic, and South Atlantic Fishery Management Councils may be provided based on scheduling availability. See **ADDRESSES** for details.

ADDRESSES: You may submit comments on this NOI, identified by NOAA–NMFS–2025–0041, by either of the following methods:

- *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2025–0041 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Instructions:* All comments received that are timely and properly submitted are a part of the public record and may be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information *(e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by us.
- *Oral Comments:* One virtual public scoping meeting will be held during the comment period.

More information, including a recorded presentation on the scoping period, a document that describes examples of measures under consideration and input requested, and the date of the public scoping remote meeting will be posted on the Plan website, *https://www.fisheries.noaa.gov/ALWTRP,* or you may contact Jennifer Goebel (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Jennifer Goebel, Atlantic Large Whale Take Reduction Team Coordinator, Greater Atlantic Region. Telephone: (978) 281–9175. Address: 55 Great Republic Drive, Gloucester, MA 01930. Email: *nmfs.gar.alwtrt@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Purpose and Need for Proposed Action

Status of North Atlantic Right Whales

North Atlantic right whales (hereafter ''right whales'') are listed as endangered under the Endangered Species Act (ESA) and considered depleted under the MMPA. After more than 2 decades of an increasing population trend peaking in 2011 with an estimated 484 whales, the population declined to an estimate of 359 living right whales in 2020 with a more recent increase to approximately 380 living right whales in 2024 (Linden 2025). The current population estimate is still well below the stock's optimum sustainable population (MMPA sec. 3(9)). An unusual mortality event (UME) was declared in 2017, when a total of 17 confirmed dead right whales were documented, many in Canadian waters. As of July 2026, the UME involves documented impacts to 176 individuals in both U.S. and Canadian waters, comprising 43 right whale mortalities, 41 seriously injured right whales, and 92 whales with sublethal injuries or illnesses. The UME considers observed and documented incidents, and while these incidents confirm human impacts on the population, the best available science predicts that the actual number of right whale deaths and serious injuries is higher, as many incidents are never observed. From 2017 through 2023, there were an estimated 147 deaths (Linden 2025). Estimated deaths for 2024, 2025, and 2026 are not yet available. NMFS will publish these data when they are available. Nevertheless, the combination of known and unknown human caused deaths and serious injuries appear to be hindering the ability of right whales to meet recovery goals.

One of the primary causes of mortality and serious injury (M/SI) of right whales is entanglement in fishing gear. Of the 176 documented incidents in the UME, 111 (63 percent) are attributed to entanglements, including 48 either killed by entanglements (11) or so seriously injured (37) that they are unlikely to survive, plus another 63 that are injured or in poor health (reduced body size, ability to reproduce) as the result of an entanglement. Scarring evidence of entanglement is observed on more than 85 percent of all right whales, with the vast majority having been entangled more than once, though only 7.8 percent of all entanglement events are seen with attached gear (Hamilton 2024). The 2023 North Atlantic Right Whale Stock Assessment Report established the potential biological removal (PBR) for the stock at 0.73 (Hayes *et al.* 2024), meaning that fewer than one right whale can be killed or seriously injured by human causes each year in order for the stock to reach its optimum sustainable population based on the data available at the time of publication. However, the U.S. and Canada implemented additional conservation measures in the early 2020s and the impact of those measures on the population could not be fully addressed in the 2023 Report.

Changes in oceanographic conditions and associated changes in prey abundance and distribution exacerbated the right whale's population decline in the late 2010s. These changes shifted the overlap between right whales, fisheries and vessel traffic into areas where protections were not previously implemented, and increased the energy required by right whales traveling farther in search of food. Range-wide, human-caused annual M/SI likely remains higher than the calculation of PBR in 2023. We have not yet calculated PBR based on the most recent data but intend to do so as part of the process of re-convening the Atlantic Large Whale Take Reduction Team (Team) later this year. Further mitigation of entanglements in U.S. commercial fisheries may be necessary to ensure that U.S. fishery-caused M/SI is below that PBR, the short-term goal under the MMPA, and to work towards the MMPA long-term goal of insignificant levels of M/SI (defined as 10 percent of PBR), taking into account the economics of the fishery, the availability of existing technology, and existing State or regional fishery management plans. The insignificance level was last calculated at 0.073/year (Hayes *et al.* 2024). In addition, while the population appears

to be exhibiting modest growth in recent years, the population is not currently achieving the average 2-percent growth rate for a period of 35 years set forth in the North Atlantic Right Whale Recovery Plan as the recovery goal under the ESA.[1]

Atlantic Large Whale Take Reduction Plan and History

The MMPA mandates that NMFS develop and implement Take Reduction Plans for preventing the depletion and assisting in the recovery of certain marine mammal stocks that are killed or seriously injured incidental to commercial fisheries. Pursuant to the MMPA, NMFS convenes Take Reduction Teams composed of stakeholders to develop recommendations that achieve a short-term goal of reducing M/SI of marine mammals covered by the plan to a rate below each stock's PBR level. NMFS considers the Team's recommendations when amending and implementing Take Reduction Plans through the rulemaking process.

The Team was first convened in 1996 to recommend measures to reduce mortalities and serious injuries of right, humpback, and fin whales incidental to certain U.S. commercial fisheries. NMFS develops and implements measures under the Plan. Since 1997, the Plan has been amended several times to reduce the impacts of fishing gear on large whales, particularly on endangered right whales, through measures that include area closures; gear configuration requirements such as the use of sinking groundline, trawling up, and weak links; and gear marking rules. In 2021, a final rule (86 FR 51970; September 17, 2021) implemented modifications to reduce the risk of M/SI of right whales caused by entanglement in the northeast American lobster and Jonah crab trap/pot fishery by approximately 60 percent, which was analyzed in a final environmental impact statement (FEIS) published on July 2, 2021 (86 FR 35288).

In May 2022, NMFS convened the Team to address large whale M/SI caused by entanglements in the other fisheries regulated under the Plan, namely the U.S. East Coast gillnet, Atlantic mixed species trap/pot, and mid-Atlantic lobster and Jonah crab trap/pot fisheries, which were not addressed by the 2021 final rule. Scoping on measures to reduce the impacts of these fisheries was conducted from August 10, 2021 through October 21, 2021 (86 FR 43996; August 11, 2021). However, in the fall of 2022, the Team received new population information showing that the right whale population decline was continuing at a high rate and confirming that most mortalities are unobserved as carcasses, thus indicating a need for greater risk reduction than previously anticipated. In addition, a 2022 summary judgment decision in *Ctr. for Biological Diversity* v. *Raimondo* ruled that the 2021 final rule failed to provide right whales with sufficient protections under the MMPA from entanglement-caused mortalities and serious injuries. 610 F. Supp. 3d 252 (D.D.C. 2022) (vacated, 2024 WL 324103 (D.D.C. Jan. 29, 2024)). Given that ruling and the updated population mortality estimate, NMFS determined that additional risk reduction was likely necessary from all fixed gear fisheries coastwide regulated under the Plan including the lobster and Jonah crab fisheries.

Given the potential for additional needed risk reduction, NMFS opened a second 30-day scoping period to gather additional public input on further modifications to the Plan from September 9 to October 11, 2022 (87 FR 55405; September 9, 2026). The Team met again in November and December 2022, and although consensus was not reached, a majority of Team members present voted in favor of a suite of recommendations for additional risk reduction measures.

Shortly after the 2022 meetings were concluded, Congress passed the Consolidated Appropriations Act, 2023 (CAA). The CAA deemed the 2021 rule sufficient for the authorization of American lobster and Jonah crab trap/pot fisheries to be in full compliance with the MMPA and ESA until December 31, 2028, reflecting Congressional intent to provide the industry with regulatory stability while feasible solutions are developed. The CAA also directs NMFS to issue ''new regulations for the American lobster and Jonah crab fisheries consistent with the [MMPA and ESA]'' that ''take effect by December 31, 2028.''

The purpose of this proposed NEPA action is to evaluate measures that may be needed in 2029 in order to fill the requirements both of section 118 of the MMPA, which regulates the taking of marine mammals incidental to U.S. commercial fishing operations and of the CAA. Scoping is an early step in the development of regulations to ensure compliance with the CAA.

Take Reduction Planning

To meet the timeline set by Congress in the CAA, we will convene a series of Team meetings in 2026 and 2027. During these meetings, the Team will discuss and may recommend measures to reduce right whale M/SI from U.S. commercial fishing gear to MMPA-compliant levels, should further reductions be required. Since the Team last met in 2022, new estimates for population abundance and mortality have been released (Linden 2025), which show a small but positive short-term (2021–2024) estimated population increase and a reduction in estimated mortality. Based on the 2023 PBR calculation and the 2019–2024 M/SI data (Hayes *et al.* 2024), entanglement-related deaths and serious injuries exceeded the MMPA required levels at the time that 2023 PBR calculation was made. However, prior to meeting with the Team, NMFS will review the best available scientific information describing right whale M/SI remaining after, among other things, the 2021 Plan modifications were fully implemented in May 2022, and the Massachusetts Restricted Area was expanded in 2024 (89 FR 8333, February 7, 2024) to determine whether additional risk reduction is necessary, and if so, identify a target for risk reduction.

If needed, NMFS anticipates employing a range of risk reduction targets to achieve PBR to take into account uncertainties regarding where and how M/SI occurs, with intent to rigorously evaluate the economic feasibility of any proposed measures. Given the annual variability and uncertainties in determining the extent to which estimated/unseen deaths and serious injuries of right whales are caused by U.S. commercial fisheries, NMFS anticipates that the Team would develop recommendations for broad risk reduction rather than a singular risk reduction target. Professional third-party facilitation of Team meetings is intended to forge mutually beneficial outcomes among the competing interests to minimize regulatory burdens and meet administration priorities, while fulfilling statutory requirements. At the Team meetings, the Team will develop recommendations for NMFS to consider in drafting a proposed rule. NMFS will incorporate any relevant new information available after Team deliberations into both proposed and final rules as appropriate during the multi-year rulemaking process. NMFS will also consider Team recommendations and any new information in furtherance of the Plan's long-term MMPA goal: to reduce, within

[1] A 2 percent increase is generally accepted as the minimum detectable rate of growth of a long-lived, slow-growing large mammal. Thirty-five years is the estimated amount of time it would take for the right whale population to double in size if the population grows at an average of 2 percent per year. North Atlantic Right Whale *(Eubalaena glacialis*) 5-Year Review: Summary and Evaluation. October 2022.

5 years of its implementation, the incidental M/SI of marine mammals incidentally taken in the course of commercial fishing operations to insignificant levels approaching a zero mortality and serious injury rate, taking into account the economics of the fishery, the availability of existing technology, and existing state or regional fishery management plans.[2]

Scoping on Modifications to the Atlantic Large Whale Take Reduction Plan

Any needed modifications to the Plan would be informed by Team recommendations, decades of discussions with Team members, as well as information obtained during scoping, and other available information. The Team will be provided with previously-discussed recommendations informed by new technologies, improved whale distribution data from increased survey efforts, and improved fishery-dependent data sources describing fishing gear distribution and configurations. A range of risk reduction considerations can be found in the scoping document on the website identified in the **ADDRESSES** section.

Modifications analyzed may affect the following fisheries currently regulated by the Plan: (1) northeast trap/pot fisheries for American lobster and Jonah crab; (2) Mid-Atlantic gillnet fisheries for monkfish, spiny dogfish, smooth dogfish, bluefish, weakfish, menhaden, spot, croaker, striped bass, large and small coastal sharks, Spanish mackerel, king mackerel, American shad, black drum, skate species, yellow perch, white perch, herring, scup, kingfish, spotted seatrout, and butterfish; (3) northeast sink gillnet and anchored float gillnet fisheries for Atlantic cod, haddock, pollock, yellowtail flounder, winter flounder, witch flounder, American plaice, windowpane flounder, spiny dogfish, monkfish, silver hake, red hake, white hake, ocean pout, skate spp., mackerel, redfish, herring, menhaden, and shad; (4) northeast drift gillnet fisheries for shad, herring, mackerel, and menhaden and any residual large pelagic driftnet effort in New England; (5) Massachusetts mixed species trap/pot; (6) Atlantic mixed species trap/pot fisheries for hagfish, shrimp, conch/whelk, red crab, Jonah crab, rock crab, black sea bass, scup, tautog, cod, haddock, Pollock, redfish (ocean perch), white hake, spot, skate, catfish, stone crab, and cunner; (7) Mid-Atlantic trap/pot fisheries for lobster and Jonah crab; (8) Atlantic trap/pot fishery for Atlantic blue crab; (9) southeast Atlantic gillnet fisheries for finfish, including, but not limited to: king mackerel, Spanish mackerel, whiting, bluefish, pompano, spot, croaker, little tunny, bonita, jack crevalle, cobia, and striped mullet; and (10) Southeast Atlantic shark gillnet fisheries for large and small coastal sharks, including but not limited to blacktip, blacknose, finetooth, bonnethead, and sharpnose sharks.

To inform Team discussions and build on past efforts, NMFS requests information from the public on the following topics: (1) vertical line reduction through gear reduction measures (trap/line caps, reduced gillnet panel lengths or numbers, ropeless retrieval devices subject to rigorous testing for safety, affordability, and operational feasibility for the fleet) or gear configuration changes (increasing nets per string or traps per trawl; lower profile gillnets through tie downs or restricted panel heights); (2) fishing effort reductions through shorter soak times or restrictions to daytime fishing; (3) measures that reduce the likelihood of severe injuries including gear tending or gear modifications to reduce the weight of gear (single traps on weak rope); (4) reducing the breaking strength of nets and ropes so that entangled whales could break free; (5) seasonal restricted areas that would prohibit persistent buoy lines or be closed to fishing in those areas where right whales can be predicted to aggregate seasonally; (6) development of a dynamic area management program that would allow real-time responses to right whale aggregations; (7) modifications to the timing or dimensions of existing seasonal restrictions, seasonal closure areas, and exemption areas; (8) updates to gear marking requirements; (9) data gaps; and (10) any additional measures not mentioned above. For more details, please visit the Atlantic Large Whale Take Reduction Plan website at *https://www.fisheries.noaa.gov/alwtrp*.

NEPA (42 U.S.C. 4321 *et seq.*) requires that Federal agencies prepare detailed statements assessing the environmental impact of and alternatives to major Federal actions significantly affecting the environment. NMFS has determined that an environmental analysis should be prepared under NEPA for the purpose of informing the next step in any rulemaking necessary to modify the Plan. We plan to prepare an environmental analysis in accordance with NEPA requirements, as amended (42 U.S.C. 4321 *et seq.*) and other Federal laws, regulations, and policies.

Summary of Potential Impacts

The environmental analysis will identify and describe the potential effects of Plan modifications on the human environment, including the natural and physical environment and the relationship of people with that environment, that are reasonably foreseeable and have a reasonably close causal relationship to the modifications. This may include such effects that occur at the same time and place as the alternatives and such effects that are later in time or occur in a different place. The alternatives that will be analyzed may include, but are not limited to, modifications to configurations of fishing gear including weak rope, weak links, trawling up, float line, line caps, effort controls, and the possible use of on-demand gear in some seasonal restricted areas; modification to fishing seasons and/or areas including the potential for dynamic management areas and changes to gear tending requirements; and modifications to gear marking requirements. Potential impacts to commercial fishermen in the above-mentioned fisheries may include, but are not limited to, severe economic strain on family-owned businesses, threats to the cultural heritage of coastal fishing communities, additional costs and labor to modify gear configurations and gear markings, labor costs associated with increased time required to retrieve gear under some gear modifications, safety hazards associated with increased time required to retrieve gear under some modifications, costs associated with the purchase of new gear, reduced profit due to reduced catches, associated gear modifications, gear moving, or gear removal and other costs associated with seasonally restricted access to fishing grounds. Potential impacts to Atlantic large whales include, but are not limited to, reduced M/SI due to a reduction in entanglement in fishing gear or reduced injury severity of any entanglements that do occur. Other potential impacts may include, but are not limited to, impacts (both beneficial and adverse) to other marine life, cultural resources, demographics, employment, and economics. Consideration of any irreversible and irretrievable commitments of Federal resources which would be involved in any proposed action should it be implemented may also be analyzed. Public comments on potential impacts

[2] NMFS may consider the information obtained when determining compliance with other laws such as with incidental take authorizations and statements under the MMPA and ESA, Consultations under section 7 of the ESA, consistency determinations under the Coastal Zone Management Act, and other applicable laws.

are requested and these potential impacts will be analyzed.

The environmental analysis may identify and describe: reasonably foreseeable environmental effects of the proposed agency action; reasonably foreseeable adverse environmental effects which cannot be avoided should the proposal be implemented; a reasonable range of alternatives to the proposed agency action, including an analysis of any negative environmental impacts of not implementing the proposed agency action in the case of a no action alternative that are technically and economically feasible and meet the purpose and need of the proposal; the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and any irreversible and irretrievable commitments of Federal resources which would be involved in the proposed agency action should it be implemented.

Schedule for the Decision-Making Process

NMFS plans to convene the Team in 2026 and 2027 to develop consensus recommendations on Plan modifications, as necessary to ensure the impacts of U.S. commercial fisheries on Atlantic large whales complies with the MMPA, while also minimizing regulatory burdens. NMFS anticipates completing an Environmental Assessment or draft environmental impact statement (DEIS), if required, by late 2027. If a DEIS is required, NMFS will publish a notice of availability requesting public comments. After the public comment period ends, NMFS will review, consider, and respond to comments received and will develop the FEIS, if an FEIS is required. NMFS will make the FEIS available to the public at or around the time NMFS publishes the final rule. NMFS will make and issue a Record of Decision in late 2028, in order to meet the timeline set forth by Congress in the CAA.

This NOI commences a public scoping period in which NMFS requests public comment on issues and potential alternatives to modify the Plan to reduce M/SI of large whales in U.S. commercial fisheries to below PBR while also reducing regulatory burden. This is not a notice of proposed rulemaking. Throughout the scoping process, Federal agencies, state, tribal, local governments, and the general public have the opportunity to help NMFS determine reasonable alternatives and potential measures to be analyzed, as well as to provide additional information.

Everyone potentially impacted by or interested in changes to the Plan is invited to participate in the public scoping process by submitting written input via the *Regulations.gov* comment portal, or by giving oral input at the scoping meeting. This scoping process aims to gather input on the gillnet and trap/pot fisheries regarding the scope of actions to be proposed for rulemaking, the development of alternatives to analyze, and the potential impacts of management actions.

Information received through this scoping process will inform the potential development of alternative risk reduction measures for an environmental analysis on modifications to the Plan. Only inputs and suggestions that are within the scope of the proposed actions will be considered when developing the alternatives for analysis. The purpose is to develop measures to fulfill the requirements of section 118 of the MMPA, which regulates the taking of marine mammals incidental to U.S. commercial fishing operations and the CAA. NMFS is also soliciting comments on measures that would further the recovery goals of ESA-listed right whales as affected by fisheries regulated under the Plan, as well as topics related to incidental take authorizations and statements under the MMPA and ESA. NMFS implements additional endangered species conservation and recovery programs under the ESA and also affords marine mammals protections under multiple programs pursuant to the MMPA.

To promote informed decision-making, input should be as specific as possible and should provide as much detail as necessary to fully inform NMFS of the commenter's position. Input should explain why the issues raised are important to the consideration of potential environmental impacts and potential alternatives to a proposed action, as well as economic and other impacts affecting the quality of the human environment.

It is important that commenters provide their input prior to the close of the scoping period and clearly articulate their concerns and contentions. Input received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for a proposed action discussed in this notice. Input submitted anonymously will be accepted and considered.

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(Authority: 42 U.S.C. 4321 *et seq.;* 16 U.S.C. 1361 *et seq.*)

Dated: August 13, 2026.

Kimberly Damon-Randall,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2026–16756 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 260707–0164]

XRIN 0648–XA008

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Issuance of an Exploration License to The Metals Company USA, LLC for ''USA–B'' (EISX–006–48–2CM–1779948024)

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of intent to prepare an Environmental Impact Statement; request for comments.

SUMMARY: NOAA announces its intent to prepare an Environmental Impact Statement (EIS) to evaluate the environmental impacts of issuing an exploration license to The Metals Company USA, LLC (TMC–USA) under the Deep Seabed Hard Mineral Resources Act (DSHMRA or ''the Act'') for the application area designated by TMC–USA as ''USA–B.'' The proposed license, if issued, would authorize TMC–USA to conduct seabed mining exploration activities (*e.g.,* vessel and autonomous vehicle operation, sonar use, and deployment of box corers)

within the seabed area beyond national jurisdiction for a period of ten years subject to terms, conditions, and restrictions. This notice announces the beginning of the scoping process under the National Environmental Policy Act (NEPA) to solicit public comments and identify relevant issues with respect to the proposed agency action. Additionally, this notice seeks public comment and input under the National Historic Preservation Act (NHPA) and its implementing regulations.

DATES: NOAA will consider written comments received by September 16, 2026.

ADDRESSES: Comments may be submitted to the Federal e-Rulemaking Portal at *https://www.regulations.gov/docket/NOAA-NOS-2026-1816* or go to *www.regulations.gov* and enter ''NOAA–NOS–2026–1816'' in the search bar. Click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

Comments must be submitted by the date and electronic method described above to ensure that the comments are received, documented, and considered by NOAA. Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered. Comments that are not related to preparation of the EIS to evaluate the impacts of issuing an exploration license to TMC–USA for the Application B Area or that contain profanity, vulgarity, threats, or other inappropriate language will not be considered. To ensure full consideration by NOAA, comments must be submitted in English. Comments that are not submitted in English may not be posted to the public dockets on *regulations.gov* or considered by NOAA. All relevant comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information or information that is otherwise sensitive or protected. NOAA will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to *dshmra.nepa@noaa.gov.*

SUPPLEMENTARY INFORMATION: DSHMRA (30 U.S.C. 1401–1473) charges the NOAA Administrator with the responsibility for issuing to U.S. citizens licenses for exploration and permits for commercial recovery of hard mineral resources from areas beyond national jurisdiction. U.S. citizens must obtain licenses and permits from NOAA before undertaking deep seabed mining exploration or commercial recovery activities, respectively. NOAA may issue licenses and permits to U.S. citizens in areas beyond national jurisdiction under DSHMRA, provided all statutory and regulatory requirements are met, including under NEPA. Before issuing a license or permit, NOAA is required under DSHMRA to prepare an EIS on the environmental impacts of the activities proposed by the applicant (30 U.S.C. 1419(d)).

On July 28, 2025, NOAA received an amended application from TMC USA for a license to conduct seabed mining exploration activities in areas beyond national jurisdiction in the Clarion-Clipperton Zone of the central Pacific Ocean.[1] NOAA determined that this application is fully compliant with the applicable information requirements of the Act and its implementing regulations. On December 23, 2025, NOAA published notice of the TMC–USA license application for public review and comment (90 FR 60064). Following the close of the public comment period and receipt of written comments from certain Federal agencies, NOAA certified TMC–USA's application for an exploration license pursuant to 30 U.S.C. 1413(c) and 15 CFR 970.400 on May 26, 2026. NOAA now announces its intent to prepare an EIS in accordance with NEPA, 42 U.S.C. 4336a(c), to evaluate the environmental impacts of issuing an exploration license to TMC–USA. The main goal of this scoping process is to help NOAA focus the analysis of the EIS on the relevant environmental issues and alternatives. Subsequently, NOAA plans to publish notice of the proposal to issue a license to TMC–USA, proposed terms, conditions, and restrictions on the license, and the draft EIS for public review and comment and host a public hearing pursuant to 30 U.S.C. 1419(d) and 1426(a).

Purpose and Need for the Proposed Action

In Executive Order 14285, ''Unleashing America's Offshore Critical Minerals and Resources,'' issued on April 24, 2025, President Donald J. Trump stated that the U.S. ''has a core national security and economic interest in maintaining leadership in deep sea science and technology and seabed mineral resources'' and ''must take immediate action to accelerate the responsible development of seabed mineral resources,'' including polymetallic nodules containing strategic minerals, that are ''vital to our national security and economic prosperity.'' To advance U.S. leadership in responsible seabed mineral development, NOAA was directed to, among other things, ''expedite the process for reviewing and issuing seabed mineral exploration licenses in areas beyond national jurisdiction under the Deep Seabed Hard Mineral Resources Act (30 U.S.C. 1401 *et seq.*), consistent with applicable law.''

In applying for an exploration license under DSHMRA, TMC–USA's objective is to determine the nature, location, and extent of hard mineral resources, and environmental characteristics in a 121,830.2 km^2 area beyond national jurisdiction comprising six noncontiguous subareas collectively located between approximately 769 miles southeast of Hawaii and 1,892 miles west of Mexico and referred to here as the ''Application B Area.'' These proposed exploration activities would be undertaken in anticipation of future commercial recovery operations of these hard mineral resources, subject to receiving a separate NOAA permit to conduct commercial recovery operations. Based on NOAA's authority under DSHMRA to issue exploration licenses to eligible applicants (30 U.S.C. 1412) and Executive Order 14285's directive, the purpose and need for NOAA's action is to determine whether to issue a license to TMC–USA to conduct exploration activities within areas beyond national jurisdiction. NOAA will make its determination after consulting with interested Federal agencies, considering public comments, and evaluating whether the exploration proposed by the applicant meets the requirements for issuance of a license. 30 U.S.C. 1415(a); 15 CFR 970.500(c). NOAA must find, among other things, that the exploration activities proposed by the applicant ''cannot reasonably be expected to result in a significant adverse effect on the quality of the environment, taking into account the analyses and information in any applicable environmental impacts statement prepared pursuant to section 1419(c) or 1419(d) of this title.'' 30 U.S.C. 1415(a)(4); 15 CFR 970.506.

[1] NOAA previously referred to the application for this exploration license as ''TMC USA Application B'' or ''Application B'' in the **Federal Register** Notice announcing receipt of this application. 90 FR 60064 (Dec. 23, 2025). The ''TMC USA Application A,'' that was also announced at that time, is not the subject of this notice of intent.

Proposed Action and Preliminary Alternatives

Pursuant to DSHMRA, NOAA plans to prepare an EIS that evaluates the proposed issuance of an exploration license to TMC–USA to carry out seabed mining exploration activities within the Application B Area. *See* 30 U.S.C. 1419(d). This license, if issued, would be valid for a period of ten years and would be subject to terms, conditions, and restrictions that NOAA would propose to include in the license. The Applicant, under the proposed license and subject to applicable requirements, would operate vessels and autonomous vehicles, use sonars and cameras, collect photographs and geotechnical samples, collect biological samples, and collect sediment samples from the seafloor through the use of box corers and multi-corers.

NOAA will evaluate reasonable alternatives to the Proposed Action, including a no action alternative. Under the no action alternative, NOAA would deny issuance of an exploration license to TMC–USA, and the proposed exploration plan described in TMC–USA application would not be authorized to proceed under DSHMRA.

In the draft EIS, NOAA is considering analyzing the following preliminary alternatives:

- Issuance of an exploration license with terms, conditions, and restrictions to TMC–USA to conduct the exploration activities and environmental mitigation and monitoring measures as proposed in TMC–USA's exploration plan.
- Issuance of an exploration license with terms, conditions, and restrictions to TMC–USA to conduct the exploration activities as proposed in TMC–USA's exploration plan, with additional and/or modified environmental mitigation and monitoring measures.
- Denial of the license (*i.e.,* no action).

NOAA welcomes comments on all preliminary alternatives as well as suggestions for additional alternatives.

Summary of Potential Impacts

NOAA expects that the primary environmental impacts from exploration activities will include those from vessel and vehicle operation, (*e.g.,* disturbance of fauna from human presence and activity), sonar use (*e.g.,* sound impacts on marine species), and sample recovery (*e.g.,* sediment disturbance from box corers). Potential effects include, but are not limited to, impacts on water quality, marine wildlife, the deep seabed, deep seabed habitat, and marine infrastructure. As appropriate, NOAA will coordinate with the U.S. Fish and Wildlife Service, National Marine Fisheries Service, Environmental Protection Agency, applicable States, and others to ensure compliance with the Endangered Species Act; Fish and Wildlife Coordination Act; Marine Protection, Research, and Sanctuaries Act; Clean Water Act; NHPA; and other applicable laws.

As part of its compliance with NHPA section 106 and its implementing regulations (36 CFR part 800), NOAA seeks comment and input from the public regarding the identification of historic properties within the Proposed Action's area of potential effects, the potential effects on those historic properties from the activities proposed by the Applicant, and any information that supports identification of historic properties under the NHPA. NOAA also solicits proposed measures to avoid, minimize, or mitigate any adverse effects on historic properties.

Cooperating Agencies

NOAA has invited the Environmental Protection Agency, the U.S. Coast Guard, and the Departments of State, Energy, and the Interior to cooperate on this EIS. NOAA requests that additional parties that have an interest in cooperating on this EIS so indicate in their response to this Notice.

Scoping Process

NOAA will consider input provided by Federal and State agencies, Territories, Tribal Governments, local governments, private parties, the public, and any other interested parties during this scoping process in the preparation of the EIS. Publication of this notice initiates the public scoping process to solicit public and agency comment regarding the full spectrum of environmental issues and concerns relating to the scope and content of the EIS including:

- information, studies, and analyses of the human and marine resources that could be affected;
- the nature and extent of the potential significant impacts on those resources;
- a reasonable range of alternatives to the proposed action; and
- mitigation and monitoring measures.

In accordance with DSHMRA, 30 U.S.C. 1419(d), NOAA anticipates that this decision making process will conclude within one year of the certification of TMC–USA's exploration application for the Application B Area.

Authority: 42 U.S.C. 4321 *et seq.,* 30 U.S.C. 1419(d).

Neil A. Jacobs,

Under Secretary of Commerce for Oceans and Atmosphere and NOAA Administrator, National Oceanic and Atmospheric Administration.

[FR Doc. 2026–16722 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–C–2026–0562]

Request for Comments on Community Outreach Office Locations in the Southwest States

AGENCY: United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is seeking information to consider regarding the selection of locations for one or more community outreach offices (COOs) in the agency's Southwest Region, which comprises Arizona, Texas, New Mexico, Oklahoma, Kansas, and Missouri.

DATES: To ensure consideration, written comments must be received by 5 p.m. ET on or before September 16, 2026, and should be submitted in accordance with the instructions in the **ADDRESSES** section. No public hearing will be held.

ADDRESSES: Comments must be submitted electronically to *NewOffices@uspto.gov.* Attachments will be accepted as MICROSOFT WORD® or ADOBE® PDF documents. To be considered, comments must be submitted to the email box. Information that the submitter does not desire to be publicly available, such as an address or phone number, should not be included in the comments.

If submission of comments to *NewOffices@uspto.gov* is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions regarding how to submit comments by mail or by hand delivery, based on the public's ability to obtain access to USPTO facilities at the time.

FOR FURTHER INFORMATION CONTACT: Chris Shipp, Chief of Staff, Office of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, at 571–272–8600.

SUPPLEMENTARY INFORMATION:

I. Background

Enabled by the 2011 Leahy-Smith America Invents Act (AIA), Public Law 112–29, the USPTO currently has regional offices (ROs) in Detroit, Michigan; San Jose, California (Silicon Valley); Dallas, Texas; and Alexandria, Virginia. The purposes of the regional offices, as originally defined in the AIA and amended by the Unleashing American Innovators Act of 2022 (UAIA), Public Law 117–328, 103 (2022), which was signed into law as part of the Consolidated Appropriations Act, 2023 on December 29, 2022, are to:

- Better connect patent filers and innovators with the Office, including by increasing outreach activities to individual innovators, small businesses, veterans, low-income populations, students, rural populations, and any geographic group of innovators that the Director may determine to be underrepresented in patent filings;
- Enhance patent examiner and administrative patent judge retention, including patent examiners and administrative patent judges from economically, geographically, and demographically diverse backgrounds;
- Improve recruitment of patent examiners;
- Decrease the number of patent applications waiting for examination; and
- Improve the quality of patent examination.

The USPTO has been focused on outreach and impact and is working on ways to better introduce, support, and assist those who may be new to the innovation ecosystem, enabling the involvement and participation of more individuals.

In addition to regional offices, the UAIA requires the USPTO to establish at least four COOs within five years from enactment of the Act (*i.e.,* no later than December 29, 2027). The purposes of the COOs are to:

- Further achieve the purposes described above for the ROs;
- Partner with local community organizations, institutions of higher education, research institutions, and businesses to create community-based programs that provide education regarding the patent system and promote the career benefits of innovation and entrepreneurship; and
- Educate prospective inventors, including individual inventors, small businesses, veterans, low-income populations, students, rural populations, and any geographic group of innovators that the Director may determine to be underrepresented in patent filings, about all public and private resources available to potential patent applicants, including the patent pro bono programs.

The Northern New England Community Outreach Office was established in January 2025 in Durham, New Hampshire. The Mountain West Community Outreach Office located in Salt Lake City, Utah, and the Northwest Frontier Community Outreach Office located in Bozeman, Montana, were established in February 2026. In July 2026, the USPTO announced two new COOs for the agency's Southeast Region, with one in Atlanta, Georgia, and another in Huntsville, Alabama.

The USPTO is seeking information to consider regarding the selection of locations for one or more COOs in Arizona, Texas, New Mexico, Oklahoma, Kansas, and Missouri.

The USPTO will use quantitative metrics and criteria to evaluate and assess the location selection for future COOs. The Office intends to consider the following classes of data (D) at a minimum:

- *D1:* Robust research activity and graduate level programs of study in areas which lead to innovations, IP, and IP-intensive companies/industries;
- *D2:* Availability and concentration of existing commercialization and business development resources (Innovation Ecosystem); and
- *D3:* Ability to support all inventors, as set forth in UAIA, Sec. 104(b)(3).

The USPTO welcomes input from all stakeholders on any matter that they believe is relevant to the overall planning and design or site selection of the USPTO COOs that will serve Arizona, Texas, New Mexico, Oklahoma, Kansas, and Missouri. Commenters are encouraged to address any or all of the statutory considerations listed in the UAIA and summarized above, any other considerations they believe the USPTO should consider, and the questions listed below.

To be considered, comments must be submitted to *NewOffices@uspto.gov.* Please cite any public data that relates to or supports your responses. If data is available but nonpublic, describe such data to the extent permissible.

II. Planning and Design Considerations of New Community Outreach Offices

With the addition of COOs to the agency's footprint, the USPTO envisions the joint mission of the COOs to be the cultivation and expansion of a vibrant innovation and entrepreneurship ecosystem supported by intellectual property across the United States. To accomplish this mission, the offices will conduct broad stakeholder engagement with innovators ranging from individual inventors to multinational business entities; establish and leverage partnerships and relationships to scale the USPTO's work; incentivize regional innovation and entrepreneurship, especially in key emerging areas (*e.g.* artificial intelligence, quantum, and distributed ledger); and promote full participation by innovators and entrepreneurs of all backgrounds, including in rural areas and from our armed services, to support U.S. innovation and job creation.

III. Specific Questions for Comment

The USPTO invites responses to the following questions:

Community Outreach Offices

1. Considering the envisioned mission described above, what essential services—including outreach, education, and customer service—should a COO provide to achieve the statutory purposes?

a. Should the services identified be delivered in person? Why or why not?

b. Should the services identified be delivered virtually? Why or why not?

2. What types of organizations should the COO seek to establish relationships and collaborations with to better leverage and scale its services?

3. Would there be a benefit for a COO to be co-located with other public sector entities/services (*e.g.* universities)?

a. If so, please describe the added value of having a shared location.

b. Which public sector entities/services would you suggest for the shared location(s)?

c. If not, please describe the benefit of having a unique location for a COO.

General Comments Regarding New Community Outreach Offices

4. What unique services should the COOs individually provide, and how should the full range of services complement each other?

5. Considering the potential classes of data listed in Part I above, what additional key indicators or data would support COO site selection?

6. What other factors should the USPTO consider when planning for the new COOs?

Location of New Community Outreach Offices

Given the statutory purposes and considerations of COOs, as discussed in Part I, and the planning and design considerations identified in Part II:

7. Which location is ideal for one or more community outreach offices (COOs) in Arizona, Texas, New Mexico, Oklahoma, Kansas, and Missouri.

8. What else should the USPTO consider when determining the ideal

locations for new Community Outreach Offices?

While the Office welcomes and values all comments from the public in response to this request, the comments submitted do not commit the Office to any further actions related to the comments, and the Office may not respond to any or every submitted comment. The Office nonetheless will consider all written submissions.

Any and all decisions made regarding the future locations of the COOs will be consistent with the criteria outlined in the UAIA and the goals and mission of the USPTO.

John A. Squires,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2026–16744 Filed 8–14–26; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket Number DARS–2026–0364; OMB Control Number 0704–0332]

Information Collection Requirement; Defense Federal Acquisition Regulation Supplement (DFARS), DoD Mentor-Protégé Program

AGENCY: Defense Acquisition Regulations System; Department of Defense (DoD).

ACTION: Notice and request for comments regarding a proposed extension of an approved information collection requirement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, DoD announces the proposed extension of a public information collection requirement and seeks public comment on the provisions thereof. DoD invites comments on: whether the proposed collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of DoD's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. The Office of Management and Budget (OMB) has approved this information collection for use under Control Number 0704–0332 through November 30, 2026. DoD proposes that OMB approve an extension of the information collection requirement, to expire three years after the approval date.

DATES: DoD will consider all comments received by October 16, 2026.

ADDRESSES: You may submit comments, identified by OMB Control Number 0704–0332, using either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: osd.dfars@mail.mil.* Include OMB Control Number 0704–0332 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Joy Dishaw, at 703–509–3255.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Appendix I, Mentor-Protégé Program; OMB Control Number 0704–0332.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Number of Respondents: 96.

Responses per Respondent: 1.9, approximately.

Annual Responses: 180.

Average Burden per Response: 2.33 hours, approximately.

Annual Burden Hours: 420.

Needs and Uses: Section 831 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 1991 (Pub. L. 101–510) required DoD to establish the DoD Pilot Mentor-Protégé Program. Section 856 of the NDAA for FY 2023 transferred section 831 of the NDAA for FY 1991 to 10 U.S.C. 4902 and authorized the DoD Mentor-Protégé Program (the ''Program'') on a permanent basis. Congress requires DoD to collect certain information from program participants in section 861, paragraph (b)(2), of Public Law 114–92. Thus, the need for this information collection is to comply with existing laws.

DoD has incorporated these information collection requirements into the DFARS in Appendix I, section I–112. Program participants agree to comply with these information collection requirements when they execute their mentor-protégé agreements, receiving the program's benefits in consideration.

This information is necessary to ensure that participants are fulfilling their obligations under the mentor-protégé agreements and furthering the purpose of the Mentor-Protégé Program as required by section 18(d)(7) of the Small Business Act (15 U.S.C. 637(d)(7). In accordance with 10 U.S.C. 4902, DoD uses the information to decide whether to approve continuation of the agreement. In addition, the information is necessary for program managers to direct developmental assistance to the most appropriate small business concerns and to ensure the program meets the Congressionally-mandated goal of enhancing the defense industrial base.

Kimberly R. Ziegler,

Editor/Publisher, Defense Acquisition Regulations System.

[FR Doc. 2026–16682 Filed 8–14–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP26–530–000; CP26–533–000]

Venture Global CP2 LNG, LLC, Venture Global CP Express, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed CP2 LNG Expansion Project, and Notice of Public Scoping Sessions

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document that will discuss the environmental effects of the CP2 LNG Expansion Project involving construction and operation of facilities by Venture Global CP2 LNG, LLC and Venture Global CP Express, LLC (Applicants) in Cameron Parish, Louisiana and Jasper County, Texas. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public interest.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental effects that could result from its action whenever it considers the issuance of an authorization. This gathering of public input is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis

in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the *NEPA Process and Environmental Document* section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on September 11, 2026. Comments may be submitted in written or oral form. Further details on how to submit comments are provided in the *Public Participation* section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental effects. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written and oral comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of these dockets on May 26, 2026, you will need to file those comments in Docket Nos. CP26–530–000 and CP26–533–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable easement agreement. You are not required to enter into an agreement. However, if the Commission approves the project, the Natural Gas Act conveys the right of eminent domain to the company for facilities constructed under section 7 of the Natural Gas Act. Therefore, if you and the company do not reach an easement agreement, the pipeline company could initiate condemnation proceedings in court. In such instances, compensation would be determined by a judge in accordance with state law. The Commission does not subsequently grant, exercise, or oversee the exercise of that eminent domain authority. The courts have exclusive authority to handle eminent domain cases; the Commission has no jurisdiction over these matters.

The Applicants provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' which addresses typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. This fact sheet along with other landowner topics of interest are available for viewing on the FERC website (*www.ferc.gov*) under the Natural Gas, Landowner Topics link.

Public Participation

There are four methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.*

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is also on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing'';

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket numbers (CP26–530–000 and CP26–533–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852; or

(4) In lieu of sending written comments, the Commission invites you to attend one of the public scoping sessions its staff will conduct in the project area, scheduled as follows:

Date and time	Location
August 25, 2026, 4:30–6:30 p.m. Central Daylight Time (CDT).	Cameron Parish Police Jury, Multi-Purpose Building, 122 Recreation Lane, Cameron, Louisiana 70631, 337–775–2617.
August 26, 2026, 4:30–6:30 p.m. CDT.	Buna Bridle Club Event Center, 520 County Road 726, Buna, Texas 77612, 409–291–1640.

The primary goal of these scoping sessions is to have you identify the specific environmental issues and concerns that should be considered in the environmental document. Individual oral comments will be taken on a one-on-one basis with a court reporter. This format is designed to receive the maximum amount of oral comments in a convenient way during the timeframe allotted.

Each scoping session is scheduled from 4:30 p.m. to 6:30 p.m. Central Daylight Time (CDT). You may arrive at any time after 4:30 p.m. There will not be a formal presentation by Commission staff when the session opens. If you wish to speak, the Commission staff will hand out numbers in the order of your arrival. Comments will be taken until 6:30 p.m. However, if no additional numbers have been handed out and all individuals who wish to provide comments have had an opportunity to do so, staff may conclude the session at 6:00 p.m. Please see appendix 1 for additional information on the session format and conduct.[1]

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in themail and are available at *www.ferc.gov* using the link called ''eLibrary.'' For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at

Your oral comments will be recorded by a court reporter (with FERC staff or representative present) and become part of the public record for this proceeding. Transcripts will be publicly available on FERC's eLibrary system (see the last page of this notice for instructions on using eLibrary). If a significant number of people are interested in providing oral comments in the one-on-one settings, a time limit of 5 minutes may be implemented for each commentor. Although there will not be a formal presentation, Commission staff will be available throughout the scoping session to answer your questions about the environmental review process. The Applicants' representatives will also be present to answer project-specific questions.

It is important to note that the Commission provides equal consideration to all comments received, whether filed in written form or provided orally at a scoping session.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Summary of the Proposed Project

The Project would increase the transportation capacity of the CP Express Pipeline System by approximately 1,900,000 dekatherms per day and increase the maximum peak liquefaction capacity by 11.7 million metric tonnes per annum. According to the Applicants, the Project would expand liquefied natural gas (LNG) production at the approved CP2 LNG Terminal Facilities where domestically produced natural gas is converted to LNG for storage and export to overseas markets.

The CP2 LNG Expansion Project would consist of the following facilities at the CP2 LNG Terminal and Marine Facilities in Cameron Parish, Louisiana:

- six liquefaction blocks, each with two single mixed refrigerant process units and ancillary support facilities;
- a 720-megawatt power plant, with five gas turbines, five heat recovery steam generators, and two steam generators;
- three gas pre-treatment facilities;
- two nitrogen removal units and three LNG expanders to remove excess nitrogen that may be present in the feed gas;
- three thermal oxidizers;
- five boil off gas compressors;
- additional utilities and safety systems; and
- one additional LNG loading dock (Berth 3) within the approved footprint of the existing, approved Marine Facilities on Monkey Island.

The following facilities would be constructed along the CP Express Pipeline in Jasper County, Texas:

- a new 227,000-horsepower greenfield compressor station (Silsbee Compressor Station); and
- two 1,000-foot-long, 48-inch-diameter natural gas pipeline laterals to provide suction and discharge to connect the compressor station to the existing, approved CP Express Pipeline.

The general location of the project facilities is shown in appendix 2.

Land Requirements for Construction

The proposed Terminal Site Expansion would disturb about 69.2 acres during construction and operation. The proposed Marine Facilities Expansion would disturb about 20.4 acres during construction and 3.4 acres during operation. Construction and operation of the Terminal Site and Marine Facilities Expansion would occur within the previously authorized footprint of the Terminal and Marine Facilities. Construction of the proposed Silsbee Compressor Station and pipeline laterals would disturb about 73.7 acres and 4.6 acres, respectively. Following construction, the Applicants would maintain about 52.8 acres and 2.0 acres for permanent operation of the compressor station and pipeline laterals, respectively. The remaining acreage would be restored and revert to former uses.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss the effects that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- geology and soils;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- socioeconomics;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid effects on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary [2] and the Commission's natural gas environmental documents web page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.[3] Agencies that would like to request cooperating agency status should follow

FERCOnlineSupport@ferc.gov or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[2] For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] Cooperating agency responsibilities are addressed in Section 107(a)(3) of NEPA (42 U.S.C. 4336(a)(3)).

the instructions for filing comments provided under the *Public Participation* section of this notice. Currently, the U.S. Coast Guard has expressed its intention to participate as a cooperating agency in the preparation of the environmental document to satisfy its NEPA responsibilities related to this project.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Offices, and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; Native American Tribes; environmental and public interest groups; other interested parties; and local libraries and media outlets. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to *GasProjectAddressChange@ferc.gov* stating your request. You must include the docket numbers CP26–530–000 and CP26–533–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from themailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached ''Mailing List Update Form'' (appendix 3).

Additional Information

Additional information about the project is available from the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *https://www.ferc.gov/news-events/events* along with other related information.

(Authority: 18 CFR 2.1)

Dated: August 12, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–16739 Filed 8–14–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL26–96–000; QF85–344–002.

Applicants: U.S. Gypsum Company, United States Gypsum Company.

Description: Petition for Declaratory Order of United States Gypsum Company.

Filed Date: 8/6/26.

Accession Number: 20260806–5183.

Comment Date: 5 p.m. ET 9/8/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2394–012; ER10–2395–012.

Applicants: Colorado Power Partners, BIV Generation Company, L.L.C.

Description: Notice of Non-Material Change in Status of BIV Generation Company, L.L.C., et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5354.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER10–2475–042; ER10–2474–041; ER10–3246–036; ER26–2531–001; ER26–2533–001; ER26–2536–001; ER24–1587–014; ER22–1385–024; ER26–2535–001; ER23–674–020; ER13–1266–064; ER15–2211–061; ER10–1520–030; ER10–1521–030.

Applicants: Occidental Power Marketing, L.P., Occidental Power Services, Inc., MidAmerican Energy Services, LLC, CalEnergy, LLC, BHE Wind Watch, LLC, Power Watch, LLC, BHER Market Operations, LLC. AlbertaEx, L.P., Rim Rock Wind, LLC, Glacier Wind 2, LLC, Glacier Wind 1, LLC, PacifiCorp, Sierra Pacific Power Company, Nevada Power Company.

Description: Notice of Non-Material Change in Status of Nevada Power Company, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5352.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER12–1316–012; ER11–2753–013.

Applicants: Cedar Point Wind, LLC, Silver State Solar Power North, LLC.

Description: Notice of Non-Material Change in Status of Silver State Solar Power North, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5351.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER16–1999–005; ER16–1998–005; ER16–2000–005; ER16–2003–005; ER16–2006–005; ER11–4625–011; ER24–2557–004; ER24–2558–003; ER24–2559–004; ER25–1756–002; ER14–608–009; ER16–2001–005; ER16–2002–005; ER16–1644–009; ER24–1653–003; ER19–537–008; ER26–729–002; ER26–730–002.

Applicants: Arges BESS LLC, Vaca Dixon BESS LLC, MRP San Joaquin Energy, LLC, MRP Pacifica Marketing LLC, MRP Generation Holdings, LLC, Midway Peaking, LLC, Malaga Power, LLC, High Desert Power Project, LLC, Hermes BESS LLC, Malaga BESS LLC, Hanford BESS LLC, Henrietta BESS LLC, Colton Power L.P., CalPeak Power—Vaca Dixon LLC, CalPeak Power—Panoche LLC, CalPeak Power—Enterprise LLC, CalPeak Power—Border LLC, CalPeak Power LLC.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

Description: Notice of Non-Material Change in Status of CalPeak Power LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5356.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER19–115–007; ER25–2682–003.

Applicants: FL Solar 8, LLC, FL Solar 5, LLC.

Description: Triennial Market Power Analysis for Southeast Region of FL Solar 5, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5355.

Comment Date: 5 p.m. ET 9/29/26.

Docket Numbers: ER20–391–020; ER21–2557–015; ER22–2662–015; ER22–2663–015; ER22–2664–015; ER23–1275–013; ER23–1276–013; ER23–1277–009; ER24–1276–007; ER24–1277–006; ER24–2249–011; ER24–2250–007; ER24–2251–010; ER24–2854–009; ER24–2855–009; ER24–2856–009; ER25–938–005; ER25–939–007; ER25–940–007; ER25–1422–005; ER26–178–001; ER26–181–001; ER26–671–001; ER26–672–001; ER26–673–001; ER26–676–002; ER26–2695–001; ER26–2696–001.

Applicants: Aron Energy Prepay 73 LLC, Aron Energy Prepay 70 LLC, Aron Energy Prepay 68 LLC, Aron Energy Prepay 66 LLC, Aron Energy Prepay 65 LLC, Aron Energy Prepay 64 LLC, Aron Energy Prepay 62 LLC, Aron Energy Prepay 60 LLC, Aron Energy Prepay 57 LLC, Aron Energy Prepay 53 LLC, Aron Energy Prepay 52 LLC, Aron Energy Prepay 51 LLC, Aron Energy Prepay 46 LLC, Aron Energy Prepay 45 LLC, Aron Energy Prepay 44 LLC, Aron Energy Prepay 43 LLC, Aron Energy Prepay 42 LLC, Aron Energy Prepay 41 LLC, Aron Energy Prepay 36 LLC, Aron Energy Prepay 35 LLC, Aron Energy Prepay 23 LLC, Aron Energy Prepay 22 LLC, Aron Energy Prepay 21 LLC, Aron Energy Prepay 16 LLC, Aron Energy Prepay 15 LLC, Aron Energy Prepay 14 LLC, Aron Energy Prepay 5 LLC, J. Aron & Company LLC.

Description: Notice of Non-Material Change in Status of J. Aron & Company LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5345.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER20–703–003; ER15–1754–003; ER15–1747–003; ER11–4051–007; ER14–1656–015; ER10–2385–018; ER23–1220–003; ER10–1597–012; ER15–1748–003; ER20–2602–004; ER15–1749–003; ER14–2945–003; ER19–2908–003; ER10–1623–010; ER10–1624–013; ER10–1625–013; ER18–1960–010; ER12–60–031; ER10–1626–017; ER17–554–004.

Applicants: Wolf Run Energy LLC, Tenaska Virginia Partners, L.P., Tenaska Power Management, LLC, Tenaska Pennsylvania Partners, LLC, Tenaska Georgia Partners, L.P., Tenaska Gateway Partners, Ltd., Tenaska Frontier Partners, Ltd., Tenaska Clear Creek Wind, LLC, Roundtop Energy LLC, Oxbow Creek Energy LLC, Nobles 2 Power Partners, LLC, Milan Energy LLC, Kiowa Power Partners, LLC, High Point Solar LLC, Elkhorn Ridge Wind, LLC, CSOLAR IV West, LLC, CSOLAR IV South, LLC, Beaver Dam Energy LLC, Alpaca Energy LLC, 41MB 8me LLC.

Description: Notice of Change in Status of 41MB 8me, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5344.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER20–2448–012; ER16–2289–011; ER21–133–012; ER18–1174–011; ER21–1962–014; ER25–590–005; ER12–1911–009; ER12–1912–009; ER12–1913–009; ER12–1915–009; ER12–1916–009; ER12–1917–009; ER16–498–016; ER16–499–016; ER16–500–016; ER14–41–017; ER14–42–017; ER21–736–013; ER16–2277–010; ER21–2634–011; ER22–2784–017.

Applicants: MN8 Energy Marketing LLC, Solar Star Lost Hills, LLC, Solar Star California XLI, LLC, RE Slate 1 LLC, RE Rosamond Two LLC, RE Rosamond One LLC, RE Mustang 4 LLC, RE Mustang 3 LLC, RE Mustang LLC, RE McKenzie 6 LLC, RE McKenzie 5 LLC, RE McKenzie 4 LLC, RE McKenzie 3 LLC, RE McKenzie 2 LLC, RE McKenzie 1 LLC, Pome BESS LLC, Mulberry BESS LLC, Imperial Valley Solar 2, LLC, HDSI, LLC, Golden Fields Solar I, LLC, American Kings Solar, LLC.

Description: Notice of Non-Material Change in Status of American Kings Solar, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5346.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER21–2557–016; ER22–2662–016; ER22–2663–016; ER22–2664–016; ER23–1275–014; ER23–1276–014; ER24–2249–012; ER24–2251–011; ER24–2854–010; ER24–2855–010; ER24–2856–010; ER25–939–008; ER25–940–008; ER26–178–002; ER26–181–002; ER26–673–002; ER26–2696–002.

Applicants: Aron Energy Prepay 73 LLC, Aron Energy Prepay 66 LLC, Aron Energy Prepay 62 LLC, Aron Energy Prepay 60 LLC, Aron Energy Prepay 53 LLC, Aron Energy Prepay 52 LLC, Aron Energy Prepay 46 LLC, Aron Energy Prepay 45 LLC, Aron Energy Prepay 44 LLC, Aron Energy Prepay 43 LLC, Aron Energy Prepay 41 LLC, Aron Energy Prepay 22 LLC, Aron Energy Prepay 21 LLC, Aron Energy Prepay 16 LLC, Aron Energy Prepay 15 LLC, Aron Energy Prepay 14 LLC, Aron Energy Prepay 5 LLC.

Description: Notice of Non-Material Change in Status of Aron Energy Prepay 5 LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5347.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER24–116–009; ER14–1140–014.

Applicants: Inspire Energy Holdings, LLC, Rhythm Ops, LLC.

Description: Notice of Non-Material Change in Status of Rhythm Ops, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5349.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER24–619–006; ER23–2899–005; ER25–1446–004.

Applicants: MS Solar 7, LLC, MS Solar 6, LLC, MS Solar 5, LLC.

Description: Triennial Market Power Analysis for Southeast Region of MS Solar 5, LLC, et al.

Filed Date: 9/29/26.

Accession Number: 20260731–5357.

Comment Date: 5 p.m. ET 9/29/26.

Docket Numbers: ER26–787–002.

Applicants: PowerTransitions Marketing LLC.

Description: Notice of Non-Material Change in Status of PowerTransitions Marketing LLC.

Filed Date: 7/31/26.

Accession Number: 20260731–5350.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER26–3294–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment of ER26–3294—SA No. 6258—re: Metadata Updater to be effective 6/1/2026.

Filed Date: 8/11/26.

Accession Number: 20260811–5142.

Comment Date: 5 p.m. ET 9/1/26.

Docket Numbers: ER26–3484–000.

Applicants: MATL LLP.

Description: § 205(d) Rate Filing: Filing of Long-Term TSR with MAG Energy to be effective 10/12/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5016.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3485–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: Compliance filing: Order No 1920 Interregional Compliance Filing to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5021.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3486–000.

Applicants: Black Hills Colorado Electric, LLC.

Description: Compliance filing: Order No. 1920 Interregional OATT Compliance Filing for WestConnect Planning Reg to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5042.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3487–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions for Improvements to the Aggregate Transmission Service Study to be effective 10/12/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5043.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3488–000.

Applicants: Black Hills Power, Inc.

Description: Compliance filing: Order No. 1920 Interregional JOATT Compliance WestConnect Planning Reg to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5044.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3489–000.

Applicants: Cheyenne Light, Fuel and Power Company.

Description: Compliance filing: Order No. 1920 Interregional OATT Compliance Filing for WestConnect Planning Reg to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5046.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3490–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: Compliance filing: Order No. 1920 Interregional OATT Compliance Filing-Westconnect Planning Region to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5063.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3491–000.

Applicants: Midcontinent Independent System Operator, Inc., AEP Indiana Michigan Transmission Company, Inc.

Description: § 205(d) Rate Filing: AEP Indiana Michigan Transmission Company, Inc. submits tariff filing per 35.13(a)(2)(iii: 2026–08–12_AEP IMTCo Revisions Related to ROE Note P to be effective 10/12/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5064.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3493–000.

Applicants: El Paso Electric Company.

Description: Compliance filing: Order No. 1920 Interregional Compliance Filing to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5069.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3494–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Amendment to Service Agreement FERC No. 864 to be effective 7/13/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5071.

Comment Date: 5 p.m. ET 9/2/26.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 12, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–16736 Filed 8–14–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–8–002; ER10–2487–008.

Applicants: Pacific Summit Energy LLC, Hermiston Generating Company, L.P.

Description: Notice of Non-Material Change in Status of Hermiston Generating Company, L.P., et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5362.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER24–1587–015; ER26–2531–002; ER26–2533–002; ER11–4670–012; ER26–2536–002; ER23–674–021; ER10–3246–037; ER22–1385–025; ER13–1266–065; ER15–2211–062; ER10–1521–031; ER10–1520–031.

Applicants: Occidental Power Services, Inc., Occidental Power Marketing, L.P., MidAmerican Energy Services, LLC, CalEnergy, LLC, BHER Market Operations, LLC., PacifiCorp, BHE Wind Watch, LLC, Rim Rock Wind, LLC, NaturEner Power Watch, LLC, Glacier Wind 2, LLC, Glacier Wind 1, LLC, AlbertaEx, L.P.

Description: Notice of Non-Material Change in Status of AlbertaEx, L.P., et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5359.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER24–2220–006.

Applicants: FL Solar 7, LLC.

Description: Triennial Market Power Analysis for Southeast Region of FL Solar 7, LLC.

Filed Date: 7/31/26.

Accession Number: 20260731–5363.

Comment Date: 5 p.m. ET 9/29/26.

Docket Numbers: ER25–2168–003; ER26–481–002; ER25–2169–003; ER24–2833–005; ER26–1227–001; ER26–1220–001; ER26–1224–001.

Applicants: Atlas BESS IV, LLC, Atlas Solar IV, LLC, Atlas Solar II, LLC, Silver Peak Solar, LLC, Atlas IX, LLC, Atlas VIII, LLC, Atlas VII, LLC.

Description: Notice of Non-Material Change in Status of Atlas VII, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5364.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER25–2308–005; ER21–445–008; ER17–1821–017; ER26–2066–003; ER25–1599–001.

Applicants: Mountain Peak Power, LLC, Canyon Peak Power LLC, Panda Stonewall LLC, Hill Top Energy Center LLC, Magnolia Power LLC.

Description: Notice of Non-Material Change in Status of Magnolia Power LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5361.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER25–3475–006; ER10–1292–020; ER10–1319–022; ER10–1276–022; ER10–1353–022; ER18–1183–015; ER18–1184–015; ER10–1287–021; ER10–1303–020; ER25–3172–004; ER26–2521–001; ER24–3028–004; ER24–3029–004; ER26–1987–001; ER23–1411–007; ER25–1962–006.

Applicants: Century Oaks Energy Storage, LLC, Newport Solar LLC, Lake

Iris Solar, LLC, Livingston Generating Station, LLC, Kalamazoo Generating Station, LLC, Hart Solar Partners, LLC, Genesee Solar Energy, LLC, Genesee Power Station Limited Partnership, Grayling Generation Station Limited Partnership, Delta Solar Power II, LLC, Delta Solar Power I, LLC, Dearborn Industrial Generation, L.L.C., Consumers Energy Company, CMS Generation Michigan Power, LLC, CMS Energy Resource Management Company, Branch Solar, LLC.

Description: Notice of Change in Status of Branch Solar, LLC, et al.

Filed Date: 7/31/26.

Accession Number: 20260731–5360.

Comment Date: 5 p.m. ET 8/21/26.

Docket Numbers: ER26–2955–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: 3215R20 People's Electric Cooperative NITSA NOA to be effective 9/1/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5079.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3495–000.

Applicants: Midcontinent Independent System Operator, Inc., Pioneer Transmission, LLC.

Description: § 205(d) Rate Filing: Pioneer Transmission, LLC submits tariff filing per 35.13(a)(2)(iii: 2026–08–12_Pioneer Revisions Related to ROE Note P to be effective 10/12/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5074.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3496–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OA, Schedule 12 & RAA, Schedule 17 RE: 2Q 2026 Member Lists to be effective 7/1/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5082.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3497–000.

Applicants: Public Service Company of Colorado.

Description: Compliance filing: 2026–08–12 Order No. 1920 Interregional OATT Compliance Filing to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5084.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3498–000.

Applicants: UNS Electric, Inc.

Description: Compliance filing: Order 1920 Second Compliance Filing to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5097.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3499–000.

Applicants: Midcontinent Independent System Operator, Inc., Michigan Electric Transmission Company, LLC.

Description: § 205(d) Rate Filing: Michigan Electric Transmission Company, LLC submits tariff filing per 35.13(a)(2)(iii: 2026–08–12_SA 4842 METC-Lakeside Energy Storage E&P (J3007) to be effective 8/12/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5106.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3500–000.

Applicants: Tucson Electric Power Company.

Description: Compliance filing: Order 1920 Second Compliance Filing to be effective 1/1/2028.

Filed Date: 8/12/26.

Accession Number: 20260812–5109.

Comment Date: 5 p.m. ET 9/2/26.

Docket Numbers: ER26–3501–000.

Applicants: TransGrid Energy Trading & Marketing LLC.

Description: Initial Rate Filing: Baseline MBR Tariff to be effective 8/13/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5124.

Comment Date: 5 p.m. ET 9/2/26.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 12, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–16737 Filed 8–14–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings

Filings Instituting Proceedings

Docket Numbers: RP26–1051–000.

Applicants: PPG Shawville Pipeline, LLC.

Description: Compliance filing: NAESB Compliance Filing 2027 to be effective 1/1/2027.

Filed Date: 8/11/26.

Accession Number: 20260811–5078.

Comment Date: 5 p.m. ET 8/24/26.

Docket Numbers: RP26–1052–000.

Applicants: Northern Natural Gas Company.

Description: § 4(d) Rate Filing: 20260811 Miscellaneous Filing to be effective 9/1/2026.

Filed Date: 8/11/26.

Accession Number: 20260811–5102.

Comment Date: 5 p.m. ET 8/24/26.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP26–987–001.

Applicants: Port Arthur Pipeline, LLC.

Description: Tariff Amendment: Amendment to Filing of Negotiated Rate FTSA to be effective 8/26/2026.

Filed Date: 8/12/26.

Accession Number: 20260812–5002.

Comment Date: 5 p.m. ET 8/24/26.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For

other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–16738 Filed 8–14–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2026–0334; FRL–13199–05–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Uses (May 2026)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt and request for comment.

SUMMARY: This document announces the Agency's receipt of and solicits comments on applications to register new pesticide products containing currently registered active ingredients that would entail a change in use pattern. The Agency is providing this notice in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA uses the month and year in the title to identify when the Agency compiled the applications identified in this notice of receipt. Unit II. of this document identifies certain applications received in 2025 and 2026 that are currently being evaluated by EPA, along with information about each application, including when it was received, who submitted the application, and the purpose of the application.

DATES: Comments must be received on or before September 16, 2026.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the *EPA File Symbol* or the *EPA Registration Number* of interest as shown in Unit II. of this document, online at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting on and visiting the docket, along with more information about dockets generally, are available at *https://www.epa.gov/.*

FOR FURTHER INFORMATION CONTACT: Each application summary in Unit II. specifies a contact division. The appropriate division contacts are identified as follows:

- RD (Registration Division) (Mail Code 7505T); Charles Smith; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action provides information that is directed to the public in general.

B. What is the Agency's authority for taking this action?

EPA is taking this action pursuant to section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(4), and 40 CFR 152.102.

C. What action is the Agency taking?

EPA is hereby providing notice of receipt and opportunity to comment on applications to register new pesticide products containing currently registered active ingredients that would entail a change in use pattern. EPA provides a notice of receipt on a monthly basis, using the month and year in the title to help distinguish one document from the other. This document identifies the applications that were received since the last notice that was issued and are currently being evaluated by EPA in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (*https://www.epa.gov/registration/participation-process-registration-actions*).

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *https://www.regulations.gov* or email. If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. In addition to one complete version of the comment that includes CBI, a copy of the comment without CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov//commenting-epa-dockets.*

II. Applications To Register New Uses

This unit provides the following information about each application received: The EPA File Symbol or Registration number(s); EPA docket ID number for the application; Name and address of the applicant; Name of the active ingredient, product type and proposed uses; and the division to contact for that application. Additional information about the application may also be available in the docket for the application as identified in this unit.

- *EPA Registration Numbers:* 1021–2871, 1021–2870, 1021–2869, 1021–2868. *Docket ID number:* EPA–HQ–OPP–2026–3730. *Applicant:* McLaughlin Gormley King Company, d/b/a MGK, 7325 Aspen Lane N, Minneapolis, MN 55428. *Active ingredient:* Veratrine. *Product type:* Insecticide. *Proposed use:* New indoor/outdoor non-food use in or on apartments, barns, commercial buildings, dumpsters and trash containers, farm structures, garages, greenhouses, homes, horses, horse stables, hotels and motels, industrial buildings, kennels, lawns, livestock barns, office buildings, ornamentals, railroad cars, resorts, sheds, theaters, transportation equipment, truck trailers, vehicles, warehouses, and zoos. *Date of receipt:* May 11, 2026. *Contact:* RD.
- *EPA File Symbol:* 53883–LAE. *Docket ID number:* EPA–HQ–OPP–2025–3061. *Applicant:* Control Solutions, Inc. 5903 Genoa Red Bluff, Pasadena, TX 77507. *Active ingredient:* Indoxacarb. *Product type:* Insecticide. *Proposed use:* Milk; cattle, meat; cattle, fat; cattle, by products. *Date of receipt:* September 26, 2025. *Contact:* RD.
- *EPA Registration Number and File Symbols:* 62719–752, 62719–TOA, 62719–TOA, 62719–TOU, 62719–TOG, 62719–TOL. *Docket ID number:* EPA–HQ–OPP–2026–3169. *Applicant:* Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, IN 46268. *Active ingredient:* Florylpicoxamid. *Product type:* Fungicide. *Proposed use:* Avocado, broccoli, hops, crop subgroup 1B (vegetables, root, except sugar beet), crop subgroup 1C (vegetables, tuberous and corm), crop group 2 (leaves of root and tuber vegetables), crop subgroup 3–07A (onion, bulb, subgroup), crop subgroup 3–07B (onion, green,

subgroup), crop group 4–16 (leafy vegetables), crop group 8–10 (fruiting vegetables), crop group 9 (cucurbit vegetables), crop group 11–10 (pome fruit), crop group 12–12 (stone fruit), crop subgroup 13–07B (bushberry subgroup), crop subgroup 13–07F (small fruit vine climbing subgroup, except fuzzy kiwifruit), crop subgroup 13–07G (low growing berry subgroup), crop group 14–12 (tree nuts), and crop subgroup 25A (herb fresh leaves subgroup). *Date of receipt:* February 12, 2026. *Contact:* RD.

• *EPA Registration Numbers:* 7969–261; 7969–262. *Docket ID number:* EPA–HQ–OPP–2025–3291. *Applicant:* BASF Agricultural Solutions US LLC, 2 TW Alexander Drive, Research Triangle Park, NC 27713. *Active ingredient:* Topramezone. *Product type:* Herbicide. *Proposed use:* Rapeseed subgroup 20A. *Date of receipt:* July 11, 2025. *Contact:* RD.

• *EPA Registration Numbers:* 81598–UG, 83100–II. *Docket ID number:* EPA–HQ–OPP–2025–3060. *Applicant:* Albaugh North America Limited, EPA Company Number 81598, 4900 Stockyard Expressway, St. Joseph, MO 64504. *Active ingredient:* Glufosinate-P-Ammonium. *Product type:* Herbicide. *Proposed use:* Berries, blueberry; berries, raspberry; canola, rapeseed; cattle, fat; cattle, meat byproducts; cattle, meat; citrus, orange; corn, field forage; corn, field, grain; corn, field, stover; corn, sweet, ears/grain; corn, sweet, forage; corn, sweet, stover; cotton seed subgroup 20C; cotton, gin byproducts; grapes; milk; olives; pome fruit, apple; pome fruit, pear; potato, tubers; poultry, fat; poultry, meat; poultry, meat byproducts; soybean, forage; soybean, hay; soybean, seed; stone fruit, cheery tart; stone fruit, cherry sweet; stone fruit, peach; stone fruit, plum; sugar beets, leaves; sugar beets, molasses; sugar beets, roots; sugar beets, tops; tree nut, almond hulls; tree nut, almond nutmeat; tree nut, pecan. *Date of receipt:* January 15, 2025. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 11, 2026.

Elizabeth Vizard,

Acting Director, Office of Pesticide Programs.

[FR Doc. 2026–16721 Filed 8–14–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2025–1774; FRL–12984–01–OCSPP]

Pesticide Program Dialogue Committee (PPDC); Notice of Charter Reestablishment; Request for Nominations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of charter reestablishment and request for nominations.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), the Pesticide Program Dialogue Committee (PPDC) is in public interest and is necessary in connection with the performance of EPA's duties. Accordingly, PPDC will be reestablished for a two-year period and renewed as determined necessary. Copies of the PPDC charter will be filed with the appropriate congressional committees and the Library of Congress. In addition, EPA is seeking member nominations for the PPDC from qualified candidates to serve a two-year term. The purpose of PPDC is to provide advice and recommendations to the EPA Administrator on issues associated with regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from use of pesticides. To maintain the representation outlined by the charter, nominees will be selected to represent: pesticide industry and trade associations; pesticide user, grower, and commodity groups; federal, state, local, and tribal governments; academia; animal welfare and public health organizations; environmental and public interest organizations; farm worker organizations; and the general public. Vacancies are expected to be filled by November 2026.

DATES: Nominations for the PPDC must be submitted within September 16, 2026.

FOR FURTHER INFORMATION CONTACT: Jeffrey Chang, Designated Federal Official (DFO) for the PPDC; telephone number: (202) 566–2213, email address: *chang.jeffrey@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of particular interest to persons who work in in agricultural settings or if you are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*); the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*); the Pesticide Registration Improvement Act (PRIA) (which amends FIFRA section 33); and the Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq.*). Potentially affected entities may include but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer, and farm worker groups; pesticide users and growers; animal welfare groups; pest consultants; state, local, and tribal governments; academia; public health organizations; and the public. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2025–1774, is available online at *https://www.regulations.gov.*

II. Background

In accordance with the Federal Advisory Committee Act (FACA), as amended, EPA is providing notice of the re-establishment of the charter of the Pesticide Program Dialogue Committee. This charter will be renewed for a two-year period, beginning on the date it is filed with the appropriate congressional committees.

The PPDC is a federal advisory committee chartered under FACA. EPA established the PPDC in September 1995 to provide policy advice, information and recommendations to the EPA Administrator through the Director of the Office of Pesticide Programs. The PPDC provides a public forum to discuss a wide variety of pesticide regulatory developments and reform initiatives, evolving public policy and program implementation issues associated with evaluating and reducing risks from the use of pesticides. The EPA will consider candidates from the following sectors: Pesticide industry and trade associations; pesticide user, grower, and commodity groups; federal, state, local, and tribal governments; academia; animal welfare and public

health organizations; environmental, public interest organizations; farm worker organizations; and the general public.

The PPDC usually meets twice a year, generally in the spring and the fall. Additionally, members may be asked to serve on work groups to develop recommendations to address specific policy issues. The average workload for members is approximately four to six hours per month.

III. Nominations

Each representative member is appointed to serve up to a two-year term. Nominations are sought to fill 21 representative member positions. We are requesting nominations to fill vacancies to represent all organizations and interests listed above. Any interested person or organization may nominate qualified people to be considered for appointment to this advisory committee. Individuals may be self-nominated. Nominations may be submitted in electronic format to Jeffrey Chang at the address listed under **FOR FURTHER INFORMATION CONTACT**.

To be considered, all nominations should include:

- Current contact information for the nominee, including the nominee's name, organization (and position within that organization), current business address, email address, and daytime telephone number;
- Brief Statement describing the nominee's interest and availability in serving on the PPDC;
- Resume or curriculum vitae;
- Short biography (no more than 2 paragraphs) describing the professional and educational qualifications of the nominee, including a list of relevant activities, or any current or previous experience on advisory committees; and
- Letter[s] of recommendation from a third party supporting the nomination. The letter should describe how the nominee's experience and knowledge will bring value to the work of the PPDC.

Other sources, in addition to this **Federal Register** notice, may also be utilized in the solicitation of nominees.

IV. Public Interest Determination

Pursuant to 41 CFR 102–3.65, this notice, announcing that the PPDC is being reestablished, must include the written public interest determination (PID) approved by the head of the agency described in 41 CFR 102–3.60(a) and any assessment provided by the General Services Administration's Committee Management Secretariat (the Secretariat). The PID included in this Unit has been provided to the Secretariat. The Secretariate has approved this PID without comment or assessment.

Pursuant to 41 U.S.C. 102–3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the Secretariat and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 U.S.C. 102–3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee. Information on the following factors for the committee was provided to the Secretariat to demonstrate that reestablishing the committee is in public interest:

1. *Annual budget:* The estimated Annual Budget for the Pesticide Program Dialogue Committee is $90,000. The estimated annual federal personnel on a full-time equivalent (FTE) basis is 0.7 FTE. The estimate for other Federal internal costs is $5,000. The committee will be composed of no more than 21 representative members who will not be paid. There will be no reimbursable costs.

2. *If applicable, the total dollar value of grants expected to be recommended during the fiscal year is:* N/A.

3. *Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership:* The committee will be composed of representative members who are selected to represent the points of view held by specific organizations, associations, or classes of individuals. In selecting members, the EPA will consider candidates from pesticide user, grower and commodity groups; consumer and environmental and public interest groups; farm worker organizations; pesticide industry and trade associations; State, local and Tribal governments; Federal government; academia; the general public; and animal welfare and public health organizations. The Agency's OGC will confirm the committee is composed of members with the necessary expertise and is fairly balanced.

4. *List of all other Federal advisory committees of the agency:*

- Science Advisory Committee on Chemicals
- National Environmental Education Advisory Council
- National Drinking Water Advisory Council
- Local Government Advisory Committee
- Human Studies Review Board
- Hazardous Waste Electronic Manifest System Advisory Board
- Great Lakes Advisory Board Chartered
- Good Neighbor Environmental Board
- Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel
- Farm, Ranch, and Rural Communities Advisory Committee
- EPA Science Advisory Board
- Environmental Financial Advisory Board
- Clean Air Scientific Advisory Committee
- Children's Health Protection Advisory Committee

5. *Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source:* EPA currently has no other committees, subcommittees or workgroups that provide independent, professional advice on ensuring that Americans are not exposed to unsafe levels of pesticides in food, protecting Americans from unreasonable risk, educating pesticide applicators and others who may be exposed to pesticides, and protecting the environment, special ecosystems, and wildlife from potential risks posed by pesticides.

6. *If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue:* Not applicable.

7. *Explanation of why the committee/subcommittee is essential to the conduct of agency business:* The PPDC is in public interest and supports EPA in performing its duties and responsibilities under FIFRA; FFDCA; the amendments to both of these major pesticide laws by the Food Quality Protection Act (FQPA) of 1996; and PRIA.

In conclusion, this public interest determination documents that reestablishing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

(Authority: 5 U.S.C. Appendix 2 *et seq.*)

Dated: August 13, 2026.

Elizabeth Vizard,

Acting Director, Office of Pesticide Programs.

[FR Doc. 2026–16755 Filed 8–14–26; 8:45 am]

BILLING CODE 6560–50–P

EXPORT–IMPORT BANK

[Public Notice: EIB–2026–0199]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP300126XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public that the Export-Import Bank of the United States (''EXIM'') has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million. Consistent with EXIM's mandate to strengthen U.S. economic competitiveness and national security, the proposed transaction supports the development of critical mineral resources essential to resilient domestic supply chains and advanced manufacturing. Comments received within the comment period specified below will be presented to the EXIM Board of Directors prior to final action on this Transaction.

DATES: Comments must be received on or before September 11, 2026 to be assured of consideration before final consideration of the transaction by the Board of Directors of EXIM.

ADDRESSES: Comments may be submitted through *Regulations.gov* at *www.regulations.gov.* To submit a comment, enter EIB–2026–0199 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2026–0199 on any attached document.

SUPPLEMENTARY INFORMATION:

Reference: AP300126XX.

Purpose and Use:

Brief description of the purpose of the transaction: To finance the development an iron ore mine in the Mesabi Range and a Direct Reduction Iron plant (7.5 million tonnes per annum) in Nashwauk, Minnesota under EXIM's Make More in America initiative.

This project advances U.S. leadership by expanding domestic segment of the steel supply chain that is foundational to infrastructure, defense systems, transportation, manufacturing, energy, shipbuilding and defense related supply chains.

The transaction is expected to enhance supply chain resilience, reduce reliance on foreign sources for this strategically important industrial capacity and support high-quality U.S. jobs.

Brief non-proprietary description of the anticipated use of the items being produced: The financing will be used for domestic purposes and will result in direct reduction iron pellets, key to electric arc furnace steel making. These pellets will be used domestically and exported internationally as per requirements under EXIM's MMIA program.

Parties:

Principal Supplier: Various U.S. Entities.

Obligor: Mesabi Metallics Company LLC

Guarantor(s): Miranda Mineral Resources LLC, Mesabi Financing Corp and Mesabi Land 1 LLC

Description of Items Being Exported: The items being exported will be direct reduction iron pellets.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *https://www.exim.gov/news/meeting-minutes.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

(Authority: Section 3(c)(10) of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635a(c)(10)).)

Matthew Paprocki,

Attorney Advisor.

[FR Doc. 2026–16688 Filed 8–14–26; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1248; FR ID 362751]

Information Collection Being Submitted to the Office of Management and Budget for Emergency Review and Approval

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written comments and recommendations for the information collection should be submitted on or before September 16, 2026.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the

information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The Commission is requesting emergency OMB processing of the information collection requirement(s) contained in this notice and has requested OMB approval no later than 35 days after the collection is received at OMB. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of Commission ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the Commission's submission to OMB will be displayed.

OMB Control Number: 3060–1248.

Title: Transition from TTY to Real-Time Text Technology, CG Docket No. 16–145 and GN Docket No. 15–178.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents and Responses: 608 respondents; 3,040 responses.

Estimated Time per Response: 2 hours to 60 hours.

Frequency of Response: Annual reporting requirements; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefit. The statutory authority can be found at §§ 4(i), 225, 255, 301, 303(r), 316, 403, 715, and 716 of the Communications Act of 1934, as amended, and Section 106 of the Twenty-First Century Communications and Video Accessibility Act of 2010, 47 U.S.C. 154(i), 225, 255, 301, 303(r), 316, 403, 615c, 616, 617; Public Law 111–260, 106, 124 Stat. 2751, 2763 (2010).

Total Annual Burden: 70,528 hours.

Total Annual Cost: No cost.

Needs and Uses: Text telephone (TTY) technology provides a way for people with disabilities to send and receive text communications over the public switched telephone network (PSTN). Changes to communications networks, particularly ongoing technology transitions from circuit switched to IP-based networks and from copper to wireless and fiber infrastructure, have affected the quality and utility of TTY technology, prompting discussions on transitioning to an alternative advanced communications technology for text communications. Accordingly, on December 16, 2016, the Commission released Transition from TTY to Real-Time Text Technology, Report and Order, document FCC 16–169, 82 FR 7699, January 23, 2017, amending its rules that govern the obligations of wireless service providers and manufacturers to support TTY technology to permit such providers and manufacturers to provide support for real-time text (RTT) over wireless IP-based networks to facilitate an effective and seamless transition to RTT in lieu of continuing to support TTY technology.

In document FCC 16–169, the Commission adopted measures requiring the following:

(a) Each wireless provider and manufacturer that voluntarily transitions from TTY technology to RTT over wireless IP-based networks and services is encouraged to develop consumer and education efforts that include (1) the development and dissemination of educational materials that contain information pertinent to the nature, purpose, and timelines of the RTT transition; (2) internet postings, in an accessible format, of information about the TTY to RTT transition on the websites of covered entities; (3) the creation of a telephone hotline and an online interactive and accessible service that can answer consumer questions about RTT; and (4) appropriate training of staff to effectively respond to consumer questions. All consumer outreach and education should be provided in accessible formats including, but not limited to, large print, Braille, videos in American Sign Language and that are captioned and video described, emails to consumers who have opted to receive notices in this manner, and printed materials. Service providers and manufacturers are also encouraged to coordinate with consumer, public safety, and industry stakeholders to develop and distribute education and outreach materials. The information will inform consumers of alternative accessible technology available to replace TTY technology that may no longer be available to the consumer through their provider or on their device.

(b) Each wireless provider that requested or will request and receive a waiver of the requirement to support TTY technology over wireless IP-based networks and services must apprise its customers, through effective and accessible channels of communication, that (1) until TTY is sunset, TTY technology will not be supported for calls to 911 services over IP-based wireless services, and (2) there are alternative PSTN-based and IP-based accessibility solutions for people with disabilities to reach 911 services. These notices must be developed in coordination with public safety answering points (PSAPs) and national consumer organizations, and include a listing of text-based alternatives to 911, including, but not limited to, TTY capability over the PSTN, various forms of PSTN-based and IP-based TRS, and text-to-911 (where available). The notices will inform consumers on the loss of the use of TTY for completing 911 calls over the provider's network and alert them to alternatives service for which TTY may be used.

Federal Communications Commission.

Aleta Bowers,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2026–16740 Filed 8–14–26; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/*

request.htm. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 1, 2026.

A. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201–2272. Comments can also be sent electronically to *Comments.applications@dal.frb.org:*

1. *Anita Boswell, the Anita Boswell IRA, Christopher Boswell, all of Harlingen, Texas; Carolyn R. Boswell, Scottsdale, Arizona; Megan Boswell, Brooklyn, New York; Thomas Chris Boswell, Austin, Texas; Cameron Hays, Denver, Colorado; Ryan S. Hays, Somerville, Massachusetts; and Kathryn Hays, Sarah Hays and the Sarah Hays IRA, all of Evergreen, Colorado;* as a group acting in concert, to retain voting shares of First San Benito Bancshares Corporation, and thereby indirectly retain voting shares of First Community Bank, both of San Benito, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–16762 Filed 8–14–26; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 16, 2026.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *Silver Queen Financial Services, Inc., Greenwood Village, Colorado;* to become a bank holding company by acquiring Colorado Federal Savings Bank, Greenwood Village, Colorado.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–16764 Filed 8–14–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Sole Source Cooperative Agreement To Fund Public Health Center of the Ministry of Health of Ukraine

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $15,000,000, for Federal Fiscal Year 2026 funding to Public Health Center (PHC) of the Ministry of Health of Ukraine, subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation. The award is expected to advance HIV and TB epidemic control in Ukraine with activities to include enhancing integrated HIV service delivery, improving antiretroviral therapy (ART) initiation and retention, and strengthening the national laboratory system to respond to emerging pathogens.

DATES: The period for this award will be September 30, 2026, through September 29, 2031.

FOR FURTHER INFORMATION CONTACT: Cristel Bender, Global Health Center, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Atlanta, GA 30329, Email: *DGHTNOFOs@cdc.gov.*

SUPPLEMENTARY INFORMATION: The sole source award seeks to advance HIV and TB epidemic control in Ukraine with activities to include enhancing integrated HIV service delivery, improving ART initiation and retention, and strengthening the national laboratory system to respond to emerging pathogens. The sole source award will also support surveillance and response to pandemic, novel influenza, and other infectious disease threats in Ukraine.

PHC of the Ministry of Health of Ukraine is the only entity that can carry out this work, as it is the lead national public health institution. It has the legislative responsibility to coordinate, implement, and monitor the country's public health programs, including HIV prevention, care, and treatment. As the central authority in Ukraine's public health system, PHC has legal and regulatory authority over national HIV policies, guidelines, and surveillance

systems. In addition, PHC has the designated responsibility to lead influenza surveillance, to support health service delivery, and to oversee the national coordination of surveillance, preparedness, prevention, and response activities for health threats and public health emergencies. This sole source award is also expected to support the recipient to improve or maintain capacity to conduct seasonal influenza surveillance and detect and respond to pandemic and novel influenza. The award is intended to enhance capacity to detect and respond to novel influenza viruses, such as highly pathogenic avian influenza, as well as to identify outbreaks of severe respiratory illness syndrome and other infectious disease threats through both epidemiologic and virologic detection. These activities supports strengthening connections between national institutions, especially National Influenza Centers, to fully participate in data sharing and maintain capacity to share specimens, as well as clinical and epidemiologic data related to influenza circulation.

Summary of the Award

Recipient: Public Health Center of the Ministry of Health of Ukraine.

Purpose of the award: The purpose of this award is to strengthen the local government to lead and take ownership of the national HIV and TB response and address emerging public health emergencies. The award will also support surveillance and response for pandemic, novel influenza, and other infectious disease threats in Ukraine.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, *et seq.*] and Public Law 110–293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), Public Law 113–56 (PEPFAR Stewardship and Oversight Act of 2013), and Public Health Service Act (42 U.S.C. 242I).

Period of performance: September 30, 2026, through September 29, 2031.

Jamie Legier,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–16733 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2026–0892]

Order Under Sections 362 and 365 of the Public Health Service Act Continuing the Suspension of the Right To Introduce Certain Persons From Countries Where a Quarantinable Communicable Disease Exists

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces it is issuing an Order under Section 362 and 365 of the Public Health Service Act, and associated implementing regulations, continuing the suspension of the right to introduce certain persons from countries where an outbreak of a quarantinable communicable disease exists. This Order was issued on August 12, 2026, and shall remain in effect through 4:59 p.m. Eastern Daylight Time (EDT) on Friday, September 11, 2026. This Order may be amended or rescinded prior to that time at the discretion of the Director.

DATES: This action took effect August 12, 2026, at 5:00 p.m. EDT. Written comments must be received on or before September 1, 2026.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2026–0892 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Global Migration Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jordan Faircloth, Deputy Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS V18–2, Atlanta, GA 30329. Phone: 404–639–7000. Email: *cdcregulations@cdc.gov.*

SUPPLEMENTARY INFORMATION: On May 18, 2026, the Acting Director of the Centers for Disease Control and Prevention signed an Order prohibiting the introduction of certain persons who have departed from, or were otherwise present within, specified countries during the last 21 days. On May 22, 2026, the Assistant Secretary for Health (ASH), HHS, signed an Amended Order that reflected updates to 42 CFR 71.40(f), which no longer provided an exemption for lawful permanent residents from such orders. CDC accepted comments on both the original Order and Amended Order through June 22, 2026, and received 3 comments.

The ASH continued the Order without change on June 21, 2026, for 30 days with a 15-day comment period; CDC received five comments in response. The ASH again continued the Order without change on July 13, 2026, for 30 days with a 15-day comment period, and no comments were received.

On August 12, 2026, the ASH signed a new Order continuing the previous Order without change. This order provides updated information regarding the status of the Ebola disease outbreak and CDC response efforts and maintains the previous travel restrictions.

This Order is effective for a period of 30 days. CDC will accept comments for this Order for 15 days using docket CDC–2026–0892.

A copy of the Order is provided below and a copy of the signed Order can be found at *https://www.cdc.gov/port-health/legal-authorities/evdorder.html.*

U.S. Department of Health and Human Services Centers for Disease Control And Prevention (CDC)

Order Under Sections 362 & 365 of the Public Health Service Act

(42 U.S.C. 265, 268) and 42 CFR 71.40

Continuing the Suspension of the Right To Introduce Certain Persons From Countries Where a Quarantinable Communicable Disease Exists

I. Executive Summary

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), issues this Order pursuant to Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265 and 268, and their implementing regulations. This Order continues the suspension of the right to introduce ''covered aliens,'' as defined herein, into the United States for a period of thirty days, subject to the outcome of an ongoing comprehensive public health risk assessment. This Order is necessary to protect the health of the United States from the serious risk posed by the introduction of

Ebola disease into the United States by covered aliens based on the outbreak of Ebola disease caused by the Bundibugyo virus confirmed present in the Democratic Republic of the Congo (DRC) and Uganda.

This Order applies to covered aliens who have departed from, or were otherwise present within, DRC, Uganda, or South Sudan during the last 21 days (regardless of their country of origin). This Order is based on an assessment of the most recently available data and current conditions regarding the Ebola disease outbreak.

This Order is time-limited and shall be in effect for 30 days from the date of issuance. This Order is intended to address the serious risk of introduction of Ebola disease into the United States, while allowing the U.S. Government to continue an ongoing assessment of the current and evolving conditions of the Ebola disease outbreak in consultation with other stakeholders.

This Order is severable from previously issued Orders under Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265 and 268, and their implementing regulations under 42 CFR part 71. Any provision of this Order held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability.

II. Authority, Scope, and Purpose

I issue this Order pursuant to Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265 and 268, and their implementing regulations under 42 CFR part 71,[1] which authorize the CDC Director to suspend the right to introduce [2] persons into the United States when the Director determines that the existence of a quarantinable communicable disease in a foreign country or place creates a serious danger of the introduction of such disease into the United States and the danger is so increased by the introduction of persons from the foreign country or place that a temporary suspension of the right of such introduction is necessary to protect public health.

This Order applies to persons who have departed from, or were otherwise present within, DRC, Uganda, and South Sudan during the last 21 days (regardless of their country of origin), including lawful permanent residents of the United States, subject to the exceptions detailed below. For purposes of this Order, I refer to persons covered by the Order as ''covered aliens.''

This Order does *not* apply to the following:

- U.S. citizens and U.S. nationals; [3]
- Members of the armed forces of the United States and associated personnel, U.S. government personnel serving overseas, associated personnel, and their spouses and children, subject to required assurances; [4]
- Persons whom customs officers determine, with approval from a supervisor, should be excepted from this Order based on the totality of the circumstances, including consideration of significant law enforcement, officer and public safety, humanitarian, and public health interests. The U.S. Department of Homeland Security (DHS) will consult with CDC regarding the standards for such exceptions to help ensure consistency with current CDC guidance and public health recommendations; and
- Persons who would otherwise be subject to this Order, who are permitted to enter the United States based on an exception provisionally granted by CDC with confirmation based on a public health assessment at time of entry under a DHS-approved process documented and shared with CDC which includes appropriate public health mitigation protocols, per CDC guidance.

The purpose of this Order is twofold. First, this Order aims to continue minimizing the number of covered aliens entering the United States who have been within countries experiencing a known or suspected outbreak of Ebola disease and thereby reduce the risk of introduction of Ebola disease into the United States. Second, this Order is intended to facilitate an ongoing public health assessment and risk profile of the Ebola disease outbreak. Thirty days is the amount of time necessary for CDC to continue monitoring the situation and determine if there has been a material change to the risk of importation and whether this Order would remain in effect or requires modification. Such information will enable the acting CDC Director to make an informed determination regarding what restrictions are necessary going forward and provide the opportunity for the development of a comprehensive mitigation and containment plan in consultation with stakeholders.

III. Factual Basis

A. Ebola Disease

Viral hemorrhagic fever refers to a group of severe illnesses caused by certain viruses that damage the body's blood vessels and affect the ability of the blood to clot properly. Viral hemorrhagic fevers include diseases such as Ebola, Marburg, Lassa fever, and dengue hemorrhagic fever.

Bundibugyo virus disease (BVD) is a severe and often fatal illness caused by one of the viruses in the Ebola family. Ebola disease outbreaks occur mainly in parts of sub-Saharan Africa and can spread rapidly in communities with limited healthcare resources. Ebola disease caused by the Bundibugyo virus is a rare form of Ebola first identified during an outbreak in Bundibugyo District, Uganda, in 2007. Bundibugyo virus is one of several species within the orthoebolavirus family and causes symptoms similar to other forms of Ebola, including fever, weakness, vomiting, diarrhea, and, in severe cases, hemorrhagic complications and organ failure. The disease spreads through direct contact with infected bodily fluids or contaminated materials.

The incubation period for Ebola disease caused by the Bundibugyo virus is typically between 2 and 21 days, with most people developing symptoms within 4 to 10 days after exposure. During this incubation period, infected persons do not spread the virus until symptoms begin.

Screening for Bundibugyo virus disease focuses on identifying symptoms and possible exposure history, such as recent travel to affected areas or contact with infected aliens. Suspected patients are evaluated for symptoms including fever, weakness, vomiting, diarrhea, and bleeding, and laboratory confirmation is performed using specialized tests such as PCR (polymerase chain reaction) to detect the virus in blood and other body fluid samples. Health authorities also use temperature checks, contact tracing, and isolation procedures to prevent transmission.

There are currently no widely approved vaccines or specific antiviral treatments for the Bundibugyo strain of Ebola disease. Treatment mainly consists of supportive care, including intravenous fluids, electrolyte replacement, oxygen support, pain and fever management, and treatment of secondary infections. Early medical care significantly improves survival chances. Robust public health measures such as early detection, rapid isolation, strong infection prevention measures (*i.e.,* use of personal protective equipment [PPE]), and monitoring of contacts are critical to controlling outbreaks and reducing deaths. A clinical trial of monoclonal antibodies is presently underway in DRC.[5] However, experts expect it will be several months before these therapeutics are potentially available for wider use.

B. Ongoing Bundibugyo Virus Disease Outbreak

The confirmed ongoing outbreak of Ebola virus disease caused by the Bundibugyo virus in DRC and Uganda continues to escalate in intensity. The outbreak remains centered in eastern DRC's Ituri Province, although cases have been identified in North Kivu, South Kivu, Haut-Uele, and Tshopo provinces. This geographic expansion is concerning, particularly given that response efforts are still not at the scale required for outbreak containment. On July 13, 2026, when the last Order was issued, DRC reported 1,873 confirmed cases and 672 deaths across 41 health zones. As of August 9, 2026, DRC reports 4,318 confirmed cases and 2,011 deaths across 53 health zones, with cases and deaths more than doubling since issuance of the July Order.

As recently as August 11, 2026, the ongoing Bundibugyo Ebola virus outbreak in DRC continues to spread despite response efforts. Although contact tracing for

[1] Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduce and Prohibition of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes, 85 FR 56424 (Sept. 11, 2020), as amended by 91 FR 31362 (May 27, 2026); 42 CFR 71.40.

[2] *Suspension of the right to introduce* means to cause the temporary cessation of the effect of any law, rule, decree, or order pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States. 42 CFR 71.40(b)(5).

[3] 42 CFR 71.40(f).

[4] 42 CFR 71.40(e)(1) and (2).

[5] WHO, *Patient enrolment begins in a scientific trial to identify the first effective treatments for Bundibugyo virus disease, https://www.who.int/news/item/02-07-2026-patient-enrolment-begins-in-a-scientific-trial-to-identify-the-first-effective-treatments-for-bundibugyo-virus-disease* (last accessed July 12, 2026).

confirmed cases has risen to approximately 78% nationwide, these efforts are still well below the operational threshold of 95% needed to successfully slow the spread of this outbreak.[6] Recent assessments indicate that the true magnitude of the outbreak may be two to four times greater than reported surveillance data suggest. Surveillance challenges persist in the most heavily affected areas, with conflict and insecurity, weak health infrastructure, and relatively porous borders in the region complicating containment efforts. Although contact tracing efforts are underway, they remain insufficient because the expected number of contacts has not yet been identified and the daily follow-up necessary to rapidly detect symptomatic individuals and ensure their prompt isolation has not been achieved.

As of August 11, 2026, Uganda reports 20 confirmed cases of Ebola disease and two confirmed deaths, as well as one probable case and one probable death. The last confirmed case was reported on June 21, 2026. Of the confirmed cases, 15 were imported cases and 5 were secondary cases linked to imported cases from DRC.[7] All cases in Uganda have been epidemiologically linked to the ongoing outbreak in DRC, with cross-border importations having occurred, resulting in secondary transmission among family members and caregivers.[8] Ugandan authorities have activated emergency response systems, expanded surveillance, and strengthened screening at borders and health facilities. Uganda has significant prior experience managing Ebola disease outbreaks, including the Sudan virus strain outbreak in 2025, which improved preparedness and response capacity. On July 28, 2026, the Republic of Uganda Ministry of Health declared the outbreak over.[9] No further transmission of the virus within Uganda has been detected and the most recent imported case was discharged from a treatment center on July 16, 2026, following two negative tests results.[10] Although the country has achieved successful containment of the outbreak, continued overland travel from DRC poses an ongoing risk of cross-border transmission, particularly among healthcare workers and in western Ugandan districts that serve as points of entry for travelers seeking medical care.

To date, South Sudan has not reported any confirmed Ebola disease cases in the current outbreak.[11] However, it is considered at high risk because of its close border with affected areas in eastern DRC, limited healthcare infrastructure, and cross-border population movement. Regional and international agencies, including WHO and Africa CDC, are supporting preparedness measures, surveillance, and coordination among the three countries to prevent wider spread. Despite these efforts and in contrast to Uganda, there continues to be a risk that the outbreak in DRC could spread to South Sudan through cross-border travel by infected individuals during the virus's incubation period, when they have been exposed but are not yet showing symptoms.

Travelers moving between affected countries and major international transit hubs could unknowingly carry the Bundibugyo virus before becoming ill. Such travelers may spread the outbreak beyond the affected countries and ultimately reach the United States. DRC, Uganda, and South Sudan are connected to the global aviation network through a series of regional and international transit hubs that provide pathways into the United States. Travelers departing from outbreak-affected regions frequently transit through densely populated metropolitan airports such as Addis Ababa Bole International Airport (ADD), Jomo Kenyatta International Airport (NBO) in Nairobi, Brussels Airport (BRU), Hamad International Airport (DOH) in Doha, Dubai International Airport (DXB), and Istanbul Airport (IST), all of which maintain extensive passenger connectivity to major U.S. gateway airports including John F. Kennedy International Airport (JFK), Washington Dulles International Airport (IAD), Hartsfield-Jackson Atlanta International Airport (ATL), Chicago O'Hare International Airport (ORD), and Los Angeles International Airport (LAX). These international transportation corridors support continuous movement of travelers between Central and East Africa and major U.S. metropolitan centers, increasing the likelihood that aliens exposed to Ebola disease could enter the United States before symptoms become apparent. Complex multi-leg itineraries and the rapid pace of international travel create substantial challenges for identifying potentially infected travelers before arrival.

A traveler infected in outbreak regions of DRC and Uganda may transit through multiple countries and major international airports before developing fever or other clinical signs of disease. The risk of Bundibugyo virus disease introduction into the United States is heightened by the virus's incubation period, which can extend up to 21 days, allowing infected persons to travel internationally while asymptomatic and therefore unlikely to be detected through routine symptom-based screening measures. The current outbreak has already demonstrated this risk: a physician infected while providing patient care in DRC traveled internationally before becoming ill and was diagnosed only after arriving in France.[12] That case required extensive public health coordination, including federal, state, and local government efforts to identify, notify, and monitor potentially exposed U.S. citizens, demonstrating that a single infected traveler can impose significant cross-border public health response demands even without onward transmission occurring within the United States. Accordingly, the interconnected nature of global air travel presents a credible pathway for Bundibugyo virus disease importation into the United States, underscoring the importance of aggressive surveillance, traveler monitoring, airport public health screening, healthcare preparedness, and rapid containment capabilities.

Travelers utilizing air transit pathways originating in or passing through DRC, Uganda, and South Sudan include non-U.S. citizens, including regional migrants, foreign contract workers, humanitarian personnel, business travelers, students, refugees, and third-country nationals moving through international aviation hubs in Africa, the Middle East, and Europe. Many travelers entering U.S.-bound itineraries from these pathways may do so under temporary visas, refugee or asylum processing mechanisms, international organizational travel, or multi-country itineraries that obscure their original point of departure. As a result, public health screening and border security systems face heightened operational complexity in identifying travelers with recent exposure histories linked to Ebola-affected regions, particularly when travelers originate from or transit through multiple jurisdictions prior to arrival at major U.S. metropolitan airports.

CDC has issued a series of Travel Health Notices (THNs) for the region; the THNs for the affected provinces have escalated over time. On August 4, 2026, CDC escalated the THN issued for Ituri and North Kivu Provinces of DRC to a Level 4 (avoid all travel).[13] A Level 3 THN (reconsider nonessential travel) is currently in place for South Kivu, Haut-Uélé, and Tshopo Provinces of DRC.[14] The rest of DRC and all of Uganda remain under a Level 2 THN (practice enhanced precautions).[15] Modifications to the THNs reflect the

[6] Ministry of Public Health, Hygiene and Social Welfare, *Situation Report on the 17th Ebola Virus Outbreak Disease/DRC—August 6, 2026, https://insp.cd/category/activite-cousp/* (last accessed August 6, 2026).

[7] WHO, *Disease Outbreak News: Ebola disease caused by Bundibugyo virus, Democratic Republic of the Congo & Uganda, https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON613* (last accessed August 7, 2026).

[8] CDC internal data.

[9] The Republic of Uganda Ministry of Health, *Uganda is officially Ebola free, https://health.go.ug/uganda-is-officially-ebola-free/* (last accessed August 6, 2026).

[10] WHO, *Disease Outbreak News: Ebola disease caused by Bundibugyo virus—Democratic Republic of the Congo, https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON614* (last accessed August 6, 2026).

[11] CDC, *Ebola Outbreak: Current Situation, https://www.cdc.gov/ebola/situation-summary/index.html* (last visited August 6, 2026).

[12] World Health Organization, *WHO Director-General's opening remarks at the media briefing—24 June 2026,* available at *https://www.who.int/news-room/speeches/item/who-director-general-s-opening-remarks-at-the-media-briefing---24-june-2026* (last accessed July 12, 2026).

[13] CDC issued a Level 2 THN (practice enhanced precautions) for Ituri and North Kivu Provinces of DRC on May 15, 2026; this was escalated to a Level 3 THN (reconsider nonessential travel) on May 18, 2026. The current Level 4 THN is available at *https://wwwnc.cdc.gov/travel/notices/level4/ebola-drc-provinces* (last accessed August 11, 2026).

[14] South Kivu was added to the Level 3 THN on May 22, 2026; Haut-Uélé and Tshopo Provinces were added on August 4, 2026. The current THN is available at *https://wwwnc.cdc.gov/travel/notices/level3/ebola-democratic-republic-of-the-congo* (last accessed August 11, 2026).

[15] CDC issued a Level 1 THN (practice usual precautions) for Uganda on May 15, 2026. On May 27, 2026, the THN for Uganda was elevated to a Level 2. On June 15, 2026, CDC issued a Level 2 THN for the remainder of DRC and Uganda. The current THN is available at *https://wwwnc.cdc.gov/travel/notices/level2/ebola-drc-uganda* (last accessed August 11, 2026).

geographic distribution of reported cases and do not indicate a reduced level of concern regarding the outbreak, which continues to expand in affected areas and poses a risk of further transmission and geographic spread.

CDC modeling indicates that, absent rapid and sustained public health interventions, the outbreak could become one of the largest Ebola epidemics ever recorded.[16] The analysis further demonstrates that early identification of cases, contact tracing, isolation and treatment of symptomatic persons, community engagement, and safe burial practices are critical to reducing transmission and mitigating outbreak growth.[17] CDC has concluded that the current outbreak is already the largest known outbreak of Bundibugyo virus disease and that large-scale, sustained public health measures are necessary to prevent further international spread of the disease and to reduce the risk of introduction of infected persons into the United States.[18] Commensurate with the deterioration of the epidemiological situation in DRC, CDC escalated its response to the outbreak to a Level 1, the highest level within the agency's Graduated Response Framework.[19] Designating the response as a Level 1 indicates the gravity of the situation and allows additional staffing support from across the response, with immediate lines of communication with agency leadership.

Restricting entry of covered aliens into the United States reduces the volume of higher-risk international arrivals requiring public health monitoring and follow-up. By limiting the number of potentially exposed travelers entering through major U.S. ports of entry, federal, state, and local public health authorities have concentrated finite surveillance, screening, contact tracing, quarantine management, and medical monitoring resources on returning U.S. citizens and U.S. nationals, including those who have worked in the outbreak areas.

Paired with the DHS arrival restrictions redirecting travelers to specific U.S. airports,[20] this approach has reduced operational strain on airport screening systems, CDC port health stations, public health laboratories, and healthcare facilities responsible for evaluating suspected Bundibugyo virus disease cases. It also has improved the ability of authorities to conduct detailed exposure assessments, ensure compliance with monitoring requirements during the 21-day incubation period, rapidly identify symptomatic travelers, and allocate specialized isolation and treatment capacity more effectively. In the context of a rapidly evolving Bundibugyo virus disease outbreak with significant cross-border mobility, prioritizing surveillance efforts toward a smaller and more traceable traveler population has strengthened the overall effectiveness of U.S. disease containment and border health security operations.

IV. Legal Basis for This Order Under Sections 362 and 365 of the Public Health Service Act and 42 CFR 71.40

CDC is issuing this Order pursuant to sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268) and the implementing regulation at 42 CFR 71.40. In accordance with these authorities, the CDC Director is permitted to prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease,[21] by issuing an Order in which the Director determines that:

(1) By reason of the existence of any quarantinable communicable disease in a foreign country (or one or more political subdivisions or regions thereof) or place there is serious danger of the introduction of such quarantinable communicable disease into the United States; and

(2) This danger is so increased by the introduction of persons from such country (or one or more political subdivisions or regions thereof) or place that a suspension of the right to introduce such persons into the United States is required in the interest of public health.[22]

Section 362 and the implementing regulation provide the Director with a public health tool to suspend introduction of persons not only to prevent the introduction of a quarantinable communicable disease, but also to aid in continued efforts to mitigate spread of that disease.[23]

The term ''introduction into the United States'' is defined in 42 CFR 71.40 as ''the movement of a person from a foreign country (or one or more political subdivisions or regions thereof) or place, or series of foreign countries or places, into the United States so as to bring the person into contact with persons or property in the United States, in a manner that the Director determines to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with a quarantinable communicable disease.'' 42 CFR 71.40(b)(1). Similarly, the term ''serious danger of the introduction of such quarantinable communicable disease into the United States'' is defined as, ''the probable introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease.'' 42 CFR 71.40(b)(3).

Section 71.40(b)(2) defines ''[p]rohibit, in whole or in part, the introduction into the United States of persons'' in Section 362 to mean ''to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States.'' *See also* 42 U.S.C. 265 (authorizing the prohibition when the danger posed by the communicable disease ''is so increased by the introduction of persons . . . from such country . . . that a suspension of the right to introduce such persons . . . is required in the interest of public health'').

As stated in the Final Rule for 42 CFR 71.40, CDC ''may, in its discretion, consider a wide array of facts and circumstances when determining what is required in the interest of public health in a particular situation . . . includ[ing] . . . [t]he overall number of cases of disease; any large increase in the number of cases over a short period of time; the geographic distribution of cases; any sustained (generational) transmission; the method of disease transmission; morbidity and mortality associated with the disease; the effectiveness of contact tracing; the adequacy of state and local health care systems; and the effectiveness of state and local public health systems and control measures.'' [24]

As stated in 42 CFR 71.40, this Order does not apply to U.S. citizens, U.S. nationals, members of the armed forces of the United States and associated personnel if the Secretary of War provides assurance to the Director that the Secretary of War has taken or will take measures such as quarantine or isolation, or other measures maintaining control over such individuals, to prevent the risk of transmission of the quarantinable communicable disease into the United States, or United States government employees or contractors on orders abroad, or their accompanying family members who are on their orders or are members of their household, if the Director receives assurances from the relevant head of agency and determines that the head of the agency or department has taken or will take measures such as quarantine or isolation, to prevent the risk of transmission of a quarantinable communicable disease into the United States.[25]

In addition, this Order does not apply to additional classes of persons excepted by the CDC Director. Creating exceptions in the Order is consistent with Section 362 and 42 CFR 71.40. Section 362 explicitly states that the prohibition of introduction into the United States may be ''in whole or in part.'' This phrase is also included in section 71.40(a) and, as explained in the Final Rule, is intended to allow the Director to narrowly tailor the use of the authority to what is required in the interest of public health.[26] As noted in the Final Rule for 42 CFR 71.40, the CDC Director may also take into account international obligations and humanitarian concerns.[27] Pursuant to this capability, CDC

[16] Mooring EQ, Koval WT, Routledge I, et al. *Modeled Scenario Projections for the Ebola Disease Outbreak Caused by Bundibugyo Virus, 2026.* MMWR Morb Mortal Wkly Rep 2026;75:285–289. DOI: *http://dx.doi.org/10.15585/mmwr.mm7522e1.*

[17] *Id.*

[18] *Id.*

[19] CDC, Internal Decision Memo, June 26, 2026.

[20] DHS, Arrival Restrictions Applicable to Flights Carrying Persons Who Have Recently Traveled From or Were Otherwise Present Within the Democratic Republic of the Congo, Uganda, or South Sudan, 91 FR 29896 (May 21, 2026).

[21] *See* Exec. Order No. 13,295, Revised List of Quarantinable Communicable Diseases (April 2, 2003) (adding viral hemorrhagic fevers, including Ebola, to the U.S. federal list of quarantinable communicable diseases).

[22] 42 U.S.C. 265; 42 CFR 71.40.

[23] 85 FR 56424 at 56425–26.

[24] *Id.* at 56444.

[25] 42 CFR 71.40(e) and (f).

[26] 85 FR 56424 at 56444.

[27] *Id.* at 56447.

is therefore excepting certain categories of persons, as described herein.

This Order will be in effect for 30 days to avert the serious danger of the introduction, transmission, and spread of Ebola disease into the United States. Finally, as directed by 42 CFR 71.40(c), this Order sets out the following:

(1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited;

(2) The period of time or circumstances under which the introduction of any persons or class of persons into the United States is being prohibited;

(3) The conditions under which that prohibition on introduction will be effective, in whole or in part, including any relevant exceptions that the Director determines are appropriate;

(4) The means by which the prohibition will be implemented; and

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

V. Determination and Implementation

Based on the foregoing, I hereby determine that Ebola disease, a highly transmissible quarantinable communicable disease, is confirmed currently present in DRC and recently present in Uganda. There is a material risk that the outbreak will spread to South Sudan. I also determine that the prevalence of Ebola disease in these foreign countries constitutes a serious danger of the introduction of this disease into the United States due to the limited screening and testing and mitigation measures currently available. Finally, I determine that a temporary 30-day suspension of the right to introduce covered aliens is necessary to protect the public health from the serious danger of the introduction of Ebola disease into the United States, pending an ongoing public health assessment of the Ebola disease outbreak.

I consulted with the Department of State, DHS, and other federal departments as needed before I issued this Order and requested that DHS aid in the enforcement of this Order because CDC does not have the capability, resources, or personnel needed to do so.[28] As part of the consultation, DHS developed operational plans for implementing this Order. These plans are consistent with the language of this Order.

Although this Order is not a rule subject to notice and comment under the Administrative Procedure Act (APA) and is issued with immediate effect, in order to ensure that the forthcoming public health risk assessment is informed by public input, the Order is being issued with a simultaneous 15-day comment period.

This Order takes effect at 5:00 p.m. Eastern Daylight Time on Wednesday, August 12, 2026. For individuals intending to travel to the United States by air, the Order will apply to flights departing after 4:59 p.m. Eastern Daylight Time on Wednesday, August 12, 2026.

* * * * *

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at Washington, DC this 12th day of August, 2026.

Dated: Admiral Brian Christine, MD, Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps Department of Health and Human Services.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data so that the public can provide input that may inform the forthcoming public health risk assessment and whether any subsequent exercise of this authority is necessary.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

Authority

The authority for this order is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265 and 268), as amended.

Brian Christine,

Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps, Department of Health and Human Services.

[FR Doc. 2026–16706 Filed 8–14–26; 8:45 am]

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[28] 42 U.S.C. 268; 42 CFR 71.40(d).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Sole Source Cooperative Agreement To Fund the Ministry of Health of Ethiopia

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $30,000,000, for Federal Fiscal Year 2026 funding to the Ministry of Health (MOH), subject to the availability of funds. Funding amounts for years 2–5 will be set at continuation. The award is expected to help build and oversee national HIV and TB programs in Ethiopia through the MOH and its affiliates.

DATES: The period for this award will be September 30, 2026, through September 29, 2031.

FOR FURTHER INFORMATION CONTACT: Cristel Bender, Global Health Center, Centers for Disease Control and Prevention, 1600 Clifton Rd NE, Atlanta, GA 30329, Email: *DGHTNOFOs@cdc.gov.*

SUPPLEMENTARY INFORMATION: The sole source award is intended to help build and oversee national HIV and TB programs in Ethiopia through the MOH and its affiliates.

The Ethiopia MOH is the only entity that can carry out this work, as it is the primary authority responsible for overseeing the health care system in Ethiopia, including preventing, providing care, and treating HIV/AIDS, mandated under Proclamation No. 1263/2021.

Summary of the Award

Recipient: Ministry of Health (MOH).

Purpose of the award: The purpose of this award is to lead and coordinate the national HIV and TB program, helping to ensure sustainable, cost effective, high-quality life-saving HIV services at national and regional levels.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, *et seq.*] and Public Law 110–293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008),

and Public Law 113–56 (PEPFAR Stewardship and Oversight Act of 2013).

Additionally, these programs are authorized under Section 307 of the Public Health Service Act, as amended [42 U.S.C. 242l], Section 301 (a) [42 U.S.C. 241 (a)] of the Public Health Service Act, as amended.

Period of performance: September 30, 2026, through September 29, 2031.

Jamie Legier,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–16731 Filed 8–14–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Sole Source Cooperative Agreement To Fund University Teaching Hospital in Zambia

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the award of approximately $30,000,000, for Federal Fiscal Year 2026 funding to Zambia's University Teaching Hospital (UTH), subject to availability of funds. Funding amounts for years 2–5 will be set at continuation. The award is expected to improve HIV and TB clinical and laboratory service delivery at referral level hospitals and provincial-level referral facilities through the national government referral facility, UTH.

DATES: The period for this award will be September 30, 2026, through September 29, 2031.

FOR FURTHER INFORMATION CONTACT: Cristel Bender, Global Health Center, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE, Atlanta, GA 30329, Email: *DGHTNOFOs@cdc.gov.*

SUPPLEMENTARY INFORMATION: The sole source award is expected to improve HIV and TB clinical and laboratory service delivery at referral level hospitals and provincial-level referral facilities through the national government referral facility, UTH.

UTH is the only entity that can carry out this work, as it is the country's national reference hospital, with a directive to provide inpatient and outpatient services for complicated cases, including advanced HIV disease cases.

Summary of the Award

Recipient: University Teaching Hospital.

Purpose of the award: The purpose of this award is to support sustainable HIV and TB service implementation through UTH.

Authority: This program is authorized under Public Law 108–25 (the United States Leadership Against HIV AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601, *et seq.*] and Public Law 110–293 (the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008), Public Law 113–56 (PEPFAR Stewardship and Oversight Act of 2013), and Public Health Service Act (42 U.S.C. 242I).

Period of performance: September 30, 2026, through September 29, 2031.

Jamie Legier,

Chief Grants Management Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–16732 Filed 8–14–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Withdrawal of the Announcement of the Intent To Award a Single-Source Cooperative Agreement to Burke Law Group, PLLC in Houston, Texas

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of intent to award a single-source cooperative agreement; withdrawal.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is withdrawing the, 'Announcement of the Intent to Award a Single-Source Cooperative Agreement to Burke Law Group, PLLC in Houston, Texas' published in the **Federal Register** on August 6, 2026, at 91 FR 50848 (FR Doc. 2026–16081).

FOR FURTHER INFORMATION CONTACT: Reina Byrd, Assistant Deputy Director, Unaccompanied Alien Children Bureau, 330 C St SW, Washington, DC 20201. Telephone: (202) 256–9497; Email: *Reina.Byrd@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Withdrawal Notice

In the **Federal Register** of August 6, 2026, at 91 FR 50848 (FR Doc. 2026–16081), page 50848, ORR published a notice announcing its intent to award a single-source cooperative agreement of up to $150,000,000 to Burke Law Group, PLLC, in Houston, Texas, to provide legal services for eligible unaccompanied alien children (UAC) in ORR care.

Burke Law Group subsequently notified ORR of its decision not to apply for the proposed cooperative agreement and withdrew from consideration on August 11, 2026. Therefore, ORR will not make the award to Burke Law Group announced in the notice published on August 6, 2026. This withdrawal does not affect ORR's continued efforts to ensure access to legal services for eligible UACs in ORR care.

Statutory Authority: Section 462 of the Homeland Security Act of 2002, 6 U.S.C. 279; William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, 8 U.S.C. 1232(c)(4) and (c)(5).

Dawnisha Helland,

Assistant Principal Deputy Director, Unaccompanied Alien Children Bureau, Office of Refugee Resettlement.

[FR Doc. 2026–16741 Filed 8–13–26; 11:15 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5376]

Type VII Veterinary Master File for Research and Development and Risk Reviews; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #260 entitled ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' This guidance describes FDA's current thinking regarding the use of Type VII Veterinary Master Files (Type VII VMFs). Type VII VMFs are appropriate for research and development of animal cells, tissues, and cell- and tissue-based products (ACTPs), gene therapies, and heritable intentional genomic alterations (IGAs) in animals.

DATES: The announcement of the guidance is published in the **Federal Register** on August 17, 2026.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–5376 for ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lynne Boxer, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–0611, *lynne.boxer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 7, 2025 (90 FR 1143), FDA published the notice of availability for a draft guidance entitled ''Type VII Veterinary Master File for Research and Development and Risk Reviews'' giving interested persons until March 10, 2025, to comment on the draft guidance. FDA received one comment on the draft guidance asking for additional time to review and comment on the draft guidance. In the **Federal Register** of April 9, 2025 (90 FR 15248), FDA extended the comment period of the draft guidance until June 9, 2025. FDA received no additional comments on the draft guidance and FDA has, therefore, made no substantive changes to the draft guidance. The guidance announced in this notice finalizes the draft guidance dated January 2025.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Type VII Veterinary Master File for Research and Development and Risk Reviews. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16711 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8328]

Agency Information Collection Activities; Proposed Collection; Comment Request; Imports and Electronic Import Entries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with our imports program.

DATES: Either electronic or written comments on the collection of information must be submitted by October 16, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–8328 for ''Imports and Electronic Import Entries.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Patrick Clouser, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5276, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Imports and Electronic Import Entries—21 CFR Part 1, Subparts D and E

OMB Control Number 0910–0046—Extension

This information collection supports the required data elements that respondents must submit when importing, or offering for import, an FDA-regulated article into the United States. Review of the data elements allows FDA to continue to meet its responsibilities pertaining to current submission requirements established by the U.S. Customs and Border Protection (CBP) related to the submission of entry information in using its Automated Commercial Environment (ACE) system, or any CBP-authorized electronic data interchange system.

Respondents (ACE filers) submit important and useful information about FDA-regulated products being imported or offered for import into the United States so that we may effectively and efficiently review products and determine their admissibility. Respondents must submit the data elements required for all imported products, as well as additional data elements as required for specific product types.

The information collection also includes our weekly entry filing program (WEF). More detailed information on Foreign Trade Zones (FTZ)/WEF, is available at *https://www.fda.gov/industry/import-basics/foreign-trade-zonesweekly-entry-filing.* The WEF program allows entry filers to file a single entry estimating the amount of merchandise anticipated to be removed from an FTZ and offered for U.S. consumption during a 7-day period. To participate, we recommend respondents who wish to file a weekly entry of FDA-regulated products with CBP to first request a preliminary assessment from FDA. As part of the assessment, we also recommend submitting specific data elements, as discussed in the assessment. The information helps us route submissions within the Agency. Information on whether a product is stored or manufactured in the zone is necessary for FDA to determine the applicable admissibility requirements. The FTZ and port information is necessary to ensure that basic requirements of CBP regulations are met. The importer of record (IOR) and manufacturer FDA establishment identification number information is requested by FDA to expedite the admissibility review. Requests to participate in the WEF process are submitted to the FDA Import Division Office covering the intended port of entry.

The information collection also includes our Import Trade Auxiliary Communication System (ITACS). ITACS is used by the import trade community and was implemented to improve communication with FDA. By utilizing ITACS, respondents to the information collection can establish an account and electronically check the status of FDA-regulated entries and lines, submit entry documentation, submit the location of goods availability for those lines targeted for examination by FDA, and check the estimated laboratory analysis completion dates for lines that have been sampled. For further information regarding ITACS, please visit our website at *https://www.fda.gov/industry/import-systems/itacs.*

The information collection also includes burden associated with the use of Form FDA 766 entitled ''Application for Authorization to Relabel or Recondition Non-compliant Articles.'' Form FDA 766 facilitates collection of information associated with certain general enforcement provisions for importing FDA-regulated articles into the United States. The form is available at *https://www.fda.gov/industry/actions-enforcement/reconditioning.*

Relatedly, the information collection includes burden associated with the use of electronic Form FDA 5054 entitled ''New Inquiry Form—Import Compliance Branch.'' Form FDA 5054 facilitates both industry's responses to drug import inquiries and the Agency's ability to track receipts of those responses. The form interfaces with current Agency IT systems for optimal utility.

Finally, the information collection includes burden associated with recommendations found in the procedural Agency guidance entitled ''Pre-Launch Activities Importation Requests (PLAIR),'' (March 2022). Historically, when applicants with a pending new drug application, abbreviated new drug application, or Center for Drug Evaluation and Research-regulated biologics licensing application (information collection associated with these submissions is currently approved under OMB control number 0910–0001) sought to import unapproved finished dosage form drug products into the United States in preparation for market launch, we considered such requests, informally referred to as ''PLAIRs,'' on a case-by-case basis. Since implementing the PLAIR program in 2013, interest continues to increase, so we have developed a more formalized process as discussed in the guidance. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pre-launch-activities-importation-requests-plair* and was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment on Agency guidance documents at any time. The guidance instructs that PLAIR submissions should be made using the applicant's letterhead and submitted by email to *CDER-OC-PLAIR@fda.hhs.gov*in a file compatible with Portable Document Format (PDF).

Description of Respondents: Respondents to the information collection are domestic and foreign importers of FDA-regulated articles being imported or offered for import into the United States and entry filers who submit import entries on behalf of these importers.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR part 1, subpart D	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Importers submission of data elements (preparing the required information).	95,307	10.14	967,069	0.08 (5 minutes)	77,366
Entry filers (unique lines only)	4,133	10,804	44,656,657	0.04466 (2.68 minutes)	1,994,336
WEF participants	10	1	10	0.87 (52 minutes)	9
ITACS; creation of new account	500	1	1	0.5 (30 minutes)	250
Form FDA 766 as required under 21 CFR 1.95.	324	1	324	0.25 (15 minutes)	81
Form FDA 5054	1,000	1	1,000	.083 (5 minutes)	83

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]—Continued

21 CFR part 1, subpart D	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submissions in accordance w/PLAIR	80	4	320	16	5,120
Total			45,625,381		2,077,245

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to reflect electronic submission data.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16712 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–E–0485; FDA–2025–E–0486; FDA–2025–E–0488; FDA–2025–E–0489; and FDA–2025–E–0490]

Determination of Regulatory Review Period for Purposes of Patent Extension; BIZENGRI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for BIZENGRI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 16, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 16, 2027. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2025–E–0485; FDA–2025–E–0486; FDA–2025–E–0488; FDA–2025–E–0489; and FDA–2025–E–0490 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BIZENGRI.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Patrick Clouser, Office of the Commissioner, Food and Drug Administration, 240–402–5276.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, BIZENGRI (zenocutuzumab-zbco). BIZENGRI is indicated for the treatment of adults with advanced unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). BIZENGRI is indicated for the treatment of adults with advanced unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received a patent term restoration application for BIZENGRI (U.S. Patent Nos. 9,248,181; 10,329,596; 11,279,770; 11,780,925; and 12,139,548) from Merus N.V. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated 10/8/2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BIZENGRI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BIZENGRI is 2,909 days. Of this time, 2,634 days occurred during the testing phase of the regulatory review period, while 275 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* 12/16/2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was 12/16/2016.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service (PHS) Act:* 3/4/2024. FDA has verified the applicant's claim that the biological license application (BLA) for BIZENGRI (BLA 761352) was initially submitted on 3/4/2024.

3. *The date the application was approved:* 12/4/2024. FDA has verified the applicant's claim that BLA 761352 was approved on 12/4/2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,594 days, 1,133 days, 633 days, 23 days, or 23 days, respectively, of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16713 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1736]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Application Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 16, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0014. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Investigational New Drug Application Requirements—21 CFR Part 312

OMB Control Number 0910–0014—Revision

This information collection supports implementation of provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) and of the licensing provisions of the Public Health Service Act (42 U.S.C. 201 *et seq.*) that govern investigational new drugs and investigational new drug applications (INDs). Implementing regulations are found in part 312 (21 CFR part 312), and provide for the issuance of guidance documents (see § 312.145 (21 CFR 312.145)) to assist persons in complying with the applicable requirements. The information collection applies to all clinical investigations subject to section 505 of the FD&C Act and include the following types of INDs:

- An Investigator IND is submitted by a physician who both initiates and investigates, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with § 312.23 or § 312.20 (21 CFR 312.23 or 312.20). It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and FDA's review takes place.

There are two IND categories: commercial and research (non-commercial).

General IND requirements include submitting an initial application as well as amendments to that application; submitting reports on significant revisions of clinical investigation plans; submitting information to the clinical trials data bank (*https://clinicaltrials.gov*) established by the National Institutes of Health/National Library of Medicine, including expanded information on certain clinical trials and information on the results of these clinical trials; and reporting information on a drug's safety or effectiveness. In addition, sponsors are required to provide to FDA an annual summary of the previous year's clinical experience. The regulations also include recordkeeping requirements regarding the disposition of drugs, records regarding individual case histories, and certain other documentation verifying clinical investigators' fulfillment of responsibilities.

Form FDA 1571 entitled ''Investigational New Drug Application (IND)'' and Form FDA 1572 entitled ''Statement of Investigator,'' were developed to assist respondents with the information collection and provide for uniform reporting of required data elements. The information is required to be submitted electronically. Individuals who are interested in receiving printed forms may send an email request to the FDA Forms Manager at *formsmanager@OC.FDA.GOV.* Fees may apply. Sponsors (including sponsor-investigators) interested in filing or updating a research IND may use a new web-based interface developed for use by mobile device or desktop to help in completing Form FDA 1571. The web-based interface also allows respondents to electronically submit completed Form FDA 1571 and associated files. Form FDA 1571 was recently updated to include the new tracking information for real world evidence and real-world data (RWE/RWD). The new RWE/RWD fields will capture submissions with RWE/RWD based on the requirements set forth in the PDUFA VII commitment letter and the resulting *Advancing Real World Evidence Program,* so that FDA can track and report on its performance related to these commitments. In addition, collection of this data will support the consistent integration of real-world evidence data into the regulatory review and approval process for new drugs and biologics. Other updates include the addition of fields necessary for ensuring compliance with enhancing security for human biospecimens. For more information regarding Forms FDA 1571 and 1572 visit *https://www.fda.gov/news-events/expanded-access/how-complete-form-fda-1571-and-form-fda-1572.* For information regarding updated FDA forms, including Forms FDA 1571 and 1572 visit *https://www.fda.gov/about-fda/forms/new-and-updated-fda-forms.*

Human drug, biological product, and device product submissions must be accompanied by Form FDA 3674, as discussed in the guidance document entitled ''Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions'' (updated November 2017), available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions.* The guidance document provides procedural instruction on completing and submitting required information to FDA. As communicated in the instructions, the certification must accompany the application or submission and be included at the time of submission to FDA.

Regulations in part 312, subpart B, specify content and format requirements for applications, amendments, annual reporting, and withdrawals, including content and format requirements for protocol and information amendments. The regulations also explain phases of an investigation and set forth principles of IND submissions. To date we have developed and issued the following guidance documents to assist respondents:

- ''*Establishment and Operation of Clinical Trial Data Monitoring Committees*'' guidance (March 2006); and
- ''*Special Protocol Assessment*'' guidance (April 2018).

All Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our

website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* that utilizes topic specific search terms.

Regulations in part 312, subpart C, describe administrative actions pertaining to respondents' requests for and responses to clinical holds, terminations, and inactive IND status determinations, as well as various types of meetings (for example, End-of-Phase 2 and Pre-new drug application (NDA) meetings).

Regulations in part 312, subpart D, set forth sponsor and investigator responsibilities, including general responsibilities; transfer of obligations to a contract research organization; recordkeeping and record retention controls; reporting responsibilities; and responsibility for disposition of unused supply of investigational drug. The regulations also provide for investigator controls including review of ongoing investigations; compliance with requirements regarding the protection of human subjects and institutional review board assurance; and disqualification of clinical investigators.

Regulations in part 312, subpart E, sets forth requirements applicable to drugs intended to treat life-threatening and severely debilitating illnesses. The regulations establish procedures to reflect that physicians and patients accept greater risk or side effects from products that treat life-threatening and severely debilitating illnesses than they would accept from products that treat less serious illnesses. The procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated.

Regulations in part 312, subpart F, include provisions pertaining to import and export requirements; foreign clinical studies not conducted under an IND; the disclosure of data and information in an IND; and the issuance of guidance documents. To date we have developed and issued the following guidance documents to assist respondents:

- ''*Oversight of Clinical Investigations*'' guidance (August 2013);
- ''*Pharmacogenomic Data Submissions*'' guidance (March 2005);
- ''*Adaptive Designs for Clinical Trials of Drugs and Biologics*'' guidance (December 2019); and
- ''*E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)*'' guidance (March 2018).

All Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* that utilizes topic specific search terms.

Regulations in part 312, subpart G, provide for drugs for investigational use in laboratory research animals or in vitro tests.

Finally, 21 CFR 300.200 requires the submission of an annual report by sponsors and manufacturers who provide an ''*eligible investigational drug*'' under the Right to Try Act. The regulation also establishes content and format elements and requires that information be submitted to FDA no later than March 31 of each year, including data for the preceding calendar year. Respondents use Form FDA 5023 entitled ''*Right to Try Reporting Requirement: Annual Summary,*'' currently available for download from our website at *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try-annual-reporting-summary.* As required by the applicable statute, section 561B of the FD&C Act (21 U.S.C. 360bbb-0a), the information is submitted to an FDA-designated point of contact, and in accordance with instructions to be posted at: *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try.*

In the **Federal Register** of March 13, 2026 (91 FR 12422) we published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received all offering general support for the information collection. Two comments pertained to FDA rulemaking (RIN 0910–AH07, Docket No. FDA–2019–N–2650) proposing to amend regulations on investigational new drug applications (INDs) to exempt from the IND requirements certain clinical investigations of lawfully marketed foods for human consumption (including both conventional foods and dietary supplements) and cosmetics when the product is to be studied to evaluate its use as a drug. While the comments fall beyond the scope of the information collection topics solicited in our 60-day notice in accordance with 5 CFR 1320.8(d)(1), we have added the comments to the respective rulemaking docket for Agency consideration.

A third comment suggested FDA increase its estimate for effort attributable to reporting elements under 21 CFR parts 312.23 and 312.33, explaining that certain first time applicants may incur more burden that our figures suggest. We acknowledge that individual respondents may incur greater than or less than the estimate proffered, however, consistent with 5 CFR 1320.5(a)(1)(iv), figures are cumulative and averaged among respondents. The comment also recommended specific automated improvements that might facilitate the submission of IND applications. As announced in the **Federal Register** of June 24, 2026 (91 FR 37996; Docket No. 2026–N–4699), FDA is inviting comment on a proposed IND pilot program. At the conclusion of the pilot, we intend to identify potential refinements to the IND review process targeting those we can address with our limited resources.

FDA greatly appreciates the comments it received, however we have made no changes to our estimates, which are as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions: §§ 312.1 through 312.10					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	454	1.528	694	24	16,656
§ 312.8; requests to charge for an investigational drug	14	1.64	23	48	1,104
§ 312.10; waiver requests	5	1	5	24	120
Subtotal Subpart A Center for Biologics Evaluation and Research (CBER)			722		17,880

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart B—Investigational New Drug Application (IND): §§ 312.20 through 312.38 (Including Forms FDA 1571, 1572, and 3674)					
§ 312.23(a) through (f); IND content and format	2,075	3.382	7,018	300	2,105,400
§ 312.30(a) through (e); protocol amendments	1,781	4.6692	8,316	284	2,361,744
§ 312.31(b); information amendments	169	2.48	419	100	41,900
§ 312.32(c) and (d); IND safety reports	224	10.59	2,372	32	75,904
§ 312.33(a) through (f); IND annual reports	971	2.2739	2,208	360	794,880
§ 312.38(b) and (c); notifications of withdrawal of an IND	712	3.057	2,177	28	60,956
Subtotal Subpart B CBER			22,510		5,440,784
Subpart C—Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modification	154	1.65	254	284	72,136
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	86	1.22	105	16	1,680
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	48	1.48	71	12	852
§ 312.47; meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	157	1.80	283	160	45,280
Subtotal Subpart C CBER			713		119,948
Subpart D—Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.53(c); investigator reports submitted to the sponsor, including Form FDA 1572, curriculum vitae, clinical protocol, and financial disclosure	1,068	5.23	5,586	80	446,880
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	4	4.25	17	48	816
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	1	1	1	48	48
§ 312.55(a); number of investigator brochures submitted by the sponsor to each investigator	473	2.224	1,052	48	50,496
§ 312.55(b); number of sponsor reports to investigators on new observations, especially adverse reactions and safe use	243	4.95	1,203	48	57,744
§ 312.56(b), (c), and (d); review of ongoing investigations and associated notifications; sponsor notifications	915	2.948	2,698	80	215,840
§ 312.58; inspection of records and reports by FDA	7	1	7	8	56
§ 312.64; number of investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	2,728	3.816	10,411	24	249,864
§ 312.70; disqualification of a clinical investigator by FDA	5	1	5	40	200
Subtotal Subpart D CBER			20,980		1,021,944
Subpart F—Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); number of written certifications and written statements submitted to FDA relating to the export of an investigational drug	18	1	18	75	1,350
§ 312.120(b); number of submissions to FDA of ''supporting information'' related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
§ 312.120(c); number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
§ 312.130; number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.342	470	8	3,760
Subtotal Subpart F CBER			3,254		93,494
Total			48,179		6,694,050

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.52(a); sponsor records for the transfer of obligations to a contract research organization.	94	2.26	212	2	424
§ 312.57; sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interest.	335	2.70	904	100	90,400
§ 312.62(a); investigator recordkeeping of the disposition of drugs.	453	1	453	40	18,120
§ 312.62(b); investigator recordkeeping of case histories of individuals.	453	1	453	40	18,120
Subtotal Subpart D CBER			2,022		127,064
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	111	1.40	155	0.5 (30 minutes)	78
§ 312.160(c) shipper records of alternative disposition of unused drugs.	111	1.40	155	0.5 (30 minutes)	78
Subtotal Subpart G CBER			310		156
Total			2,332		127,220

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	419	1	419	24	10,056
§ 312.8; requests to charge for an investigational drug	25	1.28	32	48	1,536
§ 312.10; requests to waive a requirement in part 312	68	1.5	102	24	2,448
Subtotal Subpart A Center for Drug Evaluation and Research (CDER)			553		14,040
Subpart B—Investigational New Drug Application (IND)					
§ 312.23(a) through (f); IND content and format (including Forms FDA 1571 and 3674)	4,886	1.4662	7,164	300	2,149,200
§ 312.30(a) through (e); protocol amendments	11,847	3.2367	38,346	284.25	10,899,850
§ 312.31(b); information amendments	8,094	3.30899	26,783	100	2,678,300
§ 312.32(c) and (d); IND safety reports	892	15.848	14,137	32	452,384
§ 312.33(a) through (f); IND annual reports	3,777	2.9097	10,990	360	3,956,400
§ 312.38(b) and (c); notifications of withdrawal of an IND	1,549	1.834	2,841	28	79,548
§ 312.145; Guidance Documents:					
Establishment and Operation of Clinical Trial Data Monitoring Committees (2006)	37	32.027	1,185	1.515	1,795
Special Protocol Assessment (2018)—Notification for Carcinogenicity Protocols	106	1.78	189	8	1,510
Requests for Special Protocol Assessment Reports	113	1.03	116	15	1,740
Subtotal Subpart B CDER			101,751		20,220,727
Subpart C—Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modifications	181	1.28	232	284	65,888
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	1	1	1	16	16
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	213	1.72	367	12	4,404
§ 312.47; meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	174	2.885	502	160	80,320

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subtotal Subpart C CDER			1,102		150,628
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	7	1.14	8	48	384
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	2	1	2	48	96
§ 312.56; review of ongoing investigations and associated notifications	4,570	5.4689	24,993	80	1,999,440
§ 312.58; inspection of records and reports by FDA	73	1	73	8	584
§ 312.70; disqualification of a clinical investigator by FDA.	5	1	5	40	200
Subtotal Subpart D CDER			25,081		2,000,704
Subpart F—Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); written certifications and written statements submitted to FDA relating to the export of an investigational drug	8	22.375	179	75	13,425
§ 312.120(b); submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	1,964	7.352	14,440	32	462,080
§ 312.120(c); waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	68	1.5	102	24	2,448
§ 312.130; requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
§ 312.145; Guidance Documents:					
Oversight of Clinical Investigations (2013)	88	1.5	132	4	528
Pharmacogenomic Data Submissions (2005)	1	1	1	50	50
Adaptive Designs for Clinical Trials of Drugs and Biologics (2019)	55	4.727	260	50	13,000
E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (2018)	1,880	4.916	9,242	15.012	138,744
Subtotal Subpart F CDER			24,359		630,299
§ 300.200; Right to try reporting requirements; submission of annual summary report using Form FDA 5023	10	1	10	2.5	25
Total			152,856		23,016,423

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.52(a); transfer of obligations to a contract research organization.	466	3.107	1,448	300	434,400
§ 312.57; records showing the receipt, shipment, or other disposition of the investigational drug and any financial interests.	13,000	1	13,000	100	1,300,000
§ 312.62(a); records on disposition of drugs	13,000	1	13,000	40	520,000
§ 312.62(b); records on case histories of individuals.	2,192	6.587	14,439	40	577,560
Subtotal Subpart D CDER			41,887		2,831,960

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	547	1.43	782	0.50 (30 minutes)	391
§ 312.160(c); shipper records of alternative disposition of unused drugs.	547	1.43	782	0.50 (30 minutes)	391
Subtotal			1,564		782
Total			43,451		2,832,742

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

While we have corrected an inadvertent calculation error pertaining to 21 CFR 300.200, we have otherwise retained the currently approved estimates attributable to IND requirements. We also note that reporting activities applicable to the ''Right to Try'' provisions began in 2020 and we continue to monitor the information collection activity.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16715 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–N–1560; FDA–2021–N–1351; FDA–2025–N–2549; FDA–2025–N–0426; FDA–2026–N–0746; FDA–2026–N–0497; FDA–2025–N–0953; FDA–2024–N–4467; FDA–2025–N–4942; FDA–2025–N–2195; FDA–2025–N–0354; FDA–2025–N–3215; FDA–2025–N–1108; FDA–2025–N–0419; FDA–2025–N–1210; FDA–2025–N–0414; FDA–2025–N–1115; FDA–2025–N–1109; FDA–2025–N–1330; FDA–2024–N–5943; FDA–2025–N–0351; FDA–2025–N–3656; FDA–2025–N–2220; FDA–2024–N–5890; FDA–2012–D–0429; FDA–2025–N–0348; FDA–2025–N–1812; FDA–2025–N–2548; FDA–2025–N–4348; FDA–2024–N–1055; FDA–2025–N–0615; FDA–2024–N–3762; FDA–2023–N–0894; FDA–2025–N–0308; FDA–2024–N–0668; FDA–2025–N–1732]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Electronic Products Requirements	0910–0025	5/31/2029
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910–0045	5/31/2029
Investigational Device Exemptions	0910–0078	5/31/2029
Agreement for Shipments of Devices for Sterilization	0910–0131	6/30/2029
Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including API), and AMT Designation	0910–0139	7/31/2029
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	7/31/2029
Export of Medical Devices; Foreign Letters of Approval	0910–0264	3/31/2029
Prescription Drug User Fee Program	0910–0297	1/31/2029
Mammography Standards Quality Act Requirements	0910–0309	5/31/2029
Medical Devices; Humanitarian Use Devices	0910–0332	6/30/2029
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	5/31/2029
Food Safety, Health, and Diet Survey	0910–0345	3/31/2029
510(k) Third-Party Review Program	0910–0375	6/30/2029
Medical Device Reporting	0910–0437	2/28/2029
Postmarket Surveillance of Medical Devices	0910–0449	6/30/2029

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control number	Date approval expires
Guidance for Reagents for Detection of Specific Novel Influenza A Viruses	0910–0584	6/30/2029
Authorization of Medical Products for Use Emergencies	0910–0595	5/31/2029
Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	0910–0607	6/30/2029
Electronic Submission of Medical Device Registration and Listing	0910–0625	4/30/2029
Tobacco Product Establishment Registration and Submission of Certain Health Information	0910–0650	4/30/2029
Tobacco Health Document Submission	0910–0654	4/30/2029
Current Good Manufacturing Practices for Positron Emission Tomography (PET) Drugs	0910–0667	6/30/2029
Testing Communications on Medical Devices and Radiation-Emitting Products	0910–0678	7/31/2029
Generic Drug User Fee Program	0910–0727	1/31/2029
Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products	0910–0731	4/30/2029
Center for Devices and Radiological Health Appeals Processes	0910–0738	6/30/2029
Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools	0910–0756	5/31/2029
Animal Food and Egg Regulatory Program Standards	0910–0760	5/31/2029
Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–0800	5/31/2029
Medical Device Accessories	0910–0823	3/31/2029
Data To Support Social and Behavioral Research as Used by the Food and Drug Administration	0910–0847	5/31/2029
Generic Clearance for Quick Turnaround Testing of Communication Effectiveness	0910–0876	4/30/2029
Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities	0910–0883	3/31/2029
The Real Cost Monthly Implementation Assessment	0910–0935	3/31/2029
Emerging Drug Safety Technology Program	0910–0936	5/31/2029
Small Dispensers Assessment Under the Drug Supply Chain Security Act	0910–0937	6/30/2029

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16716 Filed 8–14–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7757]

Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's third-party disclosure and recordkeeping requirements for reportable food.

DATES: Either electronic or written comments on the collection of information must be submitted by October 16, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–7757 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Christopher Colburn, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301796–8758, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Third Party Disclosure and Recordkeeping Requirements for Reportable Food—21 U.S.C. 350f

OMB Control Number 0910–0643—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), requires the establishment of a Reportable Food Registry (the Registry) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Section 417 of the FD&C Act (21 U.S.C. 350f) defines ''reportable food'' as an ''article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.'' (See section 417(a)(2) of the FD&C Act.) We believe that the most efficient and cost-effective means to implement the Registry is by utilizing our electronic Safety Reporting Portal. The information collection provisions associated with the submission of reportable food reports have been approved under OMB control number 0910–0291.

In conjunction with the reportable food requirements, section 417 of the FD&C Act also establishes third-party disclosure and recordkeeping burdens. Specifically, we may require the responsible party to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(6)(B)(i) to (ii) of the FD&C Act). Similarly, we may also require the responsible party that is notified (*i.e.,* the immediate previous source and/or immediate subsequent recipient) to notify their own immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(7)(C)(i) to (ii) of the FD&C Act).

Notification to the immediate previous source(s) and immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as email, fax, or text messaging or by telegrams, mailgrams, or first-class letters. Notification may also be accomplished by telephone call or other personal contacts, but we recommend that such notifications also be confirmed by one of the previous methods and/or documented in an appropriate manner. We may require that the notification include any or all of the following data elements: (1) the date on which the article of food was determined to be a reportable food; (2) a description of the article of food including the quantity or amount; (3) the extent and nature of the adulteration; (4) the results of any investigation of the cause of the adulteration if it may have originated with the responsible party, if known; (5) the disposition of the article of food, when known; (6) product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food; (7) contact information for the responsible party; (8) contact information for parties directly linked in the supply chain and notified under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act, as applicable; (9) the information required by FDA to be included in the notification provided by the responsible party involved under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act or required to report under section 417(d)(7)(A) of the FD&C Act; and (10) the unique number described in section 417(d)(4) of the FD&C Act (section 17(d)(6)(B)(iii)(I), (d)(7)(C)(iii)(I), and (e) of the FD&C Act). We may also require that the notification provides information about the actions that the recipient of the notification will perform and/or any other information we may require (section 417(d)(6)(B)(iii)(II) and (III) and (d)(7)(C)(iii)(II) and (III) of the FD&C Act).

Section 417(g) of the FD&C Act requires that responsible persons

maintain records related to reportable foods for a period of 2 years.

The congressionally identified purpose of the Registry is to provide a reliable mechanism to track patterns of adulteration in food which would support efforts by FDA to target limited inspection resources to protect the public health (see FDAAA, section 1005(a)(4)). The reporting and recordkeeping requirements described previously are designed to enable FDA to quickly identify and track an article of food (other than infant formula) for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals. We use the information collected under these authorities to help ensure that such products are quickly and efficiently removed from the market.

As required under section 1005(f) of FDAAA and to assist industry, we have issued the guidance entitled, ''Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007,'' which is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug.* The guidance contains questions and answers relating to the requirements under section 417 of the FD&C Act, including: (1) how, when and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 7.46 of FDA's regulations have been approved under OMB control number 0910–0249.

Description of Respondents: Mandatory respondents to this collection of information are owners, operators, or agents in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States (''responsible parties'') who have information on a reportable food. Voluntary respondents to this collection of information are Federal, State, and local public health officials who have information on a reportable food.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only).	1,200	1	1,200	0.6 (36 minutes)	720
Total	.....	.....	.....	.....	2,880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Third Party Disclosure: Although it is not mandatory under section 1005 of FDAAA that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden does not affect voluntary reporters of reportable food events.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—(mandatory reports).	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—(voluntary reports).	4	1	4	0.25 (15 minutes)	1
Total [2]	.....	.....	.....	.....	301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] For purposes of estimating number of records and hours per record, a ''record'' means all records kept for an individual reportable food by the responsible party or a voluntary reporter.

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications for a period of 2 years. However, we do not expect that records will always be kept in relation to voluntary reportable food reports.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16714 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Request; 30-Day Public Comment Request; Submission for Office of Management and Budget Review; Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities

AGENCY: Office of the National Coordinator for Health IT, Office of the Secretary, HHS.

ACTION: Request for public comments.

SUMMARY: The Office of the National Coordinator for Health IT (ONC), Office of the Secretary (OS), Department of Health and Human Services, is seeking a three-year generic clearance to collect routine customer feedback on agency service delivery and program performance related to TEFCA.

DATES: Comments on the ICR must be received on or before September 16, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is, ''Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities''.

FOR FURTHER INFORMATION CONTACT: Talisha Searcy, *talisha.searcy@hhs.gov,* or call (240) 276–0642.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Generic Clearance for the Trusted Exchange Framework and Common Agreement (TEFCA) Monitoring Activities.

Type of Collection: New Generic Collection.

Abstract: The Office of the National Coordinator for Health Information Technology (ONC) is seeking a three-year generic approval to collect routine customer feedback on agency service delivery related to TEFCA. ONC oversees a TEFCA Recognized Coordinating Entity® (RCE®) to administer aspects of TEFCA. The RCE is responsible for developing, implementing, and maintaining the Common Agreement that establishes the baseline technical and legal requirements for health information networks to share electronic health information. The data collections under this clearance will be designed to standardize monitoring and performance reports for TEFCA participants. With the number of TEFCA participants on the rise, ONC is seeking approval to collect this information from TEFCA users to enhance the efficiency of program management. In the **Federal Register** of May 11, 2026 (0990-New-60D), we published a 60-day notice requesting public comment on the proposed collection of information. We did not receive any comments in response to this notice. Thus, there were no modifications made to the content or burden hours estimated for this information collection.

Need and Proposed Use of the Information: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions and is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into TEFCA users and stakeholder perceptions, experiences, and expectations; provide an early warning of issues with the service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communication between ONC and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. If this information is not collected, vital feedback from TEFCA users and stakeholders on the ONC services will be unavailable.

Likely respondents to the data collections under this generic clearance will be the Qualified Health Information Networks® (QHINs™), which are health information networks approved to access and exchange data through TEFCA. Over each of the next three years, an estimated 15 respondents are expected to participate, with approximately 7 qualitative feedback activities occurring annually and an average of 71 responses per respondent. The frequency of response will vary by activity, with each response taking an average of 80 minutes. This results in a total estimated burden of 1,420 hours annually, or 4,260 hours over a three-year period.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
QHIN	QHIN Application	15	1	3	45
QHIN	QHIN Monthly Report	15	12	2	360

ESTIMATED ANNUALIZED BURDEN HOUR TABLE—Continued

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
QHIN	QHIN Quarterly Report	15	4	2	120
QHIN	QHIN Attestation	15	1	1	15
QHIN	TEFCA Directory Submission (weekly).	15	1040	0.033	520
QHIN	Program Evaluation or Usability Testing.	15	4	4	240
QHIN	Other	15	4	2	120
Total					1,420

Authority: 44 U.S.C. 3501 *et seq.*

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2026–16766 Filed 8–14–26; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Data Use Certification for the NIH National Institute on Drug Abuse Data Share Site

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the information collection requirement for the NIDA Data Share, the data use terms and conditions, and to request a progress report statement at the time of renewal. In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Ming Zhan, Director, Office of Data Science and Coordination, National Institute on Drug Abuse, 3WFN Room 09D14, 11601 Landsdown St, Rockville MD 20852, or call non-toll-free number (301) 480–3506 or email your request, including your address to: *ming.zhan@nih.gov.*

Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Data Use Certification for the NIDA Data Share, OMB#0925–NEW, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this proposal is to inform data requestors about terms and conditions for using data stored in the NIDA Data Share System, and to obtain signed agreements from requestors and their institutional officials attesting to their commitment to abide by the data use terms and conditions. These include using data for research purposes; adhering to human subjects research requirements; not distributing the data to non-authorized users; minimizing risk of participant identifiability; using data ethically and responsibly; and keeping the data secure. Recipients must include a brief description of their research project and submit their signed data use agreements to the data repository to gain access to Data Share data.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 127.

Estimated Annualized Burden Hours

ANNUAL BURDEN HOURS ESTIMATE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Data Request	100	1	1	100
Data Request Renewal Annual Progress Report	40	1	30/60	20
Data Request Renewal	40	1	10/60	7
Total	180	180		127

Dated: August 12, 2026.

Thomas Clarke,

Project Clearance Liaison, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. 2026–16683 Filed 8–14–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: 30-Day Comment Request; Specimen Resource Locator (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received by September 16, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Melissa Park, PRA Liaison, Office of Management Policy and Compliance, National Cancer Institute, 9609 Medical Center Drive, Room 2E196, Bethesda, MD 20892 or call non-toll-free number (240) 276–5717 or email your request, including your address to: *vivian.horovitchkelley@nih.gov.*

Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on June 12, 2026 (Vol. 91, No. 113, FR 35694) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: Specimen Resource Locator (NCI), 0925–0703: Expiration Date 08/31/2026, EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: Department of Health and Human Services (DHHS), National Institutes of Health (NIH), and National Cancer Institute (NCI) seek to obtain OMB approval to extend the Specimen Resource Locator (SRL) collection for an additional three (3) years. The availability of specimens and associated data is critical to increase our knowledge of cancer biology and to translate important research discoveries into clinical applications. The discovery and validation of cancer prevention markers require access, by researchers, to quality clinical biospecimens. In response to this need, the National Cancer Institute's (NCI) Cancer Diagnosis Program has developed and is expanding a searchable database: Specimen Resource Locator (SRL). The SRL allows scientists in the research community and the NCI to locate specimens needed for their research. The SRL lists non-commercial, either NCI or non-NCI-supported human biorepositories and their links. This administrative submission is an online form that collects information to manage and improve a program and its resources for the use of all scientists. This submission does not involve any hypothesis-driven analysis or research; only descriptive program-management metrics are used.

OMB approval is requested for three years. There are no costs to respondents other than their time. The estimated annualized burden hours are 107.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hour
Private Sector	Initial Request (Attachment 2)	70	1	5/60	6
State Government		70	1	5/60	6
Federal Government		60	1	5/60	5
Private Sector	Enter Resource (Attachment 3)	30	1	7/60	4
State Government		30	1	7/60	4
Federal Government		20	1	7/60	2
Private Sector	Enter Collection (Attachment 4)	30	3	18/60	27
State Government		30	3	18/60	27
Federal Government		20	3	18/60	18
Private Sector	Annual Update (Attachment 5)	30	1	5/60	3
State Government		30	1	5/60	3
Federal Government		20	1	5/60	2
Total			600		107

Dated: August 13, 2026.

Vivian Horovitch-Kelley,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2026–16761 Filed 8–14–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0191; Docket ID: BOEM–2026–0926]

Agency Information Collection Activities; Negotiated Noncompetitive Agreements for the Use of Outer Continental Shelf Sand, Gravel, and/or Shell Resources

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Ocean Energy Management (BOEM) proposes this information collection request (ICR) to renew Office of Management and Budget (OMB) control number 1010–0191.

DATES: Comments must be received by BOEM no later than October 16, 2026.

ADDRESSES: Send written comments on this ICR by mail to the BOEM Information Collection Clearance Officer, Anna Atkinson, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166; or by email to *anna.atkinson@boem.gov.* Please reference OMB control number 1010–0191 in the subject line of your comments. You may comment on the ICR and view related documents by searching for the docket number ''BOEM–2026–0926'' at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Atkinson by email at *anna.atkinson@boem.gov,* or by telephone at 703–787–1025. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside of the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, BOEM provides the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps BOEM assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BOEM's information collection requirements and provide the requested data in the desired format.

BOEM is soliciting comments on the proposed ICR described below. BOEM is especially interested in public comments addressing the following issues: (1) is the collection necessary to the proper functions of BOEM; (2) what can BOEM do to ensure that this information is processed and used in a timely manner; (3) is the burden estimate accurate; (4) how might BOEM enhance the quality, utility, and clarity of the information to be collected; and (5) how might BOEM minimize the burden of this collection on the respondents, including minimizing the burden through the use of information technology?

Comments that you submit in response to this notice are a matter of public record. BOEM will include or summarize each comment in its ICR to OMB for approval of this information collection. You should be aware that your entire comment—including your address, phone number, email address, or other personally identifiable information included in your comment—may be made publicly available at any time.

Even if BOEM withholds your personally identifiable information in the context of this ICR, your comment is subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552). Your information will only be withheld if a determination is made that one of the FOIA exemptions to disclosure applies. Such a determination will be made in accordance with the Department of the Interior's (DOI) FOIA implementing regulations (43 CFR part 2) and applicable law.

In order for BOEM to consider withholding from disclosure your personally identifiable information, you must identify, in a cover letter, any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. Note that BOEM will make available for public inspection, in their entirety, all comments submitted by organizations and businesses, or by individuals identifying themselves as representatives of organizations or businesses.

BOEM protects proprietary information in accordance with FOIA, DOI's implementing regulations (43 CFR part 2), and the Outer Continental Shelf Lands Act (OCS Lands Act) (43 U.S.C. 1331 *et seq.*).

Title of Collection: 30 CFR part 583, ''Negotiated Noncompetitive Agreements for the Use of Outer Continental Shelf Sand, Gravel, and/or Shell Resources.''

Abstract: This ICR concerns the paperwork requirements in the regulations at 30 CFR part 583, which address the use of OCS sand, gravel, and shell resources for shore protection, beach restoration, or coastal wetlands restoration projects by Federal, State, or local government agencies, or for use in construction projects authorized by or funded in whole or in part by the Federal Government.

The OCS Lands Act, 43 U.S.C. 1331 *et seq.,* authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of mineral resources on the OCS. Section 1337(k)(2) of title 43 authorizes the Secretary to ''. . . negotiate with any person an agreement for the use of Outer Continental Shelf sand, gravel and shell resources—(i) for use in a program of, or project for, shore protection, beach restoration, or coastal wetlands restoration undertaken by a Federal, State, or local government agency; or (ii) for use in a construction project . . . that is funded in whole or in part by or authorized by the Federal Government.'' The Secretary delegated this authority to BOEM.

OMB Control Number: 1010–0191.

Form Number: None.

Type of Review: Extension of a currently approved information collection.

Respondents/Affected Public: Potential respondents include Federal, State, or local governments.

Total Estimated Number of Annual Responses: 35 responses.

Total Estimated Number of Annual Burden Hours: 282 hours.

Respondent's Obligation: Required to retain or obtain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Non-hour Burden Cost: None.

Estimated Reporting and Recordkeeping Hour Burden: BOEM estimates that the annual reporting burden for this collection is 282 hours. BOEM has reviewed the hour burdens for requested information under this subpart. The following table details the regulatory sections containing information collections and their respective hour burden estimates.

BURDEN TABLE

Citation 30 CFR 583 subpart A	Reporting and recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
Subpart A—General—Federal, State, & local governments				
125	Apply for reconsideration to the BOEM Director within 15 days of notification; include statement of reasons; 1 copy to program office.	4	1	4
Total Subpart A			1	4

Citation 30 CFR 583 Subpart C	Reporting and recordkeeping requirement	Hour burden	Average number of annual responses	Annual burden hours
Subpart C—OCS Sand, Gravel, & Shell Resources Negotiated Agreements—State & local governments				
300	Submit to BOEM a written request to obtain agreement; including, but not limited to: detailed description of project; borrow area(s) and placement area(s); maps (geographic coordinates); G&G data; description/documentation of environmental evaluations; target dates; description of parties involved; status of required permits, licenses, or authorizations; description of potential conflicts with CZMA plans and other applicable requirements; points of contact info. of all parties involved; statement of funding.	20	6	120
305; 310(d)	Submit additional information as requested by BOEM	5	6	30
315(b);	Request BOEM Director reconsideration of a disapproved agreement.	Burden covered under 30 CFR 583 Subpart A		0
315(c)–(e)	Review, comment, and negotiate draft agreement; sign and return copies for execution by BOEM.	16	6	96
335(a)	Submit written notification to BOEM once resources authorized are obtained.	2	6	12
340	Verify that all contractors comply with 2 CFR 180 & 2 CFR 1400 in contract/transaction..	2	6	12
345	Submit written request to extend, modify, or change agreement to BOEM at least 180 days before expiration; any necessary information and evaluation documentation requested by BOEM; sign and return amendment; request BOEM Director reconsideration.	2	2	4
345(b)	Submit written request for letter amendment	2	2	4
Total Subpart C			34	278
Overall Total			35	282

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Karen Thundiyil,

Director, Office of Regulatory Affairs, Bureau of Ocean Energy Management.

[FR Doc. 2026–16684 Filed 8–14–26; 8:45 am]

BILLING CODE 4340–98–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2026–0232; EEEE500000 256E1700D2 ET1SF0000.EAQ000; OMB Control Number 1014–0018]

Agency Information Collection Activities; Oil and Gas Drilling Operations

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 16, 2026.

ADDRESSES: Send your comments on this information collection request (ICR) by either of the following methods listed below:

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2026–0232 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *Kelly.Odom@bsee.gov* or mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch;

ATTN: Kelly Odom; 45600 Woodland Road, Sterling, VA 20166. Please reference OMB Control Number 1014–0018 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Kelly Odom by email at *Kelly.Odom@bsee.gov* or by telephone at (703) 787–1775. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct, or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BSEE uses the information to ensure safe drilling operations and to protect the human, marine, and coastal environment. Among other things, BSEE specifically uses the information to ensure: the drilling unit is fit for the intended purpose; the lessee or operator will not encounter geologic conditions that present a hazard to operations; equipment is maintained in a state of readiness and meets safety standards; each drilling crew is properly trained and able to promptly perform well-control activities at any time during well operations; compliance with safety standards; and the current regulations will provide for safe and proper field or reservoir development, resource evaluation, conservation, protection of correlative rights, safety, and environmental protection. We also review well records to ascertain whether drilling operations have encountered hydrocarbons or H2S and to ensure that H2S detection equipment, personnel protective equipment, and training of the crew are adequate for safe operations in zones known to contain H2S and zones where the presence of H2S is unknown.

This ICR includes three forms. The forms use and information consist of the following:

End of Operations Report, BSEE–0125

This information is used to ensure that industry has accurate and up-to-date data and information on wells and leasehold activities under their jurisdiction and to ensure compliance with approved plans and any conditions placed upon a suspension or temporary probation. It is also used to evaluate the remedial action in the event of well equipment failure or well control loss. The Form BSEE–0125 is updated and resubmitted in the event the well status changes. In addition, except for proprietary data, BSEE is required by the OCS Lands Act to make available to the public certain information submitted on BSEE–0125.

Information on the form:

Heading—ascertain the well name, status of completion/abandonment, and operator name.

Well at Total Depth—ascertain the lease No., area name, block No., and the latitude/longitude at total depth.

Well Status Information—ascertain well status data and measured/true vertical depth of the well.

Well at Producing Zone—ascertain the location and latitude/longitude of the producing zone.

Perforated Interval(s) This Completion—ascertain well measured/true vertical depth at the top and bottom of intervals perforated for production.

Hydrocarbon Bearing Intervals—identify the top and bottom of hydrocarbon bearing intervals penetrated by the well and the type hydrocarbon (oil/gas) present.

List of Significant Markers Penetrated—to make structural correlations, in conjunction with seismic data, with other wells drilled in the area. Anticipated marker areas not penetrated (*i.e.,* not present) also provide valuable reservoir information.

Subsea Completion—Identify wells that are completed with the wellhead (tree) at the ocean floor (mud line). This data is needed to ascertain that the wellhead is protected from being damaged and that the location is marked with a buoy.

Abandonment History of Well (Casing & Obstruction)—ensure that, upon permanent plugging, the casing is cut and removed to an elevation below the ocean floor (mud line) to eliminate any hazard to navigation (fishing, trawling) unless otherwise protected and/or the location marked with a buoy.

Well Activity Report, BSEE–0133 and 0133S

The BSEE uses this information to monitor the conditions of a well and status of drilling operations. We review the information to be aware of the well conditions and current drilling activity (*i.e.,* well depth, drilling fluid weight, casing types and setting depths, completed well logs, and recent safety equipment tests and drills). The engineer uses this information to determine how accurately the lessee anticipated well conditions and if the lessee or operator is following the other approved forms that were submitted. With the information collected on BSEE–0133 available, the reviewers can analyze the proposed revisions (*e.g.,* revised grade of casing or deeper casing setting depth) and make a quick and informed decision on the request.

In addition, except for proprietary data, BSEE is required by the OCS Lands Act to make available to the public certain information submitted on Forms BSEE–0133 and –0133S.

BSEE–0133

General Information—Identifies the well name, lease operator, name of the contractor and rig or unit conducting drilling or remedial work, the water depth and the elevation.

Current Well Bore Information—This information is used to identify the well, surface location, and dates operations are initiated and concluded. Also identified is the bottom hole location, measured and true vertical depth of the well, drilling fluid (mud) weight, and blowout preventer test information needed to evaluate approval or modification applications to ensure safety and environmental protection.

Well Bore Historical Information—Identifies the dates drilling is initiated and completed or the well is abandoned, and final measured and true vertical depths reached. This information is needed to evaluate modification applications to ensure safety and protection of the environment.

Casing/Liner/Tubing Record—Identifies casing/liner/tubing hole size, pipe size, weight, grade, test pressures, setting depths, and cement volumes. This information is used to evaluate modification applications and to ascertain that operations are conducted in a safe manner as approved.

Well Activity Summary—This narrative summary provides the details of daily operations needed to confirm that operations are being conducted consistent with approved plans.

Open Hole Log Date—Serves to identify whether open hole logs, formation samples and surveys have been conducted so as to trigger the submittal of Form BSEE–0133S.

Significant Well Events—Serves to identify significant events, hazards or problems encountered during well operations and to provide narrative information detailing those events which occurred. BSEE needs this information in the assessment and approval of other well operations in the area that may encounter the same or similar hazards, risks or problems. Provides narrative information concerning any significant events. Attachments may be required, if necessary.

BSEE–0133S

General Information—Identifies the well number/name, operator name, sidetrack/bypass number, and contact name/telephone/email.

Open Hole Tools, Mud Logs, and Directional Surveys—Identifies the dates and types of open hole operations, logs, tests, or surveys conducted; the service company(s) conducting the operations; and the top and bottom of those formations logged or surveyed. Serves as an inventory to ensure that BSEE receives the data from all open hole logs/tests/surveys conducted. Open hole data is utilized in the determination of oil and gas recoverable reserves and production limits. As permitted by the regulations, the data is also made available to the public.

Identify Other Open Hole Data Collection—Identifies the conduct of other specific analyses, samples and surveys and requires the narrative description of any other surveys conducted.

Title of Collection: 30 CFR 250, Subpart D, Oil and Gas Drilling Operations.

OMB Control Number: 1014–0018.

Form Number: Forms BSEE–0125, *End of Operations Report,* BSEE–0133, *Well Activity Report,* and BSEE–0133S *Supplemental.*

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Potential respondents include Federal OCS oil, gas, and sulfur lessees and/or operators and holders of pipeline rights-of-way.

Total Estimated Number of Annual Respondents: Currently there are approximately 555 Federal OCS oil, gas, and sulfur lessees and holders of pipeline rights-of-way. Not all the potential respondents will submit information in any given year, and some may submit multiple times.

Total Estimated Number of Annual Responses: 63,744.

Estimated Completion Time per Response: Varies from 15 minutes to 23 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 83,993.

Respondent's Obligation: Responses are mandatory.

Frequency of Collection: Submissions are generally on occasion, daily, weekly, monthly, quarterly, annually, and varies by section.

Total Estimated Annual Nonhour Burden Cost: $16,000.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Kirk Malstrom,

Chief, Regulations and Standards Branch.

[FR Doc. 2026–16751 Filed 8–14–26; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Dynamic Random Access Memory (DRAM) Devices, Products Containing the Same, and Components Thereof (III), DN 3930;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Netlist, Inc. on August 11, 2026. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after

importation of certain dynamic random access memory (dram) devices, products containing the same, and components thereof (III). The complaint names as a respondent: Micron Technology, Inc. of Boise, ID; Micron Semiconductor Products, Inc. of Allen, TX; Hewlett Packard Enterprise Co. of Spring, TX; Lenovo Group Ltd. of China; Lenovo (United States) Inc. of Morrisville, NC; and Super Micro Computer, Inc. of San Jose, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, members of the public, and interested government agencies are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3930'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings unless an exemption is granted. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: August 13, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–16763 Filed 8–14–26; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

[OMB Number 1121–0381]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Juvenile Facility Census Program (JFCP)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The National Institute of Justice, Office of Justice Programs, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until September 16, 2026.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Benjamin Adams, Supervisory Social Science Analyst, National Institute of Justice, 999 North Capitol Street NE, Washington DC 20531 (email: *benjamin.adams@usdoj.gov;* telephone: 202–598–6493).

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on June 8, 2026, 91 FR 34656, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your

comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number [1121–0381]. This information collection request may be viewed at *www.reginfo.gov.* Please send a copy of submitted public comments to Benjamin Adams, email: *Benjamin.adams@usdoj.gov;* telephone: (202) 598–6493. Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for two (2) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Revision to currently approved collection.

2. *Title of the Form/Collection:* Juvenile Facility Census Program (JFCP).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form numbers are CJ–14 (Youth Characteristics Module) and CJ–15 (Facility Operations Module). The applicable components within the Department of Justice are the National Institute of Justice and the Office of Juvenile Justice and Delinquency Prevention, in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* State, local and tribal governments, individuals or households, and Private Sector-for or not for profit institutions.

Abstract: This request for clearance enables the National Institute of Justice, in collaboration with the Office of Juvenile Justice and Delinquency Prevention, to administer the 2027 Juvenile Facility Census Program (JFCP). The JFCP collects information from all secure and nonsecure residential placement facilities that house persons younger than age 21 who are being held as a result of some contact with the juvenile justice system for a law violation. This encompasses both status offenses and delinquency offenses and includes youth who are either temporarily detained by the court or committed after adjudication for an offense. The JFCP collects general information on facility characteristics and the number of youth housed, and includes two rotating content modules that are administered separately during a two-year collection cycle: the Youth Population module and the Facility Operations module. The Youth Population module collects detailed information on individual youth housed in facilities, including demographic details, placement characteristics, and length of stay. The Facility Operations module collects information on resident services, facility features, and operations. The information gathered in these national collections will be used in published reports and statistics. The reports will be made available to the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, others interested in juvenile residential facilities, and the general public via the OJP agency websites. The two data collections are being consolidated the attain cost savings and reduce respondent burden.

5. *Obligation to Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* The total estimated respondents is 1,636 for each module for each year or 6,544 for two survey administrations

7. *Estimated Time per Respondent:* It takes an average of 6 hours to complete the JFCP. The total burden for two survey administrations is 19,632, including the two rotating content modules that are administered separately during a 2-year collection cycle. The Youth Population module takes an average of 4 hours to complete. The total burden for the Youth Population module is 6,544 hours each survey administration. The Facility Operations module takes an average of 2 hours to complete. The total burden for the Facility Operations module is 3,272 hours each survey administration.

8. *Frequency:* The JFCP is a biennial data collection with two content modules administered separately during a two-year collection cycle.

9. *Total Estimated Annual Time Burden:* The average annual burden is 4,908 or 9,816 total hours for the two-year collection cycle.

10. *Total Estimated Annual Other Costs Burden:* The estimated annual cost for JFCP is $1,142,115. The estimated cost for two collection cycles is $4,568,460.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Enterprise Portfolio Management, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: August 12, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–16685 Filed 8–14–26; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1123–1NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection: Title—Requests for DOJ Certification Letters for T Visa Holders

AGENCY: Human Rights and Special Prosecutions Section, Criminal Division, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Criminal Division, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until September 16, 2026.

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request, please contact Ayn B. Ducao, Senior

Counsel, Human Rights and Special Prosecutions Section, Criminal Division, 1301 New York Ave. NW, Suite 1200, Washington, DC 20530, *T-visa.System@usdoj.gov* or (202) 616–2492.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on June 16, 2026, 91 FR 36156, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB #1123–1NEW. This information collection request may be viewed at *www.reginfo.gov.* Please submit a copy of public comments to Ayn B. Ducao, Senior Counsel, Human Rights and Special Prosecutions Section, Criminal Division, 1301 New York Ave. NW, Suite 1200, Washington, DC 20530, *T-visa.System@usdoj.gov* or (202) 616–2492.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* New collection.

2. *Title of the Form/Collection:* Requests for DOJ Certification Letters for T Visa Holders.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* 1123–1NEW.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected Public: Primary: Individuals or households.

Abstract: Eligible non-citizen victims of human trafficking victims are entitled to petition the U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS), for temporary non-immigrant ''T visas'' pursuant to 8 U.S.C. 1101(a)(15)(T). T visas allow qualifying human trafficking victims to legally remain in the U.S. for up to 4 years if they comply with reasonable law enforcement requests for assistance. 8 U.S.C. 1101(a)(15)(T). Minors and those too traumatized to assist are exempt from assisting law enforcement. 8 U.S.C. 1101(a)(15)(T)(i)(III).

Qualifying T visa holders can petition DHS to adjust to Lawful Permanent Resident status if they meet statutory requirements under 8 U.S.C. 1255(l). To apply for an adjustment of status, a T visa holder must have remained continuously present in the U.S. for at least 3 years, or until completion of the investigation or prosecution, whichever is shorter. § 1255(l); 8 CFR 245.23(a). To apply for early adjustment of status within 3 years of receiving the T visa, the T visa holder must establish that the ''Attorney General has determined that the investigation or prosecution is complete.'' 8 U.S.C. 1255(l)(A). To establish their eligibility for early adjustment with USCIS, applicants with less than 3 years of continuous physical presence as T visa holders ''must submit a document signed by the Attorney General or their designee, attesting that the investigation or prosecution is complete.'' 8 CFR 245.23(e)(2)(i)(B).

5. *Obligation to Respond:* To apply for early adjustment of status within 3 years of receiving the T visa, the T visa holder must establish that the ''Attorney General has determined that the investigation or prosecution is complete.'' 8 U.S.C. 1255(l)(A). To establish their eligibility for early adjustment with USCIS, applicants with less than 3 years of continuous physical presence as T visa holders ''must submit a document signed by the Attorney General or their designee, attesting that the investigation or prosecution is complete.'' 8 CFR 245.23(e)(2)(i)(B) (emphasis added).

6. *Total Estimated Number of Respondents:* An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: DHS reported that between 2021 and 2025, DHS approved over 9,000 T visa applications. Some portion of these approved applicants have applied or will apply for DOJ Certification letters.

7. *Estimated Time per Respondent:* Will vary depending on the documentation available to the applicant but estimated time for applicant to compile application would be on average three hours.

8. *Frequency:* Constant.

9. *Total Estimated Annual Time Burden:* Burden Hours: Assuming 2,000 applications from respondents annually with an average time per respondent of 3 hours, then the annual time burden is 6,000 hours (2,000 × 3 hours).

10. *Total Estimated Annual Other Costs Burden:*

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Enterprise Portfolio Management, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: August 13, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–16747 Filed 8–14–26; 8:45 am]

BILLING CODE 4410–14–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 24–CRB–0006–CD (2023)]

Distribution of 2023 Cable Royalty Funds

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Notice requesting comments.

SUMMARY: The Copyright Royalty Judges solicit comments on a motion of Allocation Phase Parties for partial distribution of 2023 cable royalty funds.

DATES: Comments are due on or before September 16, 2026.

ADDRESSES: Interested claimants must submit timely comments using eCRB, the Copyright Royalty Board's online

electronic filing application, at *https://app.crb.gov/.*

Instructions: All submissions must include a reference to the CRB and docket number 24–CRB–0006–CD (2023). All submissions will be posted without change to eCRB at *https://app.crb.gov/,* including any personal information provided.

Docket: For access to the docket to read submitted background documents or comments, go to eCRB, the Copyright Royalty Board's online electronic filing and case management system, at *https://app.crb.gov/* and search for docket number 24–CRB–0006–CD (2023).

FOR FURTHER INFORMATION CONTACT: Anita Brown, CRB Program Specialist, at (202) 707–7658, or *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Each year cable systems must submit royalty payments to the Register of Copyrights as required by the statutory license detailed in section 111 of the Copyright Act for the retransmission to cable subscribers of over-the air television and radio broadcast signals. *See* 17 U.S.C. 111(d). The Copyright Royalty Judges (Judges) oversee distribution of royalties to copyright owners whose works were included in a qualifying transmission and who file a timely claim for royalties.

Allocation of the royalties collected occurs in one of two ways. In the first instance, the Judges may authorize distribution in accordance with a negotiated agreement among all claiming parties. 17 U.S.C. 111(d)(4)(A), 801(b)(3)(A). If all claimants do not reach agreement with respect to the royalties, the Judges must conduct a proceeding to determine the distribution of any royalties that remain in controversy. 17 U.S.C. 111(d)(4)(B), 801(b)(3)(B). Alternatively, the Judges may, on motion of claimants and on notice to all interested parties, authorize a partial distribution of royalties, reserving on deposit sufficient funds to resolve identified disputes. 17 U.S.C. 111(d)(4)(C), 801(b)(3)(C). On August 5, 2026, representatives of the Allocation Phase Parties claimant categories [1] filed with the Judges a motion pursuant to section 801(b)(3)(C) of the Copyright Act requesting a partial distribution of 40% of the 2023 cable royalty funds on deposit. That statutory section requires that, before ruling on the motion, the Judges publish a notice in the **Federal Register** seeking responses to the motion for partial distribution to ascertain whether any claimant entitled to receive the subject royalties has a reasonable objection to the requested distribution. 17 U.S.C. 801(b)(3)(C).

Accordingly, this notice seeks comments from interested claimants on whether any reasonable objection exists that would preclude the distribution of the requested amounts of the 2023 cable royalty funds to the Allocation Phase Parties. Parties objecting to the proposed partial distribution must advise the Judges of the existence and extent of all objections by the end of the comment period. The Judges will not consider any objections with respect to the partial distribution that come to their attention after the close of the comment period.

Members of the public may read the motion by accessing the Copyright Royalty Board's electronic filing and case management system at *https://app.crb.gov* and searching for docket number 24–CRB–0006–CD (2023).

Dated: August 12, 2026.

Trevor Jefferson,

Chief Copyright Royalty Judge.

[FR Doc. 2026–16707 Filed 8–14–26; 8:45 am]

BILLING CODE 1410–72–P

[1] For the purpose of distribution of cable royalty funds, the Allocation Phase Parties are Program Suppliers, Joints Sports Claimants, Public Television Claimants, Commercial Television Claimants, Devotional Claimants, Canadian Claimants Group, National Public Radio, and the Music Claimants, who are comprised of the American Society of Composers, Authors and Publishers, SESAC Performing Rights, LLC, and Broadcast Music, Inc. The Judges have not determined, and do not by this notice determine, the universe of claimant categories for 2023 cable retransmission royalties.

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 24–CRB–0007–SD (2023)]

Distribution of Satellite Royalty Funds

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Notice requesting comments.

SUMMARY: The Copyright Royalty Judges solicit comments on a motion of Allocation Phase Parties for partial distribution of 2023 satellite royalty funds.

DATES: Comments are due on or before September 16, 2026.

ADDRESSES: Interested claimants must submit timely comments using eCRB, the Copyright Royalty Board's online electronic filing application, at *https://app.crb.gov/.*

Instructions: All submissions must include a reference to the CRB and docket number 24–CRB–0007–SD (2023). All submissions will be posted without change to eCRB at *https://app.crb.gov/* including any personal information provided.

Docket: For access to the docket to read submitted background documents or comments, go to eCRB, the Copyright Royalty Board's online electronic filing and case management system, at *https://app.crb.gov/* and search for docket number 24–CRB–0007–SD (2023).

FOR FURTHER INFORMATION CONTACT: Anita Brown, CRB Program Specialist, at (202) 707–7658, or *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: Each year satellite providers must submit royalty payments to the Register of Copyrights as required by the statutory license detailed in section 119 of the Copyright Act for the retransmission to satellite subscribers of over-the-air television broadcast signals. *See* 17 U.S.C. 119(b). The Copyright Royalty Judges (Judges) oversee distribution of royalties to copyright owners whose works were included in a qualifying transmission and who timely filed a claim for Royalties. Allocation of the royalties collected occurs in one of two ways. In the first instance, the Judges may authorize distribution in accordance with a negotiated agreement among all claiming parties. 17 U.S.C. 119(b)(5)(A), 801(b)(3)(A). If all claimants do not reach an agreement with respect to the royalties, the Judges must conduct a proceeding to determine the distribution of any royalties that remain in controversy. 17 U.S.C. 119(b)(5)(B), 801(b)(3)(B). Alternatively, the Judges may, on motion of claimants and on notice to all interested parties, authorize a partial distribution of royalties, reserving on deposit sufficient funds to resolve identified disputes. 17 U.S.C. 119(b)(5)(C), 801(b)(3)(C).

On August 5, 2026, representatives of the Allocation Phase Parties claimant categories [1] filed with the Judges a motion pursuant to section 801(b)(3)(C) of the Copyright Act requesting a partial distribution of 40% of the 2023 satellite royalty funds on deposit. That statutory section requires that, before ruling on the motion, the Judges publish a notice in the **Federal Register** seeking responses to the motion for partial distribution to ascertain whether any claimant entitled to receive the subject royalties has a reasonable objection to the requested distribution. 17 U.S.C. 801(b)(3)(C).

Accordingly, this notice seeks comments from interested claimants on

[1] For the purpose of distribution of satellite royalty funds, the Allocation Phase Parties are Program Suppliers, Joint Sports Claimants, Commercial Television Claimants, Devotional Claimants, and the Music Claimants, who are comprised of the American Society of Composers, Authors and Publishers, SESAC Performing Rights, LLC, and Broadcast Music, Inc. The Judges have not determined, and do not by this notice determine, the universe of claimant categories for 2023 satellite retransmission royalties.

whether any reasonable objection exists that would preclude the distribution of the requested amounts of the 2023 satellite royalty funds to the Allocation Phase Parties. Parties objecting to the proposed partial distribution must advise the Judges of the existence and extent of all objections by the end of the comment period. The Judges will not consider any objections with respect to the partial distribution that come to their attention after the close of the comment period.

Members of the public may read the motion by accessing the Copyright Royalty Board's electronic filing and case management system at *https://app.crb.gov* and searching for docket number 24–CRB–0007–SD (2023).

Dated: August 12, 2026.

Trevor Jefferson,

Chief Copyright Royalty Judge.

[FR Doc. 2026–16710 Filed 8–14–26; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 24–CRB–0007–SD (2023)]

Distribution of Satellite Royalty Funds

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Notice announcing commencement of distribution proceedings with request for Petitions to Participate.

SUMMARY: The Copyright Royalty Judges (Judges) announce the commencement of proceedings to determine distribution of 2023 royalties deposited with the Copyright Office under the satellite carrier license. The Judges also set the date by which all parties wishing to participate and share in the distribution of satellite retransmission royalties for 2023, must file Petitions to Participate and pay the accompanying $150 filing fee. The Judges seek a single Petition to Participate in either or both the allocation phase and the distribution phase of the satellite royalty proceeding. Any party that fails to file a petition to participate by the time set forth in this notice shall not be a participant at any stage of either proceeding, unless the Judges accept a late petition to participate pursuant to 37 CFR 351.1(d).

DATES: Petitions to Participate, the filing fee, and the additional required filing are due on or before September 16, 2026.

ADDRESSES: The petition to participate form is available online in eCRB, the Copyright Royalty Board's online electronic filing application, at *https://app.crb.gov/.*

Instructions: The petition to participate process has been simplified. Interested parties file a petition to participate by completing and filing the petition to participate form in eCRB and paying the fee in eCRB. Do not upload a petition to participate document. Additional required information regarding claims shall be filed in eCRB separately from the form and no later than the deadline for filing the petition to participate.

Docket: For access to the docket, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at *https://app.crb.gov/,* and search for Docket No. 24–CRB–0007–SD (2023).

FOR FURTHER INFORMATION CONTACT: Anita Brown, CRB Program Specialist, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Twice each year, satellite carriers deposit with the Copyright Office royalties payable for the privilege of retransmitting over-the-air television and radio broadcast signals via satellite. 17 U.S.C. 119. The Copyright Royalty Judges (Judges) oversee distribution of the royalties to copyright owners whose works are included in the retransmissions and who have filed a timely claim for royalties. Pursuant to 17 U.S.C. 803(b)(1), the Judges hereby give notice of the commencement of proceedings for distribution of satellite royalties deposited for broadcasts retransmitted in 2023 and call for interested parties to file Petitions to Participate.

Any party wishing to receive royalties payable for 2023 must file a Petition to Participate in each proceeding no later than September 16, 2026. If an interested party fails to file a Petition to Participate in response to this notice, that party will not be eligible for distribution of royalties for 2023 from the satellite fund, unless the Judges accept a late petition to participate pursuant to 37 CFR 351.1(d). The Judges will resolve all issues relating to distribution of satellite royalty funds for 2023, including existing motions regarding such funds, in this proceedings, Docket No. 24–CRB–0007–SD (2023). *See* 37 CFR 351.1(b)(2).

Commencement of Distribution Proceedings

The Judges have determined that controversies exist with regard to distribution of the satellite retransmission royalties that licensees deposited for 2023. Therefore, pursuant to Section 804(b)(8) of the Copyright Act, the Judges are causing this notice to be published in the **Federal Register** to announce the commencement of satellite distribution proceedings for 2023.

The Judges base their conclusion regarding 2023 satellite fund controversies upon the entirety of the records, including the initial motion for partial distribution. Motion of the Allocation Phase Parties for Partial Distribution of 2023 Satellite Royalty Funds (''Motion'') (eCRB no. 79335).

In the present proceeding, groups of claimants have identified themselves as arranged into program categories, *e.g.:* Program Suppliers, Joint Sports Claimants, Commercial Television Claimants, Devotional Claimants, and the Music Claimants, who are comprised of the American Society of Composers, Authors and Publishers, SESAC Performing Rights, LLC, and Broadcast Music, Inc. The Judges recognize that other claimants might not be represented by joint counsel for the groups of claimants. The Judges, therefore, provide this public notice to alert anyone who claims an interest in satellite retransmission royalties deposited for royalty year 2023.

In order to share in the royalties at issue, any claimant not joined in one of the groups identified above must file a Petition to Participate, individually or jointly with other claimants. If, at a later point in the proceedings, a claimant chooses to join a group participating through joint counsel, that claimant may withdraw its individual Petition to Participate. The prerequisites to participation in a distribution proceeding are (1) the filing (individually or jointly) of a timely and otherwise valid claim for each royalty year at issue and (2) the filing (individually or jointly) of a timely and otherwise valid Petition to Participate.

Only attorneys who are members in good standing of the bar of one or more states may represent parties before the Judges. All corporate parties must appear through counsel. Only if the petitioning party is an individual, may he or she represent himself or herself without legal counsel. 37 CFR 303.2.

The Judges hereby commence the proceedings for 2023 satellite funds under the captioned docket number 24–CRB–0007–SD (2023).

Petitions To Participate

Parties filing Petitions to Participate must comply with the requirements of section 351.1(b) of the Copyright Royalty Board's regulations.

In addition, each Petition to Participate filing must be accompanied by a filing that sets forth for each claim year, the name of each claimant, the corresponding claim number, an indication of whether the claim is an individual or joint claim, and the program category into which the claim may fall. Each Petition to Participate shall be accompanied by a Microsoft Excel spreadsheet in electronic form consisting of the following columns: Claimant; Claim Year; Claim Number; Claim Type; Allocation Phase Category. For ''Claim Type,'' participants shall enter ''I'' for an individual claimant, ''J'' for a joint claimant, and ''W'' for a claimant listed within a joint claim. The information in the column for ''Claim Category'' shall be coded 1 for syndicated programming and movies, 2 for live college and professional team sports, 3 for programs produced by local commercial television stations, 4 for public broadcasting, 5 for programs of a religious or devotional character, 6 for Canadian programs retransmitted within the United States, 7 for National Public Radio (all non-music content broadcast on NPR stations), and 8 for musical works carried on broadcast television signals. Claimants' characterization of their claims at this juncture is for ease of administration only and is not dispositive of the ultimate disposition of any claim.

Petitioners who seek to categorize any claim in a category not listed in the previous paragraph shall assign a number (starting with 9) to each new category and shall include a brief description of each new proposed category. Claimants, or claimant representatives, that assert multiple claims in a given claim year shall list each claim and claim number in a separate row. Petitioners are responsible to make a sufficient showing of a ''significant interest'' in the royalty funds at issue to avoid dismissal of the Petition to Participate.

Claimants whose claims do not exceed $1,000 in value and who include a statement in their Petitions to Participate that they will not seek distribution of more than $1,000 may file the Petition to Participate without payment of the filing fee.

Participants should conform filed electronic documents to the Judges' Guidelines for Electronic Documents, available online at *https://www.crb.gov/docs/Guidelines_for_Electronic_Documents.pdf.*

Dated: August 12, 2026.

Trevor Jefferson,

Chief Copyright Royalty Judge.

[FR Doc. 2026–16709 Filed 8–14–26; 8:45 am]

BILLING CODE 1410–72–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. 24–CRB–0006–CD (2023)]

Distribution of Cable Royalty Funds

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Notice announcing commencement of distribution proceedings with request for Petitions to Participate.

SUMMARY: The Copyright Royalty Judges (Judges) announce the commencement of proceedings to determine distribution of 2023 royalties deposited with the Copyright Office under the cable service statutory license. The Judges also set the date by which all parties wishing to participate and share in the distribution of cable retransmission royalties for 2023 must file Petitions to Participate and pay the accompanying $150 filing fee. The Judges seek a single Petition to Participate in either or both the allocation phase and distribution phase of the cable royalty proceeding. Any party that fails to file a petition to participate by the time set forth in this notice shall not be a participant at any stage of the proceeding, unless the Judges accept a late petition to participate pursuant to 37 CFR 351.1(d).

DATES: Petitions to Participate, the filing fee, and the additional required filing are due on or before September 16, 2026.

ADDRESSES: The petition to participate form is available online in eCRB, the Copyright Royalty Board's online electronic filing application, at *https://app.crb.gov/.*

Instructions: The petition to participate process has been simplified. Interested parties file a petition to participate by completing and filing the petition to participate form in eCRB and paying the fee in eCRB. Do not upload a petition to participate document. Additional required information regarding claims shall be filed in eCRB separately from the form and no later than the deadline for filing the petition to participate.

Docket: For access to the docket, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at *https://app.crb.gov/,* and search for Docket Nos. 24–CRB–0006–CD (2023).

FOR FURTHER INFORMATION CONTACT: Anita Brown, CRB Program Specialist, (202) 707–7658, *crb@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Twice each year, cable services deposit with the Copyright Office royalties payable for the privilege of retransmitting over-the-air television and radio broadcast signals via cable. 17 U.S.C. 111. The Copyright Royalty Judges (Judges) oversee distribution of the royalties to copyright owners whose works are included in the retransmissions and who have filed a timely claim for royalties. Pursuant to 17 U.S.C. 803(b)(1), the Judges hereby give notice of the commencement of the proceeding for the distribution of cable royalties deposited for broadcasts retransmitted in 2023 and call for interested parties to file Petitions to Participate.

Any party wishing to receive royalties payable for 2023 must file a Petition to Participate in each proceeding no later than September 16, 2026. If an interested party fails to file a Petition to Participate in response to this notice, that party will not be eligible for distribution of royalties for 2023 from the cable fund, unless the Judges accept a late petition to participate pursuant to 37 CFR 351.1(d). The Judges will resolve all issues relating to distribution of cable royalty funds for 2023, including existing motions regarding such funds, in these proceedings, Docket No. 24–CRB–0006–CD (2023). *See* 37 CFR 351.1(b)(2).

Commencement of Distribution Proceedings

The Judges have determined that controversies exist with regard to distribution of the cable retransmission royalties that licensees deposited for 2023. Therefore, pursuant to Section 804(b)(8) of the Copyright Act, the Judges are causing this notice to be published in the **Federal Register** to announce the commencement of the cable distribution proceeding for 2023.

The Judges base their conclusion regarding 2023 cable fund controversies upon the entirety of the record, including the initial motion for partial distribution. Motion of the Allocation Phase Parties for Partial Distribution of 2023 Cable Royalty Funds (''Motion'') (eCRB no. 79333).

In the present proceedings, groups of claimants have identified themselves as arranged into program categories, *e.g.,* Program Suppliers, Joints Sports Claimants, Public Television Claimants, Commercial Television Claimants, Devotional Claimants, Canadian

Claimants Group, National Public Radio, and the Music Claimants, who are comprised of the American Society of Composers, Authors and Publishers, SESAC Performing Rights, LLC, and Broadcast Music, Inc. The Judges recognize that other claimants might not be represented by joint counsel for the groups of claimants. The Judges, therefore, provide this public notice to alert anyone who claims an interest in cable retransmission royalties deposited for royalty year 2023.

In order to share in the royalties at issue, any claimant not joined in one of the groups identified above must file a Petition to Participate, individually or jointly with other claimants. If, at a later point in the proceedings, a claimant chooses to join a group participating through joint counsel, that claimant may withdraw its individual Petition to Participate. The prerequisites to participation in a distribution proceeding are (1) the filing (individually or jointly) of a timely and otherwise valid claim for each royalty year at issue and (2) the filing (individually or jointly) of a timely and otherwise valid Petition to Participate.

Only attorneys who are members in good standing of the bar of one or more states may represent parties before the Judges. All corporate parties must appear through counsel. Only if the petitioning party is an individual, may he or she represent himself or herself without legal counsel. 37 CFR 303.2.

The Judges hereby commence the proceedings for the 2023 cable funds under the captioned docket number 24–CRB–0006–CD (2023).

Petitions To Participate

Parties filing Petitions to Participate must comply with the requirements of section 351.1(b) of the Copyright Royalty Board's regulations.

In addition, each Petition to Participate filing must be accompanied by a filing that sets forth for each claim year, the name of each claimant, the corresponding claim number, an indication of whether the claim is an individual or joint claim, and the program category into which the claim may fall. Each Petition to Participate shall be accompanied by a Microsoft Excel spreadsheet in electronic form consisting of the following columns: Claimant; Claim Year; Claim Number; Claim Type; Allocation Phase Category. For ''Claim Type,'' participants shall enter ''I'' for an individual claimant, ''J'' for a joint claimant, and ''W'' for a claimant listed within a joint claim. The information in the column for ''Claim Category'' shall be coded 1 for syndicated programming and movies, 2 for live college and professional team sports, 3 for programs produced by local commercial television stations, 4 for public broadcasting, 5 for programs of a religious or devotional character, 6 for Canadian programs retransmitted within the United States, 7 for National Public Radio (all non-music content broadcast on NPR stations), and 8 for musical works carried on broadcast television signals. Claimants' characterization of their claims at this juncture is for ease of administration only and is not dispositive of the ultimate disposition of any claim.

Petitioners who seek to categorize any claim in a category not listed in the previous paragraph shall assign a number (starting with 9) to each new category and shall include a brief description of each new proposed category. Claimants, or claimant representatives, that assert multiple claims in a given claim year shall list each claim and claim number in a separate row. Petitioners are responsible to make a sufficient showing of a ''significant interest'' in the royalty funds at issue to avoid dismissal of the Petition to Participate.

Claimants whose claims do not exceed $1,000 in value and who include a statement in their Petitions to Participate that they will not seek distribution of more than $1,000 may file the Petition to Participate without payment of the filing fee.

Participants should conform filed electronic documents to the Judges' Guidelines for Electronic Documents, available online at *https://www.crb.gov/docs/Guidelines_for_Electronic_Documents.pdf*.

Dated: August 12, 2026.

Trevor Jefferson,

Chief Copyright Royalty Judge.

[FR Doc. 2026–16708 Filed 8–14–26; 8:45 am]

BILLING CODE 1410–72–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2026–344 and K2026–338; MC2026–345 and K2026–339]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
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I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

None. *See* Section III for summary proceedings.

III. Summary Proceeding(s)

1. *Docket No(s).:* MC2026–344 and K2026–338; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1067 and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 12, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

2. *Docket No(s).:* MC2026–345 and K2026–339; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1068, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 12, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,

Legal Assistant.

[FR Doc. 2026–16734 Filed 8–14–26; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36298; File No. 812–16041]

Parvin Decentralized Fund and Parvin Fund Management, LLC

August 13, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end investment companies to issue multiple classes of shares, to impose early withdrawal charges, and to impose asset-based distribution and/or service fees.

APPLICANTS: Parvin Decentralized Fund and Parvin Fund Management, LLC

FILING DATE: The application was filed on June 8, 2026 and amended on July 13, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time on September 7, 2026, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: J. Steven Smith, Parvin Fund Management, LLC, 401 E 8th Street, Suite 200, Sioux Falls, South Dakota 57103, *ssmith@parvinam.com,;* with copies to: Joel D. Corriero, Esq., Stradley Ronon Stevens & Young, LLP, 2005 Market Street, Suite 2600, Philadelphia, PA 19103, *JCorriero@stradley.com.*

FOR FURTHER INFORMATION CONTACT: Rachel Loko, Senior Special Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' amended and restated application, dated July 13, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, *https://www.sec.gov/search-filings.*

You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16768 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106100; File No. SR–ISE–2026–34]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Order Approving a Proposed Rule Change To Amend the Short Term Option Series Program Related to Qualifying Securities

August 12, 2026.

I. Introduction

On June 15, 2026, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the Exchange's Short Term Option Series Program to (1) permit the listing of up to two Tuesday and Thursday expirations for options on Exchange-Traded Fund Shares[3] that meet the existing ''Qualifying Securities'' criteria in Supplementary Material .03 to Options 4, Section 5; and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Options 4, Section 3(h) (defining ''Exchange-Traded Fund Shares'').

(2) permit the listing of up to two Monday and Wednesday expirations for options on Exchange-Traded Fund Shares that meet new ''Qualifying Securities'' criteria. The proposed rule change was published for comment in the **Federal Register** on July 2, 2026.[4] This order approves the proposed rule change.

II. Description of the Proposal

Currently, the Exchange's Short Term Option Series Program [5] permits the listing of up to two Monday and Wednesday expirations beyond the current week for options on certain individual stocks or Exchange-Traded Fund Shares (collectively, ''Qualifying Securities'').[6] To be eligible to be a Qualifying Security, an individual stock or Exchange-Traded Fund Share must meet the following criteria on a quarterly basis: (1) an underlying security, as measured on the last day of the prior calendar quarter, must have: (A) a market capitalization of greater than $700 billion for an individual stock based on the closing price,[7] or (B) assets under management (''AUM'') greater than $50 billion for an Exchange-Traded Fund Share based on net asset value (''NAV''); (2) monthly options volume, as measured by sides traded in the last month preceding the quarter end, of greater than 10 million options; (3) a position limit of at least 250,000 contracts; and (4) participate in the Penny Interval Program [8] (collectively, ''Qualifying Securities Criteria'').[9]

Each calendar quarter, the Exchange applies the Qualifying Securities Criteria to individual stocks and Exchange-Traded Fund Shares to determine eligibility for the following quarter.[10] The Exchange makes the list of Qualifying Securities available by the close of business on the first trading day of the quarter.[11]

The Exchange may list two Short Term Option Daily Expirations for Qualifying Securities beyond the current week for each Monday and Wednesday expiration at one time.[12] The Exchange does not list an expiry on a day when there will be an earnings announcement that takes place after market close.[13] Qualifying Securities that do not continue to meet the Qualifying Securities Criteria are no longer permitted to be listed as Monday and Wednesday expirations beginning on the second day of the following quarter.[14]

The Exchange proposes to amend rules related to Qualifying Securities expirations to: (1) add the listing of up to two Tuesday and Thursday expirations for options on Exchange-Traded Fund Shares that meet the current Qualifying Securities Criteria; [15] and (2) amend the Qualifying Securities Criteria to permit the listing of up to two Monday and Wednesday expirations for options on Exchange-Traded Fund Shares that meet new criteria.[16]

Tier 1 Qualifying Securities

The Exchange proposes to designate Exchange-Traded Fund Shares that meet the current Qualifying Securities Criteria as ''Tier 1 Qualifying Securities.'' Each calendar quarter, as it currently does for Qualifying Securities, the Exchange would apply the Qualifying Securities Criteria to Exchange-Traded Fund Shares to determine their eligibility for the following quarter as Tier 1 Qualifying Securities.[17] As noted above, the Exchange currently may list Monday and Wednesday Qualifying Securities Expirations on such Exchange-Traded Fund Shares. The Exchange proposes to list Tuesday and Thursday expirations in Tier 1 Qualifying Securities (''Tuesday and Thursday Tier 1 Qualifying Securities Expirations''), in addition to the existing Monday and Wednesday Qualifying Securities expirations.

The Exchange states that the proposed Tuesday Qualifying Securities expirations on Exchange-Traded Fund Shares for Tier 1 Qualifying Securities (''Tuesday Tier 1 Qualifying Securities Expirations'') would be similar to the current Tuesday expirations in SPDR S&P 500 ETF Trust (''SPY''), Invesco QQQ Trust (''QQQ''), and iShares Russell 2000 ETF (''IWM'') in Short Term Option Daily Expirations [18] because the Exchange may open for trading on any Monday or Tuesday that is a business day (beyond the current week) series of options on Qualifying Securities that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[19] In the event a Tuesday Tier 1 Qualifying Securities Expirations series expires on a Tuesday that is the same day that a standard expiration options series, Monthly Options Series, or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks therefore would not be consecutive.[20]

The Exchange also states that the proposed Thursday Qualifying Securities expirations on Exchange-Traded Fund Shares for Tier 1 Qualifying Securities (''Thursday Tier 1 Qualifying Securities Expirations'') would be similar to the current Thursday expirations in SPY, QQQ, and IWM in Short Term Option Daily Expirations [21] because the Exchange may open for trading on any Wednesday or Thursday that is a business day (beyond the current week) series of options on Qualifying Securities that expire at the close of business on each of the next two Thursdays that are

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[4] *See* Securities Exchange Act Release No. 105801 (June 29, 2026), 91 FR 40603 (''Notice''). Comments on the proposed rule change are available at: *https://www.sec.gov/rules-regulations/public-comments/sr-ise-2026-34.*

[5] *See* Supplementary Material .03 to Options 4, Section 5. Under the Exchange's Short Term Option Series Program, the Exchange may open for trading series of options on certain symbols that expire at the close of business of each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration series, Monthly Option Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations'').

[6] *See* Securities Exchange Act Release No. 104624 (January 16, 2026), 91 FR 2806 (January 22, 2026) (SR–ISE–2025–15) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Amend the Short Term Option Series Program to List Qualifying Securities); Supplementary Material .03 to Options 4, Section 5.

[7] The Exchange states that the closing price and the opening price shall be that of the primary exchange where the security is listed. *See* Notice, *supra* note 4, 91 FR at 40604, n.5.

[8] *See* Supplementary Material .01 to Options 3, Section 3.

[9] The Exchange has noted the expirations in Table 2 of Supplementary Material .03 to Options 4, Section 5, along with the Qualifying Securities Criteria.

[10] *See* Notice, *supra* note 4, 91 FR at 40604.

[11] *See id.* at 40605.

[12] *See id.* at 40604.

[13] *See id.* at 40605, n.8.

[14] *See id.* at 40605.

[15] The Exchange also proposes to designate such Exchange-Traded Fund Shares as ''Tier 1 Qualifying Securities.''

[16] The Exchange also proposes to designate such Exchange-Traded Fund Shares as ''Tier 2 Qualifying Securities.''

[17] *See* Notice, *supra* note 4, 91 FR at 40604, 40606. Therefore, in order to qualify as a Tier 1 Qualifying Security, an Exchange-Traded Fund Share must meet the following criteria on a quarterly basis: (1) an underlying security, as measured on the last day of the prior calendar quarter, must have AUM greater than $50 billion based on NAV; (2) monthly options volume, as measured by sides traded in the last month preceding the quarter end, of greater than 10 million options; (3) a position limit of at least 250,000 contracts; and (4) participate in the Penny Interval Program. *See* Supplementary Material .03 to Options 4, Section 5.

[18] *See supra* note 5.

[19] *See* Notice, *supra* note 4, 91 FR at 40605.

[20] Today, Tuesday expirations in SPY, QQQ, and IWM similarly skip the weekly listing in the event the weekly listing expires on the same day in the same class as a standard expiration options series, Monthly Options Series, or Quarterly Options Series. *See id.* at 40605.

[21] *See supra* note 5.

business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[22] In the event a Thursday Tier 1 Qualifying Securities Expirations series expires on a Thursday that is the same day that a standard expiration options series, Monthly Options Series, or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks therefore would not be consecutive.[23]

The Exchange states that the interval between strike prices for the proposed Tuesday and Thursday Tier 1 Qualifying Securities Expirations would be the same as those currently applicable to the Short Term Option Series Program.[24] As is the case with other equity options series listed pursuant to the Short Term Option Series Program, Tuesday and Thursday Tier 1 Qualifying Securities Expirations series would be P.M.-settled.[25]

Tier 2 Qualifying Securities

The Exchange also proposes to expand the Short Term Option Series Program to permit the listing of up to two Monday and Wednesday expirations for options on Exchange-Traded Fund Shares that meet proposed new criteria as Qualifying Securities (''Monday and Wednesday Tier 2 Qualifying Securities Expirations'').[26] The Exchange proposes to amend the Qualifying Securities Criteria in Supplementary Material .03 to Options 4, Section 5 to include separate criteria for the proposed Tier 2 Qualifying Securities. For eligibility as a Tier 2 Qualifying Security, an underlying Exchange-Traded Fund Share would be required to have (1) AUM greater than $25 billion based on NAV, as measured on the last day of the prior calendar quarter; [27] (2) monthly options volume, as measured by sides traded in the last month preceding the quarter end, of greater than 5 million options; [28] (3) a position limit of at least 250,000 contracts; and (4) participate in the Penny Interval Program (''Tier 2 Qualifying Securities Criteria'').[29]

Each calendar quarter, the Exchange would apply the proposed criteria to Exchange-Traded Fund Shares to determine eligibility for the following quarter as Tier 2 Qualifying Securities.[30] Beginning on the second trading day in the first month of each calendar quarter, the AUM for Tier 2 Qualifying Securities shall be calculated based on the NAV established on the primary exchange on the last trading day of the prior calendar quarter.[31] The data establishing the volume thresholds would be established by using data from the last month of the prior calendar quarter from The Options Clearing Corporation (''OCC'').[32] For options listed on the first trading day of a given calendar quarter, the volume shall be calculated using the last month of the quarter prior to that calendar quarter.[33] The Exchange would make the list of Qualifying Securities, including the Tier 2 Qualifying Securities, available by the close of business on the first trading day of the quarter.[34]

For the proposed Tier 2 Qualifying Securities, the Exchange would be permitted to list two Short Term Option Daily Expirations beyond the current week for each Monday and Wednesday Tier 2 Qualifying Securities Expiration at one time.[35] Tier 2 Qualifying Securities that do not continue to meet the Tier 2 Qualifying Securities Criteria would no longer be permitted to list Monday and Wednesday Tier 2 Qualifying Securities Expirations beginning on the second day of the following quarter.[36]

The Exchange states that the proposed Monday Tier 2 Qualifying Securities Expirations would be similar to the Monday expirations for existing Qualifying Securities (including the Tier 1 Qualifying Securities), among other symbols that may list a Monday expiration in Short Term Option Daily Expirations [37] because the Exchange may open for trading on any Friday or Monday that is a business day (beyond the current week) series of options on Tier 2 Qualifying Securities to expire on any Monday of the month that is a business day and is not a Monday in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[38]

The Exchange states that the proposed Wednesday Tier 2 Qualifying Securities Expirations would also be similar to the current Wednesday expirations for existing Qualifying Securities (among other symbols that may list a Wednesday expiration) in Short Term Option Daily Expirations [39] because the Exchange may open for trading on any Tuesday or Wednesday that is a business day (beyond the current week) series of options on Tier 2 Qualifying Securities to expire on any Wednesday of the month that is a business day and is not a Wednesday in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[40]

In the event a Monday or Wednesday Tier 2 Qualifying Securities Expirations series expires on the same day that a standard expiration options series, Monthly Options Series, or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks therefore would not be consecutive.[41]

The Exchange states that the interval between strike prices for the proposed Monday and Wednesday Tier 2 Qualifying Securities Expirations would be the same as those currently applicable to Monday and Wednesday expirations in existing Qualifying Securities (among other symbols that

[22] *See* Notice, *supra* note 4, 91 FR at 40605.

[23] Today, Thursday expirations in SPY, QQQ, and IWM similarly skip the weekly listing in the event the weekly listing expires on the same day in the same class as a standard expiration options series, Monthly Options Series, or Quarterly Options Series. *See id.*

[24] *See id.* at 40605–06. Specifically, the Tuesday and Thursday Tier 1 Qualifying Securities Expirations will have a strike interval of (i) $0.50 or greater for strike prices below $100, and $1 or greater for strike prices between $100 and $150 for all option classes that participate in the Short Term Option Series Program, (ii) $0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program, or (iii) $2.50 or greater for strike prices above $150. *See* Supplementary Material .03(e) to Options 4, Section 5.

[25] *See* Notice, *supra* note 4, 91 FR at 40606.

[26] *See id.*

[27] Currently, Exchange-Traded Fund Shares that are Qualifying Securities must have an AUM greater than $50 billion based on NAV. *See* Supplementary Material .03 to Options 4, Section 5.

[28] Currently, Exchange-Traded Fund Shares that are Qualifying Securities must have a monthly options volume, as measured by sides traded in the last month preceding the quarter end, of greater than 10 million options. *See* Supplementary Material .03 to Options 4, Section 5.

[29] *See* Notice, *supra* note 4, 91 FR at 40606.

[30] *See id.*

[31] *See id.*

[32] *See id.*

[33] The Exchange states that OCC data becomes available for the end of a quarter on the first trading day of a new quarter. *See id.* at 40606, n.24.

[34] *See id.* at 40406–07. The Exchange will continue to make this information available on its website. *See id.* at 40607, n.25.

[35] *See id.* at 40607. The Exchange has noted the additional expirations in Table 2 of Supplementary Material .03 to Options 4, Section 5 along with the proposed criteria for the proposed Tier 2 Qualifying Securities.

[36] *See id.*

[37] *See supra* note 5.

[38] Monday expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration. Pursuant to Options 1, Section 1(a)(50), with respect to the Short Term Option Series Program, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.

[39] *See supra* note 5.

[40] *See* Notice, *supra* note 4, 91 FR at 40607.

[41] *See id.* Pursuant to Options 1, Section 1(a)(50), with respect to the Short Term Option Series Program, a Wednesday expiration series shall expire on the first business day immediately prior to that Wednesday (*e.g.,* Tuesday of that week if the Wednesday is not a business day).

may list a Monday or Wednesday expiration) in the Short Term Option Series Program.[42] As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Monday and Wednesday Tier 2 Qualifying Securities Expirations series would be P.M.-settled.[43]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[44] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[45] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission received one supportive comment letter on the proposal.[46] The commenter states that the current short term option daily expirations on exchange-traded funds are highly liquid products, and they do not cause market disruption and may be used to hedge narrowly defined risks.[47] The commenter observes that these short-term option products are the subject of substantial retail interest, with significant trading volume on the day of expiration.[48] The commenter expects that the proposed new expirations would ''yield the same results'' as the proposal would permit additional expirations for only the most liquid exchange-traded funds and would provide investors with expanded and more effective hedging tools.[49]

In support of its proposal, the Exchange states that it does not believe that any market disruptions would be encountered with the introduction of Tuesday and Thursday Tier 1 Qualifying Securities Expirations and Monday and Wednesday Tier 2 Qualifying Securities Expirations.[50] The Exchange states that it currently trades P.M.-settled Short Term Option Series that expire Monday, Tuesday, Wednesday and Thursday on several symbols[51] and has not experienced any market disruptions or issues with capacity.[52] In addition, the Exchange states that it has surveillance programs in place to detect manipulative trading in the proposed option expirations, in the same way that it monitors trading in the current Short Term Option Series Expirations.[53] The Exchange states it has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Tier 1 Qualifying Securities Expirations and the proposed Monday and Wednesday Tier 2 Qualifying Securities Expirations.[54]

The Exchange's proposal, which is limited to Exchange-Traded Fund Shares that meet either the existing Qualifying Securities Criteria or the new Tier 2 Qualifying Securities Criteria, is reasonably designed as a limited expansion of the Short Term Options Series Program. The proposal would add a small overall number of weekly expirations because the Exchange will limit the number of Tuesday and Thursday Tier 1 Qualifying Securities Expirations to two Tuesday expirations and two Thursday expirations beyond the current week and the number of Monday and Wednesday Tier 2 Qualifying Securities Expirations to two Monday and two Wednesday expirations beyond the current week.[55] Furthermore, the Qualifying Securities Criteria (including the Tier 2 Qualifying Securities Criteria) will limit the number of eligible Qualifying Securities, and the associated Qualifying Securities Expirations, so that any potential impact on the options market will accordingly be limited. However, the Commission expects the Exchange to monitor the trading of the options listed as a result of the proposal to evaluate whether any issues develop.

The existing Qualifying Securities Criteria applicable to Exchange-Traded Fund Shares—which require (1) an AUM greater than $50 billion based on NAV; (2) monthly options volume greater than 10 million options; (3) a position limit of at least 250,000 contracts; and (4) participation in the Penny Interval Program—should help to ensure that Tier 1 Qualifying Securities, as well as the options on such securities, are highly liquid and actively traded.[56]

Further, as discussed above, the Tier 2 Qualifying Securities Criteria require Exchange-Traded Fund Shares to have (1) AUM greater than $25 billion based on NAV; (2) monthly options volume, as measured by sides traded in the last month preceding the quarter end, greater than 5 million options; (3) a position limit of at least 250,000 contracts; and (4) participate in the Penny Interval Program.[57] Although the Tier 2 Qualifying Securities Criteria would have lower AUM and monthly options volume eligibility requirements than the existing Qualifying Securities Criteria, they would include the same 250,000-contract position limit and Penny Interval Program participation requirements. Therefore, the proposed criteria would help to ensure that Tier 2 Qualifying Securities, as well as the options on such securities, are highly liquid and actively traded.[58]

If the Exchange chooses to modify the Qualifying Securities Criteria, the proposed Tier 2 Qualifying Securities Criteria, or any other aspect of the proposal, it will be required to file a proposed rule change with the Commission, which will subject the proposed rule change to the notice and comment process.

Based on the foregoing, the Commission believes the proposal reasonably balances the Exchange's desire to accommodate investor demand by offering a wider array of investment opportunities with the need to avoid unnecessary proliferation of options series. Additionally, and as noted above, this limited expansion of Qualifying Securities expirations may provide the investing public and other market participants more flexibility to closely

[42] *See id.;* Supplementary Material .03(e) to Options 4, Section 5.

[43] *See* Notice, *supra* note 4, 91 FR at 40607.

[44] 15 U.S.C. 78s.

[45] 15 U.S.C. 78s(b)(5).

[46] *See* letter from Caitlin Farrell-Starbuck, Global Head of Compliance, Susquehanna International Group, LLP, dated July 22, 2026, *supra* note 4.

[47] *See id.* at 1.

[48] *See id.*

[49] *See id.*

[50] *See* Notice, *supra* note 4, at 40606, 40608.

[51] *See id.* at 40606, 40608; *see also id.* at 40604, n.4 (''[t]he Exchange currently permits expirations in SPY, IWM, QQQ on Mondays, Tuesdays, Wednesdays and Thursdays. Also, the Exchange permits expirations in GLD, SLV and TLT on Mondays and Wednesdays. Finally, the Exchange permits expirations in USO and UNG on Wednesdays.'').

[52] *See id.* at 40606, 40608.

[53] *See id.* at 40621.

[54] *See id.* at 40606, 40608.

[55] *See id.* at 40615. The Exchange analyzed Exchange-Traded Fund Shares that would have qualified as either Tier 1 Qualifying Securities (iShares Bitcoin Trust ETF (IBIT) and Financial Select Sector SPDR Fund (XLF)) or as Tier 2 Qualifying Securities (VanEck Semiconductor ETF (SMH), Energy Select Sector SPDR (XLE), iShares MSCI Emerging Markets ETF (EEM)) as of April 2026. According to the Exchange, expanding the Short Term Option Series Program to include IBIT, XLF, SMH, XLE and EEM would increase the amount of strikes by approximately 0.16%. *See id.* at 40608.

[56] *See supra* notes 6–9 and accompanying text.

[57] *See supra* notes 26–29 and accompanying text.

[58] According to the Exchange, substantially less than 1% of Exchange-Traded Fund Shares would meet the Tier 2 Qualifying Securities Criteria. *See* Notice, *supra* note 4, at 40619.

tailor their investment and hedging decisions in these options, thus allowing them to better manage their risk exposure. For these reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act [59] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[60] that the proposed rule change (SR–ISE–2026–34) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[61]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16695 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36294; 812–16016]

Elevation Series Trust and Norris Perné and French LLP

August 12, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act, as well as from certain disclosure requirements in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements'').

SUMMARY OF APPLICATION: The requested exemption would permit Applicants to enter into and materially amend subadvisory agreements with subadvisers without shareholder approval and would grant relief from the Disclosure Requirements as they relate to fees paid to the subadvisers.

APPLICANTS: Elevation Series Trust and Norris Perné and French LLP.

FILING DATE: The application was filed on April 17, 2026 and amended on June 12, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m. Eastern Time, on September 7, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: JoAnn M. Strasser, Thompson Hine LLP, 41 S. High Street, Suite 1700, Columbus, Ohio 43215, *JoAnn.Strasser@thompsonhine.com;* with copies to Nicholas Adams, Elevation Series Trust, c/o Norris Perné and French LLP, 1700 Broadway, Suite 2100, Denver, CO 80290.

FOR FURTHER INFORMATION CONTACT: Rachel Loko, Senior Special Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' amended application, dated June 12, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.*

You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16702 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106103; File No. SR–MIAX–2026–33]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule Regarding the Routing Fee Table

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Options Exchange Fee Schedule (''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the exchange grouping of options exchanges within the routing fee table in Section

[59] 15 U.S.C. 78s(b)(5).

[60] 15 U.S.C. 78s(b)(2).

[61] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

1(c) of the Fee Schedule, Fees for Customer Orders Routed to Another Options Exchange, to add applicable Member [3] orders routed to MX2 LLC (''MX2'') and Investors Exchange LLC (''IEX''), in anticipation of the launch of MX2 Options and IEX Options, the new options trading facilities of MX2 and IEX.[4] The Exchange also proposes to update the routing fee table to reflect the name change of ''Nasdaq BX Options'' to ''Nasdaq Texas Options.'' [5] Additionally, the Exchange proposes to update the exchange groupings of options exchanges within the routing fee table, specifically to remove ''MIAX Pearl'' from the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.25 fee tier and amend the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.40 fee tier to add ''MIAX Pearl.''

Currently, the Exchange assesses routing fees based upon (i) the origin type of the order; (ii) whether or not it is an order for standard option classes in the Penny Interval Program [6] (''Penny classes'') or an order for standard option classes which are not in the Penny Interval Program (''Non-Penny classes'') (or other explicitly identified classes); and (iii) to which away market it is being routed. This assessment practice is identical to the routing fees assessment practice currently utilized by the Exchange's affiliates, MIAX PEARL, LLC (''MIAX Pearl''), MIAX Emerald, LLC (''MIAX Emerald''), and MIAX Sapphire, LLC (''MIAX Sapphire''). This is also similar to the methodology utilized by the Cboe BZX Exchange, Inc. (''Cboe BZX Options''), a competing options exchange, in assessing routing fees. Cboe BZX Options has exchange groupings in its fee schedule, similar to those of the Exchange, whereby several exchanges are grouped into the same category, dependent upon the order's origin type and whether it is a Penny or Non-Penny class.[7]

In anticipation of the launch of the options trading facilities of MX2 and IEX in the second half of 2026, the Exchange has determined to amend the exchange groupings of options exchanges within the routing fee table to include MX2 and IEX and the anticipated associated costs of routing customer orders to MX2 and IEX for execution. In determining to amend its routing fee table to determine which category MX2 and IEX belong to the Exchange took into account anticipated transaction fees and rebates assessed by the away markets to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market.

The Exchange's proposal to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is a conforming and non-substantive change in nature designed to ensure that the Exchange's Fee Schedule accurately reflects the name of the away market orders are being routed to and executed on.

As a result of conducting a periodic review of the current transaction fees charged by away markets the Exchange has determined to remove ''MIAX Pearl'' from the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' 1.25 fee tier and amend the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' 1.40 fee tier to add ''MIAX Pearl.'' This change is being made as MIAX Pearl recently amended its fee schedule and increased the transaction fee per contract for orders in Non-Penny classes in Professional capacities which remove liquidity.[8]

The impact of these proposed changes will be increased routing options for Members, a clearer Fee Schedule, and a Fee Schedule that better reflects the associated costs. The Exchange notes that routing through the Exchange is optional and that Members will continue to be able to choose where to route applicable Member orders. Under this proposed change, the Exchange will not amend the fees associated with the exchange groupings. This proposal merely seeks to add MX2 and IEX to the exchange groupings, amend the name of a market, and amend the exchange groupings as described in the routing fee table below.

According, with the proposed change, the routing fee table will be as follows:

Description	Fees
Routed, Priority Customer, Penny Program, to: NYSE American, Cboe, Cboe EDGX Options, Nasdaq PHLX (except SPY), Nasdaq MRX, MIAX Sapphire	$0.15
Routed, Priority Customer, Penny Program, to: BOX	0.30
Routed, Priority Customer, Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, Nasdaq ISE, NOM, Nasdaq PHLX (SPY only), MIAX Emerald, MIAX Pearl, Nasdaq Texas Options, MEMX, MX2 Options, IEX Options	0.65
Routed, Priority Customer, Non-Penny Program, to: NYSE American, BOX, Cboe, Cboe EDGX Options, Nasdaq PHLX, Nasdaq MRX, MIAX Sapphire	0.15
Routed, Priority Customer, Non-Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, MIAX Pearl, MIAX Emerald, Nasdaq GEMX, NOM, Nasdaq Texas Options, Nasdaq ISE, MEMX, MX2 Options, IEX Options	1.00
Routed, Public Customer that is not a Priority Customer, Penny Program, to: NYSE American, NYSE Arca Options, Cboe BZX Options, BOX, Cboe, Cboe C2, Cboe EDGX Options, Nasdaq GEMX, Nasdaq ISE, Nasdaq MRX, MIAX Pearl, MIAX Emerald, NOM, Nasdaq PHLX, Nasdaq Texas Options, MEMX, MIAX Sapphire, MX2 Options, IEX Options	0.65

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Securities Exchange Act Release Nos. 104152 (September 30, 2025), 90 FR 47867 (October 2, 2025) (SR–MX2–2025–01) (Self-Regulatory Organizations; MX2 LLC; Order Granting Approval to a Proposed Rule Change To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called MX2 Options); 103998 (September 18, 2025), 90 FR 45861 (September 23, 2025) (SR–IEX–2025–02)(Self-Regulatory Organizations; Investors Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 3, To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called IEX Options).

[5] Nasdaq BX, Inc. (''Nasdaq BX'') recently converted from a corporation organized under the laws of the state of Delaware to a limited liability company (''LLC'') organized under the laws of the state of Texas and changed its name to ''Nasdaq Texas, LLC.'' (''Nasdaq Texas''). *See* Securities Exchange Act Release No. 104736 (January 29, 2026), 91 FR 4980 (February 3, 2026) (SR–BX–2026–005) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Repeal the Restated Certificate of Incorporation and Adopt a Certificate of Formation and Company Agreement.).

[6] *See* Exchange Rule 510(c).

[7] *See* Cboe U.S. Options Fee Schedules, BZX Options, effective July 1, 2026 ''Fee Codes and Associated Fees,'' at *https://www.cboe.com/us/options/membership/fee_schedule/bzx/.*

[8] *See* MIAX Pearl Options Exchange Fee Schedule (effective July 1, 2026), Transaction Fees, *available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Options_Fee_Schedule_07012026.pdf; see also* Securities Exchange Act Release No. 105894 (July 13, 2026), 91 FR 43694 (July 16, 2026) (SR–PEARL–2026–34) (Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule To Amend Certain Fees and Rebates Applicable to Transactions in Non-Penny Classes for All Origins).

Description	Fees
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE American, Cboe, Nasdaq PHLX, Cboe EDGX Options, NOM	1.00
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe C2, BOX, MIAX Sapphire	1.15
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE Arca Options, Nasdaq GEMX, Nasdaq MRX, MIAX Emerald	1.25
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe BZX Options, Nasdaq ISE, Nasdaq Texas Options, MEMX, MIAX Pearl, MX2 Options, IEX Options	1.40

The purpose of the proposal is to adjust and amend the routing fee groups for orders routed to other exchanges to better reflect the associated costs for that routed execution in Penny and Non-Penny classes as determined by the fees and rebates at the executing exchange. In determining to adjust and amend its groupings, the Exchange took into account anticipated transaction fees assessed by the away market to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market. The Exchange uses unaffiliated routing brokers to route orders to the away markets; the costs associated with the use of these services are included in the routing fees specified in the Fee Schedule. This routing fees structure is not only similar to the Exchange's affiliates, MIAX Pearl, MIAX Emerald, and MIAX Sapphire, but is also comparable to the structure in place at Cboe BZX Options,[9] a competing options exchange. The Exchange's routing fee structure approximates the Exchange's anticipated costs associated with routing orders to away markets. The per-contract transaction fee amount associated with each grouping closely approximates the Exchange's all-in cost (plus an additional, non-material amount) [10] to execute that corresponding contract(s) at that corresponding exchange. The Exchange notes that in determining whether to include certain exchanges in a certain groupings of options exchanges in the routing fee table, the Exchange considered the transaction fees and rebates assessed by away markets, and determined to amend the grouping of exchanges that assess transaction fees for routed orders within a similar range. This same logic and structure applies to all of the groupings in the routing fee table. By utilizing the same structure that is utilized by the Exchange's affiliates, MIAX Pearl, MIAX Emerald, and MIAX Sapphire, the Exchange's Members will be assessed routing fees in a similar manner. The Exchange believes that this structure will minimize any confusion as to the method of assessing routing fees between the three exchanges. The Exchange notes that its affiliates, MIAX Pearl, MIAX Emerald, and MIAX Sapphire, will file to make the same proposed routing fee changes contained herein.

Implementation

The proposed rule changes will become effective on August 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the routing fee table of exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed change seeks to recoup costs that will be incurred by the Exchange when routing customer orders to MX2 and IEX on behalf of Members and does so in the same manner to all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees and rebates assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed additions of MX2 and IEX to the exchange groupings would increase the routing options available to Members. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) to execute the corresponding contract at the corresponding exchange.

The Exchange believes that the proposed change is equitable and not unfairly discriminatory because all Members' orders in Penny classes and Non-Penny classes routed to MX2 and IEX will be uniformly assessed the corresponding fee.

The proposed non-substantive change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Act and comply and enforce compliance with the provisions of the Act by its Members and persons associated with its Members, because it would ensure that the Exchange's Fee Schedule accurately reflects the correct name of the away market to which orders are being routed to and executed on and therefore contribute to the orderly operation of the Exchange by adding clarity and transparency. In addition, the proposed

[9] The Cboe BZX Options fee schedule is similar to the Exchange's Fee Schedule in that it has exchange groupings, whereby several exchanges are grouped into the same category. *See supra* note 7.

[10] This amount is to cover de minimis differences/changes to away market fees (*i.e.,* minor increases or decreases) that would not necessitate a fee filing by the Exchange to re-categorize the away exchange into a different grouping. Routing fees are not intended to be a profit center for the Exchange and the Exchange's target regarding routing fees and expenses is to be as close as possible to net neutral.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

change would reduce potential investor and market participant confusion and therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that investors and market participants can more easily navigate and understand the Exchange's Fee Schedule. The proposed change would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased transparency and clarity, thereby reducing potential confusion.

The Exchange believes that the proposed changes to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed changes to the routing fee table exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed changes seek to recoup costs that are incurred by the Exchange when routing orders for Public Customers that are not Priority Customers to away markets on behalf of Members and does so in the same manner for all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed re-categorization of certain exchange groupings would enable the Exchange to better reflect the costs and fees associated with routing orders to other exchanges for execution.

The Exchange places away markets in the fee tier grouping that best approximates the Exchange's costs and fees to route the orders in that segment to that away market. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) [14] to execute the corresponding contract at the corresponding exchange. The Exchange believes its tier structure represents the best approach to reflect the costs and fees associated with routing and executing orders on other exchanges. As noted above, this routing fee structure is comparable to the structure in place on at least one other competing options exchange, Cboe BZX Options.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed changes to add MX2 and IEX to the routing fee table will impose any burden on intramarket competition. Rather, the Exchange believes that the proposal will promote competition by increasing the available away markets to which Members can route orders to.

The proposed change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is not intended to address competitive issues but rather is concerned solely with updating the Exchange's Fee Schedule to reflect the name change of Nasdaq BX to Nasdaq Texas.

The Exchange's proposed re-categorization of certain exchange groupings is intended to enable the Exchange to recover the costs it incurs to route orders to away markets. The costs to the Exchange to route orders to away markets for execution primarily includes the transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange does not believe that this proposal imposes any unnecessary burden on competition because it seeks to better reflect the costs and fees incurred by the Exchange when routing orders to away markets on behalf of Members and notes that at least one other options exchange has a similar routing fee structure.[16]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2) [18] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2026–33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2026–33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2026–33 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16696 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

[14] *See supra* note 10.

[15] *See supra* notes 7 and 9.

[16] *See supra* note 7.

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106080; File No. SR–OCC–2026–008]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change by The Options Clearing Corporation Concerning Amendments to Its Rules To Establish a Procedures-Based Approach for Determining Product Eligibility During Overnight or Extended Trading Sessions Utilizing Its Current ETH Risk Management Framework

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on July 30, 2026, The Options Clearing Corporation (''OCC'' or ''Corporation'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change would amend OCC's Rules to establish a procedures-based approach for determining product eligibility during overnight or extended trading sessions (''ETH'')[3] utilizing its current ETH risk management framework. Currently, the only products that OCC clears in ETH sessions are index options listed by Cboe Global Markets, Inc. (''Cboe'') and index futures listed by Cboe Futures Exchange, LLC (''CFE''). The proposed changes would create a framework for risk managing other products that an ''Exchange''[4] may propose to trade outside of regular trading hours while maintaining the established risk management framework.[5]

The proposed changes would allow OCC to accommodate requests from any participating Exchange, including CFE's request to trade options on index futures outside of regular trading hours and Cboe's proposal, which was approved by the Commission,[6] to amend its Global Trading Hours to allow trading of multi-listed equity options.[7] Other Exchanges subsequently filed similar changes to their rules.[8] In addition, OCC has designed the changes to create a framework for evaluating other products that an Exchange may propose to be traded outside of regular trading hours in the future that can be effectively risk-managed within OCC's established frameworks and procedures. To the extent OCC determines that changes to its existing ETH procedures would be necessary to support a particular product trading at a particular time, the proposed change would provide that such changes would be made in accordance with (i) OCC's regulatory obligations (*e.g.,* filing obligations under Section 19 of the Exchange Act) and (ii) the Participant Exchange Agreement[9] between OCC and the national securities exchanges or OCC's agreement with a requesting futures market.[10]

OCC filed the proposed changes to OCC's Rules and the Extended Trading Hours Set-Up and Monitoring Procedure as Exhibits 5A and 5B to File No. SR–OCC–2026–008, respectively. Material proposed to be added as currently in effect is underlined and material proposed to be deleted is marked in strikethrough text. All capitalized terms not defined herein have the same meaning as set forth in the OCC By-Laws and Rules.[11]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. *Purpose*

OCC is a self-regulatory organization (''SRO'') that is registered as a covered clearing agency (''CCA'') under the Exchange Act, as amended, and a derivatives clearing organization (''DCO'') under the Commodity Exchange Act. OCC is also a derivatives clearing organization registered with the Commodity Futures Trading Commission (the ''CFTC'') that clears futures products for CFE, and MIAX Futures Exchange, LLC (''MIAX''),[12] both designated contract markets by the CFTC pursuant to Section 5 of the Commodity Exchange Act.[13] In its role as a CCA and central counterparty (''CCP''), OCC is the guarantor for all contracts cleared through OCC, assuming the role of buyer to every seller and the seller to every buyer to ensure the prompt and accurate settlement of securities. In its capacity as a CCP, OCC is exposed to certain risks, including credit risk,[14] because OCC is obligated to perform pursuant to its By-Laws and Rules even when one of its members defaults. OCC manages its credit risk through various safeguards to ensure that it has sufficient financial resources in the event of a Clearing Member failure. For example, OCC periodically collects

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''ETH'' means trading periods outside of normal exchange trading hours.

[4] OCC's By-Laws define ''Exchange'' to include, among other things, a national securities exchange or a futures market.

[5] *See* Exchange Act Release Nos. 74268 (Feb. 12, 2015), 80 FR 8917 (Feb. 19, 2015) (SR–OCC- 2014–24) (Order approving Proposed Rule Change concerning Extended and Overnight Trading Sessions, establishing the framework now being expanded) and 74241 (Feb. 10, 2015), 80 FR 8383 (Feb. 17, 2015) (SR–OCC–2014–812) (Notice of No Objection to Advance Notice concerning Extended and Overnight Trading Sessions).

[6] *See* Exchange Act Release No. 105569 (May 28, 2026), 91 FR 33005 (June 02, 2026) (SR–CBOE–2025–079) (Order Approving Proposed Rule Change, as Modified by Amendment No. 1, to Allow for Extended Trading of Multi-Listed Equity Options).

[7] Cboe proposes expanding the trading hours for multi-listed equity options to include a morning session from 6:30 a.m. to 8:25 a.m. Central time, while also evaluating the inclusion of a curb session from 3:00 p.m. Central time to 3:15 p.m. Central time as an extension of its Regular Trading Hours. *See* Exchange Act Release No. 104160 (Sep. 30, 2025), 90 FR 48091 (Oct. 3, 2025) (SR–CBOE–2025–079).

[8] *See, e.g.,* Exchange Act Release No. 105785 (June 26, 2026), 91 FR 40061 (July 1, 2026) (SR–MRX–2026–11); Exchange Act Release No. 105704 (June 16, 2026), 91 FR 37201 (June 22, 2026) (SR–NYSEAMER–2026–34).

[9] In 2025, OCC and the national securities exchanges for which it provides clearance and settlement services executed the Amended and Restated Participant Exchange Agreement (hereinafter, the ''Participant Exchange Agreement'') following Commission approval of a proposed rule change filed by OCC. *See* Exchange Act Release No. 103436 (July 11, 2025), 90 FR 32045 (July 16, 2025) (SR–OCC–2025–006).

[10] Pursuant to Article XII, Section 1 of OCC's By-Laws, (Conditions for the Corporation to Clear Futures, Futures Options or Commodity Options for an Exchange), OCC has executed a clearing agreement with CFE. OCC has also filed an agreement with MIAX Futures Exchange, LLC, which is pending execution in advance of that Exchange's anticipated launch this year. *See* Exchange Act Release No. 103271 (June 16, 2025), 90 FR 26377 (June 20, 2025) (SR–OCC–2025–008).

[11] OCC's By-Laws and Rules can be found on OCC's public website, available at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

[12] OCC is anticipated to commence clearing services for MIAX futures in May of 2026.

[13] 7 U.S.C. 7.

[14] Credit risk is the risk that OCC would not maintain sufficient financial resources to cover exposures.

margin collateral from its Clearing Members, which is designed to cover the credit exposures they individually present to OCC with a high degree of confidence. OCC also maintains authority and has established procedures for collecting additional margin from Clearing Members on an intraday basis due to changes in positions [15] or changes in prices.[16]

The clearance of trades that occur outside of regular trading hours presents OCC with certain additional considerations from a risk management perspective. First, OCC is limited in its ability to issue and collect intraday margin calls from a Clearing Member presenting increased risk to OCC. Second, trading outside of regular hours presents greater operational risk due to reduced Clearing Member operational and risk staff available to address issues that might arise during extended hours. Third, OCC has observed that for those products that currently trade ETH, the markets for such options typically have more limited market liquidity, which can lead to higher transaction costs for participants seeking to initiate or unwind positions during ETH sessions. These market dynamics carry risk management implications. Shallow market environments can manifest price gapping,[17] where modest trades can lead to outsized market moves and can lead to changes in valuations of positions and thus, increases in margin requirements. Another consideration is the behavior of market makers, who may scale back quoting activity during extended trading hours due to wider uncertainty, lower volumes, and less capacity to hedge. If market maker participation decreases during extended trading hours, it could lead to episodic volatility and a degradation of price discovery.

OCC manages these risks for products that currently trade in ETH sessions through its ETH procedures. In 2015, OCC established its ETH procedures [18] for certain products proposed by Cboe and CFE to be traded outside of regular trading hours, including index options and index futures.[19] The ETH procedures allow for the provision of clearing and settlement services to participant exchanges subject to compliance with OCC's risk management procedures and controls. As described in more detail below, these procedures were designed to reduce and mitigate the risks associated with clearing trades executed in ETH sessions, and included the following components and controls: (i) qualification criteria used to approve Clearing Members for ETH sessions, including ETH deposit requirements, (ii) systemic controls to identify trades executed during ETH sessions by Clearing Members not approved for such sessions, (iii) enhancements to OCC's overnight monitoring of trades submitted by Exchanges during ETH sessions, (iv) enhancements to OCC's credit controls with respect to monitoring Clearing Members' credit risk during ETH sessions, including procedures for contacting an Exchange offering ETH sessions in order to invoke use of the Exchange's kill switch, and (v) rule enforcement actions such as taking appropriate disciplinary action against Clearing Members who attempt to clear during ETH session without first obtaining requisite approvals.

These ETH procedures were also designed to work in conjunction with the risk controls of the Exchanges that offer ETH sessions. Such Exchange risk controls consist of: (1) price reasonability checks, (2) controls to prevent orders from being executed beyond a certain percentage (determined by the Exchange), (3) activity based protections which focus on risk beyond price, such as a high number of trades occurring in a set period of time, and (4) kill switch capabilities, which may be initiated by the Exchange and can cancel all open quotes or all orders of a particular participant.

While these procedures were designed to facilitate the clearing of index options and index futures, Exchanges, including CFE and Cboe, have requested that OCC expand its support for other products during the ETH sessions. First, CFE has requested that OCC provide clearance and settlement services for options on VIX futures (''VX Futures Options'') [20] during the same hours in which VIX futures currently trade. Second, Cboe, Nasdaq and NYSE have filed proposed changes to their Global Trading Hours for multi-listed equity options.[21] Specifically, these proposals would establish an early morning session from 6:30 a.m. Central Time to 8:25 a.m. Central Time and an afternoon session from 3:00 p.m. Central Time to 3:15 p.m. Central Time for trading of multi-listed equity options. These proposals also limit the number of equity options classes that may be designed for its Global Trading Hours to 100 option classes and establish criteria for eligibility based on average daily options volume, market capitalization of the underlying equity, and average daily trading volume of the underlying equity. Cboe has stated these criteria will help ensure options designated for trading in its Global Trading Hours will have sufficient demand and liquidity to support a Global Trading Hours market.[22]

OCC has evaluated these proposed changes to Exchange rules to determine whether OCC has the legal authority, operational capacity and risk management processes in place to support the clearance and settlement of such products during such hours. OCC evaluates each proposed product using criteria that include, among other things: (1) compatibility with OCC's existing margin methodology, (2) availability of real-time settlement pricing, and (3) consistency with OCC's operations risk management requirements.

OCC has determined to treat the proposed early morning session as extended trading hours, and to extend OCC's ETH procedures to that activity. OCC believes that extending the ETH procedures to the early morning trading session is prudent from a risk management perspective to address potential operational and market risk associated with trading in such early morning session. OCC's ETH procedures have operated without disruption through multiple periods of high volatility since 2015. The proposed products are not new to OCC, as single-name equity options and options on VX futures are already cleared by OCC during regular trading hours and margined using OCC's existing margin

[15] *See* Exchange Act Release No. 102768 (Apr. 3, 2025), 90 FR 15274 (Apr. 9, 2025) (SR–OCC–2024–010).

[16] *See* Exchange Act Release No. 82355 (Dec. 19, 2017), 82 FR 61060, 61064 (Dec. 26, 2017) (SR–OCC–2017–007) (codifying in the Margin Policy the issuance of a margin call when unrealized losses are observed for an account, based on start-of-day positions and updated prices). OCC has also filed, and the Commission has approved, a proposed rule change to transition from start-of-day to current positions; this change is pending implementation with Ovation launch. *See* Exchange Act Release No. 103677 (Aug. 11, 2025), 90 FR 39229 (Aug. 14, 2025) (SR–OCC–2025–007).

[17] The term ''Price gapping'' refers to situations where security prices leap to a higher or lower level without any intermediate trading activity at the prices in between.

[18] *See supra* note 5. OCC now proposes to formally file such procedure as a rule.

[19] OCC's By-Laws define (i) an ''index future'' as a future on an index of securities of commodities, and (ii) an ''index option contract'' as any option contract the underlying interest of which is a securities index or commodities index.

[20] VX Futures Options are options on Cboe Volatility Index (''VX'') futures. VX futures are cash-settled futures on the Cboe Volatility Index (''VIX Index'').

[21] *See supra* notes 7–8.

[22] *See* Exchange Act Release No. 105153 (Apr. 6, 2026), 91 FR 18010, 18013 (Apr. 9, 2026) (SR–CBOE–2025–079) (Amendment No. 1).

methodology. Further, the Exchanges' proposed eligibility criteria would limit initial participation to the most liquid U.S. equity options, reducing the risk of outsized credit exposures to OCC during the early morning session. In addition, consistent with OCC's Rule 609,[23] any credit risk accumulated during the early morning session is subject to OCC's start of business margin call at 8:30 a.m. CT, at which time settlement banks are open and OCC can collect any required additional margin deposit.

OCC's determination that its existing ETH procedures are adequate to manage the risks associated with the proposed extension of ETH rests not only on product compatibility, but also on the material enhancements and substantial build-out to its risk management processes and systems in the years since the ETH procedures were first implemented. For example, OCC has made enhancements to its proprietary margin methodology, the System for Theoretical Analysis and Numerical Simulations (''STANS''), including by, among other things:

(i) incorporating daily price and returns data of securities; [24]

(ii) incorporating variations in implied volatility; [25]

(iii) enhancing its models for generating theoretical values for listed options [26] and the futures products that OCC clears; [27]

(iv) establishing a risk-based liquidation charge to account for the costs of liquidating a defaulting Clearing Member's portfolio; [28]

(v) establishing procedures for adjusting certain parameters when the products OCC clears and the markets it serves experience high volatility; [29]

(vi) enhancing the models to better account for the risk of short-dated options; [30] and

(vii) implementing and enhancing backtesting procedures for monitoring the performance of the models and establishing a margin charge should OCC identify backtesting deficiencies at the Clearing Member level.[31]

Further, OCC has made enhancements to its intraday risk monitoring and collection of margin resources to cover intraday risk, including by establishing an Intraday Risk Charge and thresholds for margin calls during regular trading hours, similar to the procedures for ETH established in 2014.[32] Further enhancements to the intraday risk process have been designed and will be implemented upon migration to OCC's new clearance and settlement system, Ovation.[33]

In addition, beginning in 2018, OCC also implemented a comprehensive stress testing methodology that it uses to size its Clearing Fund and call for additional resources if stressed exposures exceed certain thresholds, to ensure that OCC maintains sufficient financial resources to cover the loss of the two Clearing Member groups presenting the largest stressed exposures to OCC in extreme but plausible market conditions.[34] OCC has also diversified its access to liquidity through the addition of new liquidity facilities and liquidity providers to ensure OCC has sufficient qualifying liquid resources to meet liquidity demands in such stressed conditions,[35] including liquidity demands arising from OCC's election under its accord with the National Securities Clearing Corporation (''NSCC'') to step into the shoes of a Clearing Member for whom NSCC has ceased to act in order to ensure the continued settlement of exercise and assignment activity for physically settled options through NSCC's CNS system.[36] Taken together, OCC believes that these risk management enhancements help to ensure that OCC's existing ETH procedures are sufficient to support the expanded ETH sessions.[37]

OCC has also determined that it may support the proposed afternoon session as regular trading hours, regardless of whether that trading session is classified as regular trading hours, a curb session, or some other designation under the rules of an Exchange. OCC believes treating such activity as within regular trading hours is consistent with the definition of ETH under its existing ETH procedures.

This proposed rule change would amend OCC's Rules to establish a legal framework governing OCC's authority to determine product eligibility and session hours for ETH clearing, and to accommodate Exchange proposals to expand the products and hours covered by its ETH procedures. Specifically, the proposed amendments would: (i) clarify that OCC determines what constitutes ''regular trading hours'' and ''extended trading hours'' for purposes of OCC's operations and risk management (*i.e.,* this determination is independent of how a particular Exchange may categorize such trading under its rules);

[23] *See* OCC Rule 609.

[24] *See* Securities Exchange Act Release No. 83326 (May 18, 2018), 83 FR 25081 (May 31, 2018) (SR–OCC–2017–022).

[25] *See* Securities Exchange Act Release No. 84879 (Dec. 20, 2018), 83 FR 67392 (Dec. 28, 2018) (SR–OCC–2018–014); Securities Exchange Act Release No. 95319 (July 19, 2022), 87 FR 44167 (July 25, 2022) (SR–OCC–2022–001).

[26] *See* Securities Exchange Act Release No. 86731 (Aug. 22, 2019), 84 FR 45188 (Aug. 28, 2019) (SR–OCC–2019–005).

[27] *See* Securities Exchange Act Release No. 85873 (May 16, 2019), 84 FR 23620 (May 22, 2019) (SR–OCC–2019–002); Securities Exchange Act Release No. 89392 (July 24, 2020), 85 FR 45938 (July 30, 2020) (SR–OCC–2020–007); Securities Exchange Act Release No. 90139 (Oct. 8, 2020), 85 FR 65886 (Oct. 16, 2020) (SR–OCC–2020–012); Securities Exchange Act Release No. 91833 (May 10, 2021), 86 FR 26586 (May 14, 2021) (SR–OCC–2021–005); Securities Exchange Act Release No. 100528 (July 15, 2024), 89 FR 58736 (July 19, 2024) (SR–OCC–2024–008).

[28] *See* Securities Exchange Act Release No. 86119 (June 17, 2019), 84 FR 29267 (June 21, 2019) (SR–OCC–2019–004).

[29] *See* Securities Exchange Act Release No. 102057 (Jan. 6, 2025), 90 FR 714 (Jan. 6, 2025) (SR–OCC–2024–014).

[30] *See* Securities Exchange Act Release No. 102203 (Jan. 15, 2025), 90 FR 7721 (Jan. 22, 2025) (SR–OCC–2024–016).

[31] *See* Securities Exchange Act Release No. 73749 (Dec. 5, 2014), 79 FR 73673 (Dec. 11, 2014) (SR–OCC–2014–810); Securities Exchange Act Release No. 75290 (June 24, 2015), 80 FR 37323 (June 30, 2015) (SR–OCC–2014–810); Securities Exchange Act Release No. 100998 (Sep. 11, 2024), 89 FR 76171 (Sep. 17, 2024) (SR–OCC–2024–009).

[32] *See* Securities Exchange Act Release No. 102768 (Apr. 3, 2025), 90 FR 15285 (Apr. 9, 2025) (SR–OCC–2024–010).

[33] *See* Securities Exchange Act Release No. 103677 (Aug. 11, 2025), 90 FR 39229 (Aug. 14, 2025) (SR–OCC–2025–007).

[34] *See* Securities Exchange Act Release No. 83561 (June 11, 2018), 83 FR 27957 (June 15, 2018) (SR–OCC–2018–006); Securities Exchange Act Release No. 83735 (July 27, 2018), 83 FR 37855 (Aug. 2, 2018) (SR–OCC–2018–008); Securities Exchange Act Release No. 87717 (Dec. 11, 2019), 84 FR 68985 (Dec. 17, 2019) (SR–OCC–2019–009); Securities Exchange Act Release No. 87718 (Dec. 11, 2019), 84 FR 68992 (Dec. 17, 2019) (SR–OCC–2019–010); Securities Exchange Act Release No. 89014 (June 4, 2020), 85 FR 35446 (June 10, 2020) (SR–OCC–2020–003); Securities Exchange Act Release No. 90827 (Dec. 30, 2020), 86 FR 659 (Jan. 6, 2021) (SR–OCC–2020–015); Securities Exchange Act Release No. 100147 (May 15, 2024), 89 FR 44752 (May 21, 2024) (SR–OCC–2024–006); Securities Exchange Act Release No. 103597 (July 30, 2025), 90 FR 36461 (Aug. 4, 2025) (SR–OCC–2025–009).

[35] *See* Securities Exchange Act Release No. 76821 (Jan. 4, 2016), 81 FR 3208 (Jan. 20, 2016) (SR–OCC–2015–805); Securities Exchange Act Release No. 88317 (Mar. 4, 2020), 85 FR 13681 (Mar. 9, 2020) (SR–OCC–2020–801); Securities Exchange Act Release No. 88971 (May 28, 2020), 85 FR 34257 (June 3, 2020) (SR–OCC–2020–804); Securities Exchange Act Release No. 89039 (June 10, 2020), 85 FR 36444 (June 16, 2020) (SR–OCC–2020–803); Securities Exchange Act Release No. 95327 (July 20, 2022), 87 FR 44457 (July 26, 2022) (SR–OCC–2022–802); Securities Exchange Act Release No. 95670 (Sep. 2, 2022), 87 FR 55048 (Sep. 8, 2022) (SR–OCC–2022–803); Securities Exchange Act Release No. 103047 (May 15, 2025), 90 FR 21800 (May 21, 2025) (SR–OCC–2025–801).

[36] *See* Securities Exchange Act Release No. 99735 (Mar. 14, 2024), 89 FR 19907 (Mar. 20, 2024) (SR–OCC–2023–007); Securities Exchange Act Release No. 104350 (Dec. 9, 2025), 90 FR 57796 (Dec. 12, 2025) (SR–OCC–2025–013).

[37] OCC intends to monitor ETH activity as volumes develop to determine if any changes to its existing procedures are necessary to support current or future products.

(ii) provide that contracts cleared during extended trading hours will be subject to OCC's established ETH procedures; (iii) provide that OCC will determine in its sole discretion, and for the protection of OCC, its Clearing Members and the general public, whether the risk of a product proposed by an Exchange to be traded in extended trading hours may be managed under OCC's existing ETH procedures; and (iv) provide that if OCC determines that an Exchange's proposal requires changes to its existing ETH procedures, such changes will be made in accordance with (a) OCC's regulatory obligations and (b) OCC's agreement with the Exchange. These changes are designed to both accommodate existing Exchange requests, as well as to serve as a foundation for evaluating future Exchange requests to trade products outside of regular trading hours, while ensuring that if OCC needs to make changes to its operations and risk management processes to accommodate such requests, such changes would remain consistent with OCC's regulatory obligations and agreements with the Exchanges. OCC does not intend this proposal to solve every issue raised by the industry's transition to 24/7 trading,[38] nor does OCC believe those issues need to be resolved to support the trading hours under the current Exchange proposals. Rather, this proposed rule change is designed to support an incremental step towards a continuous trading environment and to provide a framework for future steps.

Existing ETH Procedures

OCC manages the risk associated with clearance and settlement of trades in ETH sessions through ETH procedures, approved by the Commission, that include (i) qualification criteria for Clearing Member participation, (ii) systemic controls to detect unauthorized trading by participants that have not qualified to trade in ETH sessions, (iii) overnight monitoring of Clearing Members' credit risk during ETH sessions, (iv) credit controls to address potential increased exposure during ETH sessions, and (v) rule enforcement should Clearing Members trade in ETH sessions without prior approval. Under the proposed rule changes discussed below, these procedures would apply to the clearance and settlement of trading in hours that OCC has determined are outside of regular trading hours.

Qualification Criteria

In order to mitigate risks associated with clearing for ETH sessions, Clearing Members that participate in such trading sessions are required to provide contact information to OCC for operational and risk personnel available to be contacted by OCC during such sessions. In addition, OCC requires that Clearing Members participating in an ETH session post additional margin in a designated account in order to mitigate against the risk that OCC cannot draft a Clearing Member's bank account during an ETH session.[39] OCC has also adopted procedure whereby, on a quarterly basis, it confirms its record of Clearing Members eligible for ETH sessions with a similar record maintained by Exchanges offering such ETH sessions.

With respect to providing operational and risk contacts, under OCC Rule 201(b), each Clearing Member is required to maintain facilities for conducting business with OCC, and a representative of the Clearing Member authorized in the name of the Clearing Member to take all action necessary for conducting business with OCC is required to be available at the facility during such hours as may be specified from time-to-time by OCC. Similarly, OCC Rules 203(c) and (d) require Clearing Members to ensure that they have the appropriate number of qualified personnel and to maintain the ability to process anticipated volumes and values of transactions. OCC uses this existing authority to require Clearing Members trading during ETH sessions to maintain operational and risk staff that may be contacted by OCC during such sessions.

OCC charges Clearing Members qualified to participate in ETH sessions additional margin requirement in an amount of the lesser of $10 million or 10% of the Clearing Member's net capital (''ETH margin add-on''), which is equal to the first monitoring risk threshold (described below) and which would be collected as part of regular morning settlement. Clearing Members must identify the proprietary account that would be charged the ETH margin add-on amount. The ETH margin add-on requirement is intended to provide OCC with additional margin assets should a Clearing Member's credit risk increase during ETH sessions.[40] Clearing Members that do not have sufficient excess margin on deposit with OCC to meet the ETH margin add-on amount are required to deposit additional funds with OCC to satisfy the ETH margin add-on requirement as part of regular morning settlement.[41]

OCC Clearing Members wishing to participate in trading activity during ETH trading sessions must receive OCC's approval, before an Exchange would grant trading privileges for such sessions. OCC also confirms that an Exchange offering ETH trading sessions has implemented a procedure to periodically (*i.e.,* quarterly) validate its record of approved clearing firms against OCC's record of Clearing Members approved for ETH sessions. Any discrepancies between the two records would be promptly resolved by either the Clearing Member obtaining approval at OCC for ETH sessions, or by the Exchange revoking the clearing firm's trading privileges for ETH sessions.

Systemic Controls

OCC has implemented systemic controls so that trades submitted to OCC during ETH sessions that have been executed by Clearing Members not approved for such trading sessions would be reviewed by OCC staff after acceptance but before being processed (each such trade being a ''Reviewed Trade''). OCC would contact the submitting Exchange regarding each Reviewed Trade in order to determine if the trade is a valid trade. If the Exchange determines that the Reviewed Trade was in error such that, as provided in Article VI, Section 7(c), a new or revised trade information is required to properly clear the transaction, OCC expects the Exchange would instruct OCC to disregard or ''bust'' the trade. If the Exchange determines that the Reviewed Trade was not in error, then OCC would clear the Reviewed Trade[42] and take appropriate

[38] OCC has published a whitepaper outlining a vision and roadmap for how U.S. listed options markets could evolve toward a 24/7 model, beginning with a phased transition to a 22/5 trading and clearing environment. *See* Considerations of a Continuous Trading Environment and Implications for Central Clearing of U.S. Listed Options: Perspectives on CCP Issues from a Utility Model Clearinghouse (Sept. 2025), *available at https://www.theocc.com/newsroom/views/2025/09-29-white-paper-considerations-of-a-continuous-trading-environment.*

[39] Clearing Members will be required to designate a proprietary bank account to ensure that OCC has a general lien on the assets in the account and can use them to satisfy any obligation of the Clearing Member to OCC.

[40] Clearing Members approved for ETH sessions who do not meet the ETH margin add-on requirement for a given ETH session are treated like a Clearing Member not approved ETH sessions, as described below.

[41] Under OCC Rule 601, OCC has the discretion to fix the margin requirement for any account at an amount that it deems necessary or appropriate under the circumstances to protect the interests of Clearing Members, OCC and the public.

[42] OCC is obligated under the Participant Exchange Agreement to accept and clear all matched trades in accordance with OCC's By-Laws and Rules reported to it by participating exchanges. The Participant Exchange Agreement does not provide OCC with authority to reject matched

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disciplinary action against the non-approved Clearing Member, as described below. OCC believes that clearing the Reviewed Trade is appropriate in order to avoid potentially harming the Clearing Member approved for ETH sessions that is on the opposite side of the transaction.

Overnight Monitoring

OCC has implemented additional overnight monitoring in order to better monitor Clearing Members' credit risk during ETH sessions. Such monitoring of credit risk is similar to existing OCC practices concerning futures cleared during overnight trading hours and includes automated processes within ENCORE to measure, by Clearing Member: (i) the aggregate mark-to-market amounts of a Clearing Member's positions, including positions created during overnight trading, based on current prices using OCC's Portfolio Revaluation system, (ii) the aggregate incremental margin produced by all positions resulting from transactions executed during overnight trading, and (iii) with respect to options cleared during ETH sessions, the aggregate net trade premium positions resulting from trades executed during ETH trading (each of these measures being a ''Credit Risk Number''). Hourly credit reports are generated containing the Credit Risk Numbers expressed in terms of both dollars and, except for the mark-to-market position values, as a percentage of net capital for each Clearing Member trading during ETH sessions. The Credit Risk Numbers are the same information used by OCC staff to evaluate Clearing Member exposure during regular trading hours and, in addition to OCC's knowledge of its Clearing Members' businesses, are effective measures of the risk presented to OCC by each Clearing Member. OCC's Operations staff review such reports as they are generated and, in the event that any of the Credit Risk Numbers for positions established by a Clearing Member during an ETH session exceeds established thresholds, staff would alert OCC's Market Risk staff [43] of the exceedance in accordance with established procedures, as described below. Market Risk staff follow a standardized process concerning such exceedances, including escalation to OCC's management, if required by such process.

With respect to OCC's escalation thresholds, if any Credit Risk Number of a Clearing Member approved for ETH sessions is $10 million or more, or any Credit Risk Number equals 10% or more of the Clearing Member's net capital, an email is generated with a Level 1 Exceedance. This threshold functions as an early warning system, alerting Market Risk and Member Services to a developing credit risk situation before it reaches levels requiring more urgent intervention. At this tier, Operations staff notifies Market Risk and Member Services by email; Market Risk reviews the notification and assesses whether immediate action is warranted. More prescriptive remedial action is not required at this tier because the exposure level is covered by the pre-positioned ETH margin add-on, which OCC holds at the start of each ETH session. The higher thresholds require progressively more urgent action because they represent exposures that exceed that buffer.

If any Credit Risk Number of a Clearing Member approved for ETH sessions is $50 million or more, or equals 25% or more of the Clearing Member's net capital, Operations staff would be required to contact, by telephone and email: (i) Market Risk and Member Services, (ii) the applicable Exchange for secondary review, and (iii) the Clearing Member's designated contacts. The on-call Market Risk duty officer would also consider if additional action is necessary, which may include contacting a designated executive officer in order to issue an intra-day margin call pursuant to OCC Rule 609, increase the Clearing Member's margin requirement in order to prevent the withdrawal of a specified amount of excess margin collateral, if any, the Clearing Member has on deposit with OCC pursuant to OCC Rule 601, or contacting the Exchange in order to invoke use of its kill switch. A Rule 601 margin requirement increase and Rule 609 intraday margin call are tools that reflect the operational constraints for ETH trading during hours in which banks may not be open, such as overnight. If banks are not open, OCC would not be able to collect additional cash during the hours in which such trading was taking place. In that case, OCC Rule 601 serves as a real-time tool that takes effect immediately, preventing a Clearing Member from withdrawing excess collateral already on deposit with OCC, without requiring a cash transfer. When settlement banks reopen, Rule 609 enables OCC to collect additional funds where a Clearing Member's existing excess collateral is insufficient to cover the incremental risk incurred during ETH. OCC Rule 601 also allows OCC to reduce the amount it would need to draft for a Rule 609 margin call by the amount of excess collateral the Clearing Member has on deposit at OCC.

If any Credit Risk Number is $75 million or more, or equals 50% or more of the Clearing Member's net capital, Operations staff would be required to contact, by telephone and email, Market Risk staff, the on-call Market Risk duty officer and a designated executive officer. Such officer would be responsible for reviewing the circumstances and determining whether to implement credit controls, which are described in greater detail below and include: issuing an intra-day margin call, increasing a Clearing Member's margin requirement in order to prevent the withdrawal of a specified amount of excess margin collateral, if any, the Clearing Member has on deposit with OCC, whether further escalation is warranted in order for OCC to take protective measures pursuant to OCC Rule 305, or contact the Exchange in order to invoke use of its kill switch. OCC believes that these thresholds strike an appropriate balance between effective risk monitoring and operational efficiency.

Credit Controls

In order to address credit risk associated with trading during ETH sessions, and as described above, OCC collects the ETH margin add-on from Clearing Members and monitors and analyzes the impact that positions established during such sessions have on a Clearing Member's overall exposure. Should the need arise based on threshold breaches described above, and pursuant to OCC Rule 609, OCC may require the deposit of additional margin (''intra-day margin'') by any Clearing Member that increases its incremental risk as a result of trading activity during ETH sessions. Should a Clearing Member's exposure significantly increase, OCC has the authority under OCC Rule 601 to increase a Clearing Member's margin requirement which would restrict its ability to withdraw excess margin collateral.

Furthermore, if a Clearing Member's trading activity during ETH sessions causes its exposure to exceed OCC's intra-day margin call threshold, OCC would require the Clearing Member to deposit intra-day margin equal to the incremental risk presented by the Clearing Member. Specifically, if a Clearing Member has a current risk charge [44] exceeding 25% and a loss of

trades from exchanges or allow it to require that exchanges implement preventative controls.

[43] OCC's Member Services staff will also receive alerts in order to contact Clearing Members as may be necessary.

[44] The current risk charge is the margin risk charge used for intraday portfolio revaluation

greater than $50,000 from an ETH session(s), OCC would initiate an intra-day margin call, subject to OCC's policies and procedures.[45] The margin call amount would be calculated using positions and prices as of the most recent snapshot generated during the ETH session.[46] Accordingly, OCC would know at approximately 8:30 a.m. (Central Time) if an intra-day margin call on a Clearing Member would be initiated based on breaches of this threshold.[47] This ''start of business'' margin call is in addition to daily margin OCC collects from Clearing Members pursuant to OCC Rule 605, any intra-day margin call that OCC may initiate as a result of regular trading sessions or special margin call that OCC may initiate.

In addition to, or instead of, requiring additional intra-day margin, OCC Rule 601[48] and OCC's Margin Policy work together to authorize Market Risk staff to increase a Clearing Member's margin requirement which may be in an amount equal to an intra-day margin call.[49] Any increased margin requirement will remain in effect until the next business day. This action would immediately prevent Clearing Members from withdrawing any excess margin collateral (in the amount of the increased margin requirement) the Clearing Member has deposited with OCC. With respect to clearing trades executed in ETH sessions, and in the event OCC requires additional margin from a Clearing Member, Market Risk staff may use increased margin requirements as a means of collateralizing the increase in incremental risk a Clearing Member incurred during such sessions.[50] Such action may be taken by OCC instead of or in addition to issuing an intra-day margin call depending on the amount of excess margin a Clearing Member has on deposit with OCC and the amount of the incremental risk presented by such Clearing Member. This intra-day margin call process as described in the preceding paragraph, including OCC's ability to manually increase Clearing Members' margin requirements, mitigates the risk that OCC is under-collateralized as a result of overnight trading hours.

Moreover, a designated executive officer may call an Exchange offering ETH sessions to invoke use of its kill switch. The kill switch would prevent a Clearing Member (or the market participant clearing through a Clearing Member) from executing trades on the Exchange during a given ETH session or, if needed, stop all trading during a given ETH session. Finally, pursuant to OCC Rule 307B, the Chief Executive Officer or the Chief Operating Officer of OCC, in certain circumstances, has the authority to impose limitations and restrictions on the transactions, positions and activities of a Clearing Member. This authority would be used, as needed, in the event a Clearing Member accumulates significant credit risk during ETH sessions, or a Clearing Member's activities during such trading sessions otherwise warrant OCC taking protective action.

Rule Enforcement Actions

In order to deter Clearing Members from attempting to participate in ETH sessions without authorization as well as appropriately enforce the above-described processes, OCC maintains authority to initiate a rule enforcement action against a Clearing Member that attempts to participate in ETH sessions without first obtaining the necessary approval. As described above, Clearing Members not approved for ETH sessions who trade during ETH sessions would have their trades reviewed by OCC staff. Clearing Members who attempted to participate in ETH sessions that did not obtain the necessary approval to do so may be subject to a minor rule violation fine.[51] In addition, if a Clearing Member's operational or risk contacts for ETH sessions were unavailable had OCC attempted to contact such individuals, the Clearing Member may be subject to a minor rule violation fine. OCC has existing processes in place to monitor for Clearing Member violations of OCC's Rules and such processes would also apply to Clearing Member activity during ETH sessions.

Proposed Changes

OCC proposes amendments to its Rules and its ETH procedures to accommodate any participating Exchange request, including CFE's and Cboe's proposals for extended trading hours in VX Futures Options and multi-listed equity options, to establish a legal framework for the consideration of an Exchange's future extension of trading hours for these or other products. Specifically, OCC proposes to amend Rule 402, which is currently reserved, to establish a rule concerning products cleared outside of regular trading hours. In addition, OCC proposes to make changes to its ETH Procedure to amend the definition of ''extended trading hours'' to encompass not only hours in which U.S. payment systems are closed, as ETH is currently defined therein, but also to incorporate hours in which OCC has determined there may be heightened operational risk or market risk. In addition, OCC proposes to revise its ETH procedures to define the end of the ETH monitoring window as the start of regular trading hours. This revision would clarify to Clearing Members that OCC will conduct uninterrupted monitoring throughout all ETH sessions including the proposed early morning session between 6:30 a.m. and 8:25 a.m. CT.

Proposed Rule 402

Rule 402 would clarify that products executed on an Exchange outside of regular trading hours, as determined by OCC, would be subject to OCC's established procedures for the risk management of cleared contracts during ETH sessions, as is the case for index options and index futures traded in ETH sessions today. Accordingly, the amended Rule would provide OCC's authority to determine whether a product proposed to be traded at a particular time would be subject to OCC's procedures for the management of risk during regular trading hours or those for ETH. For example, OCC has determined that the proposed Exchange extension of trading hours for multi-listed equity options from 3:00 p.m. Central to 3:15 p.m. Central may be considered regular trading hours under OCC's rules. Such extension does not raise the same concerns, or to the same degree, about the availability of U.S. payment systems or Clearing Member staffing to support such trading during such hours that motivated the design of the ETH procedures. This rule also clarifies that it is OCC that determines whether particular hours are considered regular trading hours or extended trading hours for purposes of OCC's

margin calls; but updated with any change in risk charge occurring from depositing or withdrawing Specific Deposit, Escrow Deposit, or Valued Securities collateral.

[45] *See* Exchange Act Release No. 82355 (Dec. 19, 2017), 82 FR 61060, 61064 (Dec. 26, 2017) (SR–OCC–2017–007) (codifying in the Margin Policy that ETH intraday margin calls would be subject to a minimum value established in OCC's procedures).

[46] *See supra* note 32.

[47] OCC has current credit exposure data available at or near the close of each ETH session on which to base the determination whether to initiate a start-of-business margin call at 8:30 a.m. CT.

[48] In addition, OCC Rule 601 provides OCC with the authority to fix the margin requirement for any account or any class of cleared contracts at such amount as it deems necessary or appropriate under the circumstances to protect the respective interests of Clearing Members, OCC and the public.

[49] Clearing Members frequently deposit margin at OCC in excess of requirements.

[50] Clearing Members would be able to substitute the locked-up collateral during normal time frames (*i.e.,* 6:00 a.m. to 5:00 p.m. (Central Time) for equity securities).

[51] *See* OCC Rule 1201(b).

own rules and operations. How a particular Exchange classifies such hours under Exchange Rules is not determinative. For example, Cboe initially proposed to consider the afternoon session as a ''curb'' session,[52] and then subsequently amended its proposal to consider it an extension Cboe's Regular Trading Hours.[53] OCC would make its own determination of how to classify an Exchange's proposed hours based on the impact on OCC's operations and risk management.

Proposed Rule 402 would further provide that OCC would determine, at its sole discretion and for the protection of OCC, its Clearing Members and the general public, whether the risk of a product proposed by an Exchange to be traded in extended trading hours may be managed under OCC's existing ETH procedures. As such, Rule 402 documents OCC's authority to evaluate the proposed expansion of ETH sessions and products to determine whether OCC's risk management procedures are adequate to support the expansion. As discussed above, the current ETH procedures were designed with index options and index futures in mind. The procedures may not be sufficient to address the risks associated with the trading of all products at all hours, particularly the risks of overnight trading in equity options.[54] However, OCC believes that its existing ETH procedures are adequate to address the risks associated with the proposed early morning session. As discussed above, OCC already clears and margins these products during regular trading hours using its existing margin methodology. In addition, the Exchanges' proposed eligibility criteria further limits participation, confining the scope of eligible products to the most liquid names. Beyond this, the early morning session would run from 6:30 a.m. to 8:25 a.m. CT, and any credit risk accumulated during that brief period is subject to OCC's start of business margin authority at 8:30 a.m., when settlement banks are open and OCC can collect additional margin.

Should any other Exchange propose similar hours for similar products, the Rule would also allow OCC to accommodate that Exchange's request. OCC's review and determination of products or hours to be added to ETH sessions, as documented in proposed Rule 402, would also align OCC's Rules with provisions of the Participant Exchange Agreement. Specifically, the Participant Exchange Agreement provides that to the extent OCC agrees to undertake a program or project for a particular Exchange, OCC shall be prepared to undertake comparable programs and projects for each other Exchange that requests it to do so, without discrimination as to schedules, costs, or other terms and conditions. Accordingly, OCC cannot deny a request from a similarly situated Exchange for similarly situated products under the proposed framework. The Participant Exchange Agreement further provides that ''each Exchange shall comply with operational specifications for Options including for extended and overnight trading hours specified by OCC and supported by OCC's By-Laws and Rules.'' [55] Proposed Rule 402 is therefore designed to be consistent with and provide transparency in OCC's Rules regarding OCC's existing ETH Procedures, which the Exchanges agreed to abide by under the Participant Exchange Agreement.

In addition, OCC respectfully suggests that the Commission consider requesting that any Exchange submitting a proposal to extend its trading hours for products cleared by OCC to consult with OCC in advance of such proposal about OCC's anticipated treatment of such hours and any changes that will be necessary to OCC's ETH procedures to support the proposal, and encourage such Exchange provide that information in its filing. Providing such information in Exchange filings would allow the Commission to more wholistically evaluate an Exchange's proposal and its potential impact on clearance and settlement. In addition, should the Commission be concerned with how OCC proposes to classify the trading hours or the suitability of OCC's existing ETH procedures to manage the risks, such concerns could be addressed earlier in the process, thereby promoting efficiency and avoiding unnecessary delay to an Exchange's planned implementation of expanded trading hours.

Finally, proposed Rule 402 would provide that if OCC determines that an Exchange's proposal to allow trading in certain products at certain hours requires changes to OCC's existing ETH procedures, such changes would be made in accordance with (i) OCC's regulatory obligations and (ii) OCC's agreement with the Exchange, including the Participant Exchange Agreement or any agreement with a futures market under Article XII, Section 1 of OCC's By-Laws. Accordingly, Rule 402 would provide transparency that should OCC determine that changes to the ETH procedures are necessary, any such changes must be made consistent with OCC's regulatory obligations, including its obligation to file proposed rule changes with the Commission under Exchange Act Section 19(b) [56] and Rule 19b–4 [57] thereunder. In addition, for transparency, proposed Rule 402 would also refer to and be consistent with OCC's obligations under its agreements with the Exchanges. For example, the Participant Exchange Agreement requires OCC to use commercially reasonable efforts to maintain sufficient operational capacity to clear new options on behalf of the Exchanges and to expand operations capabilities as expeditiously as possible and as warranted to facilitate an Exchange's ability to clear new options. Accordingly, should OCC determine that changes to the ETH procedures are required to support an expansion, OCC would make commercially reasonable efforts to implement changes to its ETH procedures, including filing any necessary proposed rule changes, as expeditiously as possible.

ETH Procedure

OCC also proposes to formally file the ETH Procedure as a rule.[58] Although the ETH Procedure has governed OCC's ETH program since its inception, it was not filed as a rule at that time. OCC is now proposing to codify it as a rule to provide Clearing Members transparency on the program's governance and operational requirements.

In addition to formally filing the ETH Procedure as a rule, OCC proposes to make the following changes:

(i) Extended ETH Monitoring Window. OCC proposes to clarify within the ETH Procedure that ETH credit risk monitoring and Clearing Member eligibility validation would occur during the same monitoring window,

[52] *See* Exchange Act Release No. 93819 (Dec. 15, 2021), 86 FR 73038 (Dec. 23, 2021) (SR–CBOE–2021–071).

[53] *See* Exchange Act Release No. 94484 (Mar. 4, 2022), 87 FR 17359 (Mar. 28, 2022) (SR–CBOE–2021–071).

[54] The proposed framework would accommodate products that can be risk managed within OCC's existing ETH procedures without modification. Should a proposed product or session require changes to those procedures, OCC will submit any required regulatory filing with the Commission.

[55] OCC's Amended and Restated participant Exchange Agreement has been filed and approved as a rule by the Commission. *See* Exchange Act Release No. 103738 (Aug. 15, 2025), 90 FR 40875 (Aug. 21, 2025) (SR–OCC–2025–011), 103436 (Jul. 11, 2025), 90 FR 32045 (Jul. 17, 2025) (SR–OCC–2025–006).

[56] 15 U.S.C. 78s(b)(1).

[57] 17 CFR 240.19b–4.

[58] As noted above, the procedure was established in 2015 following Commission approval in connection with the proposal to provide for extended trading hours. *See supra* note 5. OCC now proposes to codify its procedures to provide certainty and transparency on OCC's ETH framework.

with both processes continuing until the start of regular trading hours at 8:30 a.m. Under the current procedure, the monitoring window was not expressly defined with reference to the start of regular trading hours. The proposed change would clarify to Clearing Members that both processes would remain active for the full duration of any ETH session.

(ii) Publication of ETH Procedure and Eligible Products List. OCC proposes to publish both the ETH Procedure and a list of ETH eligible products and their associated clearing sessions on OCC's public website. OCC also proposes to establish a new requirement within the ETH Procedure to issue an Information Memorandum whenever the ETH Procedure is amended or products are added to or removed from the eligible list. A new eligibility review is required each time an Exchange proposes to expand the products eligible for ETH clearing or to expand the hours for an existing product beyond what has previously been reviewed and determined. These changes are designed to provide Clearing Members and other market participants with transparency on the scope of OCC's ETH program, and any material changes to the program. In addition, OCC also proposes to remove from the ETH Procedure the header information identifying the procedure owner, rule-filed designation, and version number, as well as the related documents and revision history sections. This information does not constitute a rule and will continue to be maintained in OCC's internal policy governance system of record. Consolidating this information in a single system of record is appropriate and efficient and reduces the risk of inconsistency between the system of record and the Procedure itself.

(iii) Revised Clearing Members ETH Approval Process. OCC proposes to clarify Market Risk's role in reviewing and approving Clearing Member applications for ETH participation. Under the revised procedure new or existing Clearing Members seeking to participate during ETH Sessions must, in addition to meeting baseline requirements, receive approval from an FRM Officer.[59] Market Risk would assess each Clearing Member eligibility for ETH participation by evaluating that Clearing Member's: (1) financial condition, (2) operational readiness, and (3) risk profile. Market Risk would present a recommendation to the FRM Officer who would approve or deny the Clearing Member's ETH participation. The determination would be documented via email. Given the expanded scope of OCC's ETH eligible products, the ETH approval process would provide OCC with a more disciplined approach to managing the credit and operational risks associated with ETH participation.

(iv) ETH Product Eligibility Integration. OCC proposes to also clarify that the ETH product eligibility determination would be separately incorporated into its New Product review process, to ensure these products would be evaluated according to the established standards defined in the New Product Procedure. Under the revised procedure, when an Exchange proposes a new product or trading session for ETH clearing, OCC will evaluate the proposal through its established new product review framework, taking into account operational, financial risk, regulatory, and trading session designation factors. This change makes explicit a process OCC already follows and ensures that ETH product eligibility is subject to the same documented standards applicable to all new products OCC proposes to clear.

(v) ETH Exceedance Review. OCC proposes to also document within the ETH Procedure the process that OCC uses to review and categorize exceedances identified by its credit risk monitoring process during ETH sessions. Specifically, the revised procedure clarifies that not all monitoring alerts reflect actual ETH trading losses as exceedances may be attributed to non-trading activities. The revised procedure provides that Core Clearing would verify whether an exceedance resulted from ETH trade activity and would document cases where the exceedance is confirmed to result from non-trade activity.

Finally, OCC proposes to make certain additional conforming, clarifying, and non-substantive administrative changes to the ETH Procedure, including grammatical corrections and updated departmental references to reflect current organizational titles and responsibilities.

Proposed Amendment to Rule 307B

OCC proposes to amend Rule 307B to add a fifth use case to paragraph (a) to clarify the protective measures that may be imposed on a Clearing Member. The proposed amendment would codify OCC's existing authority under Rule 307B to authorize the Chief Executive Officer, Chief Operating Officer, or a Designated Officer of the Corporation, such as an FRM Officer, to revoke a Clearing Member's authorization to participate in ETH sessions as such officer deems necessary or appropriate in the circumstances. Such authority to revoke a Clearing Member's ETH authorization may be exercised where material changes to that Clearing Member's financial condition, operational readiness, or risk profile presents risks to OCC that warrant the imposition of protective measures. Prior to the proposed amendment, Rule 307B did not specifically address ETH participation; OCC's authority to restrict a Clearing Member's access to ETH session was derived from Rule 307B(a)(1) pursuant to which OCC may prohibit or impose limitations on the clearance of any transactions that increase credit or liquidity risk.[60] OCC believes that stating this authority explicitly, rather than relying on current rule 307B(a)(1) is necessary and beneficial because the existing Rule 307B(a)(1) provides general authority to restrict clearing activity, which does not specifically address the revocation of a Clearing Member's ETH participation, which is a distinct operational mechanism. An express rule provision would eliminate any interpretative ambiguity on the scope of OCC's authority for this use case, which would also reduce the risk of potential disputes. Since the proposed amendment adds a new use case to paragraph (a) of Rule 307B, any revocation would continue to be subject to the existing review procedures set forth in Rule 307B(b) and (c). Those procedures afford affected Clearing Members the opportunity to request review by OCC's Risk Committee, to receive advance notice of any hearing, to be heard and to present evidence, and to be represented by counsel.

2. Statutory Basis

For the following reasons, OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,[61] Rule 17ad–22(e)(1),[62] Rule 17ad–22(e)(6),[63] and Rule 17ad–22(e)(13)[64] thereunder.

Section 17A(b)(3)(F) of the Act[65] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent

[59] Officers are identified in OCC's By-Laws. *See* OCC By-Law Art IV. In this context, an FRM Officer would include any member of FRM appointed by the Chief Executive Officer or Chief Operating Officer, including a Managing Director, Executive Director or Executive Principal. *Id.,* at § 9.

[60] OCC Rule 307B(a)(1).

[61] 15 U.S.C. 78q–1(b)(3)(F).

[62] 17 CFR 240.17ad–22(e)(1).

[63] 17 CFR 240.17ad–22(e)(6).

[64] 17 CFR 240.17ad–22(e)(13).

[65] 15 U.S.C. 78q–1(b)(3)(F).

applicable, derivative agreements, contracts, and transactions, and, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency. As noted above, markets evolve and expand. To keep up, Exchanges have increasingly sought to offer new products and/or longer trading sessions to market participants. OCC believes the Exchanges' requests to offer additional products during ETH, including options on index futures, single name equity options, and other product types demonstrates market evolution toward increased trading during ETH. The adoption of the procedures-based approach promotes prompt and accurate clearance by enabling OCC to efficiently evaluate an Exchange's expansion of its trading hours against established criteria, thereby allowing markets to respond to demand while maintaining safety standards. This proposed rule change maintains the core risk controls established in 2014 and provides for a scalable operational framework to accommodate trading in ETH sessions that can be risk-managed within OCC's existing procedures. OCC would continue to maintain its current framework for monitoring and risk mitigation in ETH sessions. Moreover, OCC believes that the proposed changes provide additional clarity for the industry by defining ETH sessions as trading periods outside of Exchanges' normal trading hours. In addition, OCC believes the proposed amendment to Rule 307B strengthens its ability to manage risks arising from ETH activity by providing an express mechanism to revoke a Clearing Member's ETH authorization where material changes to that Clearing Member's financial condition, operational readiness, or risk profile warrant the imposition of protective measures.

OCC believes the proposed changes are also consistent with the requirements in Rule 17ad–22(e)(1) under the Act.[66] Rule 17ad–22(e)(1) requires that each covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent, and enforceable legal basis for each aspect of its activities in all relevant jurisdictions.[67] The changes are designed to modify OCC's Rules to provide additional transparency by stating that the products eligible for trading in ETH sessions will be subject to OCC's established procedures as well as to define ETH sessions and standard trading hours by reference to normal exchange trading hours. The procedures-based approach establishes clear product eligibility criteria in OCC's procedures rather than enumerating each product type in OCC's Rules. This framework would enable market participants to understand eligibility requirements while enabling OCC to authorize new products without resorting to filing separate rule changes for each new product proposed for trading during ETH sessions. Therefore, OCC believes that the proposed changes promote compliance and consistency with the requirements in Rule 17ad–22(e)(1) to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent and enforceable legal basis.

Rule 17ad–22(e)(6)[68] requires OCC to, among other things, establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, (i) considers and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market, and (ii) marks participant positions to market and collects margin, including variation margin or equivalent charges if relevant, at least daily and includes the authority and operational capacity to make intraday margin calls in defined circumstances. OCC's ETH margin framework comprises three interlocking layers that, when taken together produce margin commensurate with the risks and particular attributes of each relevant product, portfolio, and market during ETH sessions, and maintain OCC's capacity to mark positions to current market prices and initiate intraday margin calls on an intraday basis. As described above, OCC's margin methodology constitutes the first layer that produces product- and portfolio-commensurate margin for all products cleared by OCC during regular trading hours. No changes to that methodology are required to extend its coverage to ETH sessions. OCC's second layer is its ETH credit risk monitoring, comprising the Portfolio Revaluation and Intraday Margins systems. These systems provide P&L and margin monitoring during ETH sessions, and support OCC's tiered escalation framework and intraday margin call authority. This proposal extends the monitoring and escalation framework to all products authorized for ETH clearing without modification to either system. OCC's third layer is its ETH margin add-on that is charged to any Clearing Member participating in ETH sessions. The add-on was specifically designed to address OCC's inability to collect incremental margin when settlement banks are closed. For the foregoing reasons, OCC believes the proposed rule change is consistent with Rules 17ad–22(e)(6).[69]

OCC believes the proposed changes are also consistent with the requirements in Rule 17ad–22(e)(13) under the Act.[70] Rule 17ad–22(e)(13) requires a covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to ensure the covered clearing agency has the authority and operational capacity to contain losses and liquidity demands and continue to meets its obligations, by, at a minimum, requiring the covered clearing agency's participants and, when practicable, other stakeholder to participate in the testing and review of its default procedures, including any close-out procedures, at least annually and following material changes thereto. OCC's established exchange controls and periodic review procedures are specifically tailored to oversee Clearing Member trading activity during the ETH sessions. These procedures ensure that OCC possesses the authority and operational readiness to monitor trades and coordinate Clearing Member approvals with participant exchanges. Such proactive oversight mitigates uncollateralized credit and liquidity exposures, enabling OCC to take timely action to contain losses and manage liquidity demands while fulfilling its obligations, consistent with Rule 17ad–22(e)(13).[71]

For the above reasons, OCC believes that the proposed rule change is consistent with Section 17A of the Exchange Act[72] and the rules and regulations thereunder applicable to OCC.

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act[73] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe that the proposed rule change would impose any burden on competition not necessary or

[66] 17 CFR 240.17ad–22(e)(1).

[67] *Id.*

[68] 17 CFR 240.17ad–22(e)(6).

[69] *Id.*

[70] 17 CFR 240.17ad–22(e)(13).

[71] *Id.*

[72] 15 U.S.C. 78q–1.

[73] 15 U.S.C. 78q–1(b)(3)(I).

appropriate in furtherance of the purposes of the Act. As discussed above, OCC proposes to amend its Rules to accommodate the issuance, clearance and settlement of a broader and expanded range of products in the ETH sessions subject to its existing risk management procedures. As discussed above, determination of product eligibility would be governed by criteria specified in OCC's procedures ensuring consistent application across all participant Exchanges and products. While certain Exchanges may not yet have developed the controls and processes necessary to support ETH trading, and doing so may entail both time and cost, putting those Exchanges that have already done so at a competitive advantage, OCC believes that the Exchange risk controls for ETH trading, working in tandem with OCC's ETH procedures, are necessary and appropriate for properly managing the risks associated with the clearance and settlement during ETH sessions consistent with the requirements of the Exchange Act and OCC's regulatory obligations thereunder, including OCC's obligations discussed above to (i) maintain a risk-based margin system commensurate with the risks of each relevant product, portfolio and market;[74] and (ii) ensure it has the authority and operational capacity to take timely action during ETH sessions to continue to meet its obligations.[75]

In addition, OCC does not believe that the proposed extension of the ETH procedures to the early morning sessions, including qualification criteria for ETH trading and the payment of the ETH margin add-on charge described above, imposes a burden on competition amongst OCC's Clearing Members that is not necessary or appropriate in furtherance of the Exchange Act. The qualification criteria and the charge would be applied uniformly across all Clearing Members participating in ETH sessions. OCC believes that the ETH margin add-on remains necessary and appropriate to ensure that OCC covers its credit exposure to its participants that produces margin levels commensurate with the risks and particular attributes of the options markets in such ETH sessions, consistent with Rule 17ad–22(e)(6)(i) under the Exchange Act.[76] OCC plans to, on an annual basis, bring the ETH margin add-on to the Financial Risk Advisory Committee (''FRAC'') and the FRAC Risk Committee for discussion in light of changes in the market.

For these reasons, OCC believes the proposed rule change would not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–OCC–2026–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–OCC–2026–008. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of such filing will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to File Number SR–OCC–2026–008 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[77]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16690 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

[74] 17 CFR 240.17ad–22(e)(6)(i)–(ii).

[75] 17 CFR 240.17ad–22(e)(13).

[76] *Id.*

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, August 20, 2026.

PLACE: The meeting will be held via remote means and at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

[77] 17 CFR 200.30–3(a)(12).

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: August 13, 2026.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2026–16767 Filed 8–13–26; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106105; File No. SR–SAPPHIRE–2026–30]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Sapphire Options Exchange Fee Schedule Regarding the Routing Fee Table

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, MIAX Sapphire, LLC (''MIAX Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the exchange grouping of options exchanges within the routing fee table in Section 1)b) of the Fee Schedule, Fees for Customer Orders Routed to Another Options Exchange, to add applicable Member[3] orders routed to MX2 LLC (''MX2'') and Investors Exchange LLC (''IEX''), in anticipation of the launch of MX2 Options and IEX Options, the new options trading facilities of MX2 and IEX.[4] The Exchange also proposes to update the routing fee table to reflect the name change of ''Nasdaq BX Options'' to ''Nasdaq Texas Options.''[5]

Additionally, the Exchange proposes to update the exchange groupings of options exchanges within the routing fee table, specifically to remove ''MIAX Pearl'' from the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.25 fee tier and amend the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.40 fee tier to add ''MIAX Pearl.''

Currently, the Exchange assesses routing fees based upon (i) the origin type of the order; (ii) whether or not it is an order for standard option classes in the Penny Interval Program[6] (''Penny classes'') or an order for standard option classes which are not in the Penny Interval Program (''Non-Penny classes'') (or other explicitly identified classes); and (iii) to which away market it is being routed. This assessment practice is identical to the routing fees assessment practice currently utilized by the Exchange's affiliates, Miami International Securities Exchange, LLC (''MIAX''), MIAX PEARL, LLC (''MIAX Pearl''), and MIAX Emerald, LLC (''MIAX Emerald''). This is also similar to the methodology utilized by the Cboe BZX Exchange, Inc. (''Cboe BZX Options''), a competing options exchange, in assessing routing fees. Cboe BZX Options has exchange groupings in its fee schedule, similar to those of the Exchange, whereby several exchanges are grouped into the same category, dependent upon the order's origin type and whether it is a Penny or Non-Penny class.[7]

In anticipation of the launch of the options trading facilities of MX2 and IEX in the second half of 2026, the Exchange has determined to amend the exchange groupings of options exchanges within the routing fee table to include MX2 and IEX and the anticipated associated costs of routing customer orders to MX2 and IEX for execution. In determining to amend its routing fee table to determine which category MX2 and IEX belong to the Exchange took into account anticipated transaction fees and rebates assessed by the away markets to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market.

The Exchange's proposal to rename ''Nasdaq BX Options'' to ''Nasdaq Texas

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of MIAX Sapphire Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Securities Exchange Act Release Nos. 104152 (September 30, 2025), 90 FR 47867 (October 2, 2025) (SR–MX2–2025–01) (Self-Regulatory Organizations; MX2 LLC; Order Granting Approval to a Proposed Rule Change To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called MX2 Options); 103998 (September 18, 2025), 90 FR 45861 (September 23, 2025)(SR–IEX–2025–02)(Self-Regulatory Organizations; Investors Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 3, To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called IEX Options).

[5] Nasdaq BX, Inc. (''Nasdaq BX'') recently converted from a corporation organized under the laws of the state of Delaware to a limited liability company (''LLC'') organized under the laws of the state of Texas and changed its name to ''Nasdaq Texas, LLC.'' (''Nasdaq Texas''). *See* Securities Exchange Act Release No. 104736 (January 29, 2026), 91 FR 4980 (February 3, 2026) (SR–BX–2026–005) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Repeal the Restated Certificate of Incorporation and Adopt a Certificate of Formation and Company Agreement.).

[6] *See* Exchange Rule 510(c).

[7] *See* Cboe U.S. Options Fee Schedules, BZX Options, effective July 1, 2026 ''Fee Codes and Associated Fees,'' at *https://www.cboe.com/us/options/membership/fee_schedule/bzx/.*

Options'' is a conforming and non-substantive change in nature designed to ensure that the Exchange's Fee Schedule accurately reflects the name of the away market orders are being routed to and executed on.

As a result of conducting a periodic review of the current transaction fees charged by away markets the Exchange has determined to remove ''MIAX Pearl'' from the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.25 fee tier and amend the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.40 fee tier to add ''MIAX Pearl.'' This change is being made as MIAX Pearl recently amended its fee schedule and increased the transaction fee per contract for orders in Non-Penny classes in Professional capacities which remove liquidity.[8]

The impact of these proposed changes will be increased routing options for Members, a clearer Fee Schedule, and a Fee Schedule that better reflects the associated costs. The Exchange notes that routing through the Exchange is optional and that Members will continue to be able to choose where to route applicable Member orders. Under this proposed change, the Exchange will not amend the fees associated with the exchange groupings. This proposal merely seeks to add MX2 and IEX to the exchange groupings, amend the name of a market, and amend the exchange groupings as described in the routing fee table below.

According, with the proposed change, the routing fee table will be as follows:

Description	Fees
Routed, Priority Customer, Penny Program, to: NYSE American, Cboe, Cboe EDGX Options, MIAX, Nasdaq PHLX (except SPY), Nasdaq MRX	$0.15
Routed, Priority Customer, Penny Program, to: BOX	0.30
Routed, Priority Customer, Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, Nasdaq ISE, NOM, Nasdaq PHLX (SPY only), MIAX Pearl, MIAX Emerald, Nasdaq Texas Options, MEMX, MX2, IEX Options	0.65
Routed, Priority Customer, Non-Penny Program, to: NYSE American, BOX, Cboe, Cboe EDGX Options, MIAX, Nasdaq PHLX, Nasdaq MRX	0.15
Routed, Priority Customer, Non-Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, NOM, MIAX Pearl, MIAX Emerald, Nasdaq Texas Options, Nasdaq ISE, MEMX, MX2, IEX Options	1.00
Routed, Public Customer that is not a Priority Customer, Penny Program, to: NYSE American, NYSE Arca Options, Cboe BZX Options, BOX, Cboe, Cboe C2, Cboe EDGX Options, Nasdaq GEMX, Nasdaq ISE, Nasdaq MRX, MIAX, MIAX Pearl, MIAX Emerald, NOM, Nasdaq PHLX, Nasdaq Texas Options, MEMX, MX2, IEX Options	0.65
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE American, MIAX, Cboe, Nasdaq PHLX, Cboe EDGX Options, NOM	1.00
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe C2, BOX	1.15
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE Arca Options, Nasdaq GEMX, Nasdaq MRX, MIAX Emerald	1.25
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe BZX Options, Nasdaq ISE, Nasdaq Texas Options, MEMX, MX2, IEX Options, MIAX Pearl	1.40

The purpose of the proposal is to adjust and amend the routing fee groups for orders routed to other exchanges to better reflect the associated costs for that routed execution in Penny and Non-Penny classes as determined by the fees and rebates at the executing exchange. In determining to adjust and amend its groupings, the Exchange took into account anticipated transaction fees assessed by the away market to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market. The Exchange uses unaffiliated routing brokers to route orders to the away markets; the costs associated with the use of these services are included in the routing fees specified in the Fee Schedule. This routing fees structure is not only similar to the Exchange's affiliates, MIAX, MIAX Pearl, and MIAX Emerald, but is also comparable to the structure in place at Cboe BZX Options,[9] a competing options exchange. The Exchange's routing fee structure approximates the Exchange's anticipated costs associated with routing orders to away markets. The per-contract transaction fee amount associated with each grouping closely approximates the Exchange's all-in cost (plus an additional, non-material amount) [10] to execute that corresponding contract(s) at that corresponding exchange. The Exchange notes that in determining whether to include certain exchanges in a certain groupings of options exchanges in the routing fee table, the Exchange considered the transaction fees and rebates assessed by away markets, and determined to amend the grouping of exchanges that assess transaction fees for routed orders within a similar range. This same logic and structure applies to all of the groupings in the routing fee table. By utilizing the same structure that is utilized by the Exchange's affiliates, MIAX, MIAX Pearl, and MIAX Emerald, the Exchange's Members will be assessed routing fees in a similar manner. The Exchange believes that this structure will minimize any confusion as to the method of assessing routing fees between the three exchanges. The Exchange notes that its affiliates, MIAX, MIAX Pearl, and MIAX Emerald, will file to make the same proposed routing fee changes contained herein.

Implementation

The proposed rule changes will become effective on August 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is

[8] *See* MIAX Pearl Options Exchange Fee Schedule (effective July 1, 2026), Transaction Fees, *available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Options_Fee_Schedule_07012026.pdf*; *see also* Securities Exchange Act Release No. 105894 (July 13, 2026), 91 FR 43694 (July 16, 2026) (SR–PEARL–2026–34) (Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule To Amend Certain Fees and Rebates Applicable to Transactions in Non-Penny Classes for All Origins).

[9] The Cboe BZX Options fee schedule is similar to the Exchange's Fee Schedule in that it has exchange groupings, whereby several exchanges are grouped into the same category. *See supra* note 7.

[10] This amount is to cover de minimis differences/changes to away market fees (*i.e.,* minor increases or decreases) that would not necessitate a fee filing by the Exchange to re-categorize the away exchange into a different grouping. Routing fees are not intended to be a profit center for the Exchange and the Exchange's target regarding routing fees and expenses is to be as close as possible to net neutral.

consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the routing fee table of exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed change seeks to recoup costs that will be incurred by the Exchange when routing customer orders to MX2 and IEX on behalf of Members and does so in the same manner to all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees and rebates assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed additions of MX2 and IEX to the exchange groupings would increase the routing options available to Members. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) to execute the corresponding contract at the corresponding exchange.

The Exchange believes that the proposed change is equitable and not unfairly discriminatory because all Members' orders in Penny classes and Non-Penny classes routed to MX2 and IEX will be uniformly assessed the corresponding fee.

The proposed non-substantive change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Act and comply and enforce compliance with the provisions of the Act by its Members and persons associated with its Members, because it would ensure that the Exchange's Fee Schedule accurately reflects the correct name of the away market to which orders are being routed to and executed on and therefore contribute to the orderly operation of the Exchange by adding clarity and transparency. In addition, the proposed change would reduce potential investor and market participant confusion and therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that investors and market participants can more easily navigate and understand the Exchange's Fee Schedule. The proposed change would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased transparency and clarity, thereby reducing potential confusion.

The Exchange believes that the proposed changes to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed changes to the routing fee table exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed changes seek to recoup costs that are incurred by the Exchange when routing orders for Public Customers that are not Priority Customers to away markets on behalf of Members and does so in the same manner for all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed re-categorization of certain exchange groupings would enable the Exchange to better reflect the costs and fees associated with routing orders to other exchanges for execution.

The Exchange places away markets in the fee tier grouping that best approximates the Exchange's costs and fees to route the orders in that segment to that away market. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) [14] to execute the corresponding contract at the corresponding exchange. The Exchange believes its tier structure represents the best approach to reflect the costs and fees associated with routing and executing orders on other exchanges. As noted above, this routing fee structure is comparable to the structure in place on at least one other competing options exchange, Cboe BZX Options.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed changes to add MX2 and IEX to the routing fee table will impose any burden on intramarket competition. Rather, the Exchange believes that the proposal will promote competition by increasing the available away markets to which Members can route orders to.

The proposed change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is not intended to address competitive issues but rather is concerned solely with updating the Exchange's Fee Schedule to reflect the name change of Nasdaq BX to Nasdaq Texas.

The Exchange's proposed re-categorization of certain exchange groupings is intended to enable the Exchange to recover the costs it incurs to route orders to away markets. The costs to the Exchange to route orders to away markets for execution primarily includes the transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange does not believe that this proposal imposes any unnecessary burden on competition because it seeks to better reflect the costs and fees incurred by the Exchange when routing orders to away markets on

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 10.

[15] *See supra* notes 7 and 9.

behalf of Members and notes that at least one other options exchange has a similar routing fee structure.[16]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2) [18] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2026–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2026–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–SAPPHIRE–2026–30 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16697 Filed 8–14–26; 8:45 am]

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[16] *See supra* note 7.

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4.

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106083; File No. SR–CboeBZX–2026–063]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Fee Schedule

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2026, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend its Fee Schedule by: (i) removing Step-Up Tier 2; (ii) adopting a new Single MPID Investor Tier; and (iii) removing the ETP and Closed-End Fund LMM Liquidity Provision Rates which expired on June 30, 2026. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/equities/regulation/rule_filings/bzx/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''BZX Equities'') by: (i) removing Step-Up Tier 2; (ii) adopting a new Single MPID Investor Tier; and (iii) removing the ETP and Closed-End Fund LMM Liquidity Provision Rates which expired on June 30, 2026. The Exchange proposes to implement these changes effective August 3, 2026.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 17 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Securities Exchange Act of 1934 (the ''Act''), to which market participants may direct their order flow. Based on publicly available information,[3] no single registered equities exchange has more than 15% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays rebates to members that add liquidity and assesses fees to those that remove liquidity. The Exchange's Fee Schedule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (July 23, 2026), available at *https://www.cboe.com/us/equities/market_statistics/.*

sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity.[4] For orders in securities priced below $1.00, the Exchange does not provide a rebate for orders that add liquidity and assesses a fee of 0.30% of the total dollar value for orders that remove liquidity.[5] Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Step-Up Tiers

Under footnote 2 of the Fee Schedule, the Exchange currently offers various Step-Up Tiers that provide enhanced rebates for orders yielding fee codes B,[6] V[7] and Y[8] where a Member reaches certain add volume-based criteria, including ''growing'' its volume over a certain baseline month. The Exchange now proposes to discontinue Step-Up Tier 2 as the Exchange no longer wishes to, nor is required to, maintain such tier. More specifically, the proposed change removes this tier as the Exchange would rather redirect future resources and funding into other programs and tiers intended to incentivize increased order flow. Additionally, the Exchange proposes to remove the definitions of ''Step-Up ADAV,''[9] ''Step-Up ADV,''[10] ''Step-Up Add TCV,''[11] Step-Up Remove TCV,''[12] and ''Tape B Step-Up Add TCV''[13] as these definitions are no longer used in the Exchange's Fee Schedule and also proposes to remove the reference to footnote 2 in the ''Fee Code and Associated Fees'' section of the Fee Schedule as footnote 2 will be designated ''Reserved.''

Single MPID Investor Tiers

Under footnote 4 of the Fee Schedule, the Exchange offers Single MPID Investor Tiers. In particular, the Exchange currently offers two Single MPID Investor Tiers that provide enhanced rebates for orders yielding fee codes B, V and Y where an MPID reaches certain add volume-based criteria. The Exchange now proposes to adopt a new Single MPID Investor Tier 3. The proposed criteria for Single MPID Investor Tier 3 is as follows:

- Single MPID Investor Tier 3 provides an enhanced rebate of $0.0032 per share in securities priced at or above $1.00 to qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y) where: (1) MPID has an ADAV[14] as a percentage of TCV[15] ≥ 0.45% or MPID has an Ex-Subdollar ADAV[16] as a percentage of Ex-Subdollar TCV[17] ≥ 0.45%; and (2) MPID has a Tape C ADV[18] as a percentage of the Tape C TCV ≥ 0.60% or MPID has an Ex-Subdollar Tape C ADV as a percentage of Ex-Subdollar Tape C TCV ≥ 0.60%.

For purposes of the proposed Single MPID Investor Tier 3, ''Tape C ADV'' means ADV in Tape C securities. ''Tape C TCV'' means TCV in Tape C securities. ''Ex-Subdollar Tape C ADV'' means Tape C ADV that excludes executions in securities priced below $1.00. ''Ex-Subdollar Tape C TCV'' means Tape C TCV that excludes executions in securities that have an average daily price below $1.00. These definitions are consistent with the existing definitions of ''Ex-Subdollar ADAV'' and ''Ex-Subdollar TCV'' that already appear on the Exchange's Fee Schedule and are tailored to apply to Tape C securities.

The proposed Single MPID Investor Tier 3, like other Single MPID Investor Tiers, is intended to provide an additional opportunity to incentivize MPIDs to earn an enhanced rebate by promoting increased displayed and non-displayed liquidity and Tape C participation, contributing to a deeper, more liquid market and providing even more execution opportunities for active market participants. Incentivizing an increase in liquidity adding volume through enhanced rebate opportunities encourages liquidity-adding Members on the Exchange to increase transactions and take execution opportunities provided by such increased liquidity, together providing for overall enhanced price discovery and price improvement opportunities on the Exchange. As such, increased overall order flow benefits all Members by contributing towards a robust and well-balanced market ecosystem. The Exchange notes that the proposed Single MPID Investor Tier 3 does not represent a significant departure from existing criteria. The Exchange further notes that the Ex-Subdollar alternative prongs are designed to prevent Members from being disadvantaged in months where elevated subdollar volume inflates TCV, ensuring that the tier criteria remains achievable and equitable regardless of market conditions.

ETP and Closed-End Fund LMM Liquidity Provision Rates

Under footnote 14 of the Fee Schedule, the Exchange details pricing for its Lead Market Makers (''LMMs'') in BZX-listed securities. In particular, under footnote 14(B), the Exchange currently details the ETP and Closed-End Fund LMM Liquidity Provision Rates payable daily on a per-security basis to Qualified ETP LMMs, comprising Base Rates and Enhanced Rates tables (the ''Base and Enhanced Rates'') based on average aggregate daily auction volume in ETP LMM Securities.[19] These prior payout-structure rates were effective through June 30, 2026.

The Exchange now proposes to remove the Base and Enhanced Rates from its Fee Schedule. The Exchange previously updated the payout structure of its LMM program; performance tracking for the new payouts began in June 2026 with the new payouts starting in July 2026, and the prior payout

[4] *See* BZX Equities Fee Schedule, Standard Rates.

[5] *Id.*

[6] Fee code B is appended to displayed orders that add liquidity to BZX in Tape B securities.

[7] Fee code V is appended to displayed orders that add liquidity to BZX in Tape A securities.

[8] Fee code Y is appended to displayed orders that add liquidity to BZX in Tape C securities.

[9] ''Step-Up ADAV'' means ADAV in the relevant baseline month subtracted from the prior month's ADAV.

[10] ''Step-Up ADV'' means ADV in the relevant baseline month subtracted from the prior month's ADV.

[11] ''Step-Up Add TCV'' means ADAV as a percentage of TCV in the relevant baseline month subtracted from the prior month's ADAV as a percentage of TCV.

[12] ''Step-Up Remove TCV'' means ADV resulting from orders that remove liquidity as a percentage of TCV in the relevant baseline month subtracted from the prior month's ADV resulting from orders that remove liquidity as a percentage of TCV.

[13] ''Tape B Step-Up Add TCV'' means ADAV in Tape B securities as a percentage of TCV in the relevant baseline month subtracted from the prior month's ADAV in Tape B securities as a percentage of TCV.

[14] ''ADAV'' means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[15] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[16] ''Ex-Subdollar ADAV'' means ADAV that excludes executions in securities priced below $1.00.

[17] ''Ex-Subdollar TCV'' means TCV that excludes executions in securities that have an average daily price below $1.00.

[18] ''ADV'' means average daily volume calculated as the number of shares added and removed, different from ''ADAV'' which means only shares added, per day.

[19] ''ETP LMM Securities'' means BZX-listed ETP and Closed-End Fund securities for which a Member is an LMM.

structure remained in effect only through June 30, 2026.[20] Because the new payout structure is now fully in effect, the Exchange proposes to remove the Base and Enhanced Rates from its Fee Schedule. The Exchange no longer wishes to, nor is required to, maintain the prior rates. More specifically, the proposed change removes these rates as the Exchange would rather redirect future resources and funding into other programs and tiers intended to incentivize increased order flow.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[21] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[22] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[23] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4)[24] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to adopt Single MPID Investor Tier 3 reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. Specifically, the Exchange's proposed Single MPID Investor Tier 3 is not a significant departure from existing criteria, is reasonably correlated to the enhanced rebate offered by the Exchange and other competing exchanges,[25] and will continue to incentivize Members to submit order flow to the Exchange. Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[26] including the Exchange,[27] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules or rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

In particular, the Exchange believes its proposed Single MPID Investor Tier 3 is reasonable because the proposed tier will be available to all Members and provide all Members with an opportunity to receive an enhanced rebate. The Exchange further believes its proposed Single MPID Investor Tier 3 will provide a reasonable means to encourage liquidity adding displayed orders in Members' order flow to the Exchange and to incentivize Members to continue to provide liquidity adding volume to the Exchange by offering them an opportunity to receive an enhanced rebate on qualifying orders. An overall increase in activity would deepen the Exchange's liquidity pool, offer additional cost savings, support the quality of price discovery, promote market transparency and improve market quality, for all investors.

The Exchange believes that its proposed Single MPID Investor Tier 3 is reasonable as the proposed criteria does not represent a significant departure from the criteria currently offered in the Fee Schedule. The Exchange also believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members will be eligible for the proposed Single MPID Investor Tier 3 and have the opportunity to meet the tier's criteria and receive the corresponding enhanced rebate if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any MPIDs qualifying for the proposed Single MPID Investor Tier 3. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on the prior month's volume, the Exchange anticipates that at least one MPID will be able to satisfy the proposed Single MPID Investor Tier 3. The Exchange also notes that proposed changes will not adversely impact any Member's ability to qualify for enhanced rebates offered under other tiers. Should a Member not meet the proposed new criteria, the Member will merely not receive that corresponding enhanced rebate.

The Exchange believes that its proposal to discontinue Step-Up Tier 2, the associated definitions, and reference to footnote 2 in the ''Fee Codes and Associated Fees'' section of the Fee Schedule is reasonable because the Exchange is not required to maintain this tier or provide Members an opportunity to receive enhanced rebates. The Exchange believes the proposal to discontinue this tier and remove the associated definitions and references to footnote 2 is also equitable and not unfairly discriminatory because it applies to all Members (*i.e.,* the tier will not be available for any Member). The Exchange also notes that the proposed rule change to remove this tier merely results in Members not receiving an enhanced rebate, which, as noted above, the Exchange is not required to offer or maintain. Furthermore, the proposed rule change to eliminate Step-Up Tier 2 enables the Exchange to redirect resources and funding into other programs and tiers intended to incentivize increased order flow.

Furthermore, the Exchange believes that its proposal to remove the Base and Enhanced Rates that expired on June 30, 2026, is reasonable because the Exchange is not required to maintain these rates nor provide ETP LMMs an opportunity to receive the rates. The Exchange believes its proposal to remove the Base and Enhanced Rates is equitable and not unfairly discriminatory because it applies to all ETP LMMs uniformly (*i.e.,* the Base and Enhanced Rates that expired on June 30,

[20] *See* Securities Exchange Act Release No. 105667 (June 11, 2026); 91 FR 36181 (June 16, 2026); SR–CboeBZX–2026–051 (''LMM Fee Filing'').

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] *Id.*

[24] 15 U.S.C. 78f(b)(4).

[25] *See* NYSE Arca Equities Fee Schedule, NYSE Arca Marketplace, General, Applicable Credits and Fees, Tiered Credits for Providing Displayed Liquidity, available at *https://www.nyse.com/markets/nyse-arca/trading-info/fees.*

[26] *See e.g.,* EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[27] *See e.g.,* BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

2026, will not be available for any ETP LMM). The proposed rule change merely results in ETP LMMs not receiving the Base and Enhanced Rates, which, as noted above, the Exchange is not required to offer or maintain. Further, ETP LMMs remain eligible for the revised volume-based payout structure under the new program, which was effective July 1, 2026. In addition, the proposed rule change to remove the Base and Enhanced Rates enables the Exchange to redirect resources and funding into other programs and tiers intended to incentivize increased order flow.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed adoption of Single MPID Investor Tier 3 does not impose an unnecessary burden as all Members are eligible to receive the enhanced rebate under the proposed tier. The Exchange does not believe the proposed changes burden competition, but rather, enhances competition as it is intended to increase the competitiveness of BZX by amending existing pricing incentives in order to attract order flow and incentivize participants to increase their participation on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

The proposed changes to discontinue Step-Up Tier 2 and remove the associated definitions and references to footnote 2 will not impose any burden on intramarket competition because the change applies to all Members uniformly, as in, the tier and definitions will no longer be available to any Member.

The proposed change to remove the ETP and Closed-End Fund LMM Liquidity Provision Rates will not impose any burden on intramarket competition because the change applies to all ETP LMMs uniformly in that the prior rates will no longer be available to any ETP LMM.

Next, the Exchange believes the proposed rule changes do not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 15% of the market share.[28] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [29] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .'' [30] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [31] and paragraph (f) of Rule 19b–4 [32] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeBZX–2026–063 on the subject line.

[28] *Supra* note 3.

[29] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[30] NetCoalition v. SEC, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[31] 15 U.S.C. 78s(b)(3)(A).

[32] 17 CFR 240.19b–4(f).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2026–063. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2026–063 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106093; File No. SR–SAPPHIRE–2026–31]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Sapphire Options Exchange Fee Schedule To Amend Fees and Rebates for Professional Customer Orders for QCC and cQCC Transactions, and Establish a Tiered Fee Structure for Away Market Maker Facilitation of Customer QFOs or cQFOs

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, MIAX Sapphire, LLC (''MIAX Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Sapphire Options Exchange Fee Schedule to: (1) reduce the initiating and contra-side fees applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor; (2) reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor; and (3) establish a tiered fee structure applicable to Trading Floor transactions where a Member firm directs a paired order to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes (all terms described below).

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to: (1) reduce the initiating and contra-side fees applicable to Professional Customer[3] orders for QCC[4] and cQCC[5] transactions on the Exchange's Electronic Book[6] and Trading Floor;[7] (2) reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor; and (3) establish a tiered fee structure applicable to Trading Floor transactions where a Member[8] firm directs a paired QFO[9] or cQFO[10] to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker[11] of the Member firm, depending on certain breakup percentages and minimum sizes.

Proposal To Reduce Initiating and Contra-Side Fees for Professional Customer Orders for QCC and cQCC Transactions

First, the Exchange proposes to amend Sections 1)a)ii)–iii) and 1)c)ii)–

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''Professional Customer'' for the purposes of the Fee Schedule shall mean a Public Customer that is not a Priority Customer. *See* the Definitions section of the Fee Schedule. ''Public Customer'' means a person that is not a broker or dealer in securities. *Id.*

[4] A QCC transaction is comprised of an 'initiating order' to buy (sell) at least 1,000 contracts that is identified as being part of a qualified contingent trade, coupled with a contra-side order to sell (buy) an equal number of contracts. *See* Fee Schedule, Sections 1)a)ii) and 1)c)ii).

[5] A cQCC transaction is comprised of an 'initiating complex order' to buy (sell) where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, coupled with a contra-side complex order or orders to sell (buy) an equal number of contracts. The stock handling fee for the stock leg of cQCC transactions is described in Section 1)a)v) of the Fee Schedule for electronic transactions. The stock handling fee for the stock leg of cQCC transactions is described in Section 1)c)vi) of the Fee Schedule for Trading Floor transactions. *See* Fee Schedule, Sections 1)a)iii) and 1)c)iii).

[6] ''Electronic Book'' means the Exchange's Simple Order Book and Strategy Book. *See* the Definitions section of the Fee Schedule and Exchange Rule 100. The ''Simple Order Book'' is the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 100. The ''Strategy Book'' is the Exchange's electronic book of complex orders. *Id.*

[7] ''Trading Floor'' or ''Floor'' means the physical trading floor of the Exchange located in Miami, Florida. The Trading Floor shall consist of one ''Crowd Area'' or ''Pit'' where Floor Participants will be located and option contracts will be traded. The Crowd Area or Pit shall be marked with specific visible boundaries on the Trading Floor, as determined by the Exchange. A Floor Broker must represent all orders in an ''open outcry'' fashion in the Crowd Area. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[8] *See* Exchange Rule 100.

[9] ''Qualified Floor Order'' or ''QFO'' is a two-sided order with an initiating side and a contra-side. QFOs may also be complex orders as defined in Rule 518(a) (''cQFO'') with no more than the applicable number of legs as determined by the Exchange and communicated to Participants via Regulatory Circular. *See* the Definitions section of the Fee Schedule and Exchange Rule 2040.

[10] ''Complex Qualified Floor Order'' or ''cQFO'' has the meaning ascribed to such term in the Exchange Rules. *See* the Definitions section of the Fee Schedule and Exchange Rule 2040.

[11] ''Away Market Maker'' for the purposes of the Fee Schedule shall mean a non MIAX Sapphire Market Maker. *See* the Definitions section of the Fee Schedule.

iii) of the Fee Schedule to reduce the initiating and contra-side fees applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor. Currently, the Exchange assesses Professional Customers the same initiating and contra-side fee of $0.12 per contract side for QCC and cQCC transactions that occur either on the Exchange's Electronic Book or on the Trading Floor. The Exchange now proposes to reduce this fee such that the Exchange will assess Professional Customers the same initiating and contra-side fee of $0.00 per contract side for QCC and cQCC transactions that occur either on the Exchange's Electronic Book or on the Trading Floor. The purpose of these changes is for business and competitive reasons. The proposed changes will also align the Exchange's fee for such transactions with the similar fee structures in place at other exchanges for both electronic and trading floor QCC (and/or cQCC) transactions for professional customer orders.[12]

Proposal To Reduce Rebates Applicable to Professional Customer Orders for QCC and cQCC Transactions

Next, the Exchange proposes to amend Sections 1)a)ii)–iii) of the Fee Schedule to reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book. Currently, for EEMs[13] entering Professional Customer orders for both QCC and cQCC electronic transactions, the Exchange provides EEMs the following rebates: ($0.07) per contract when the contra-side is a Priority Customer;[14] ($0.17) per contract when the contra-side is a Professional Customer; and ($0.25) per contract when the contra-side is all other market participants (*i.e.,* MIAX Sapphire Market Maker,[15] Away Market Maker, Non-Member Broker-Dealer, and Firm). The Exchange now proposes to reduce these rebates. In particular, the Exchange proposes that for EEMs entering Professional Customer orders for both QCC and cQCC electronic transactions, the Exchange will provide EEMs the following rebates: ($0.00) per contract when the contra-side is a Priority Customer; ($0.00) per contract when the contra-side is a Professional Customer; and ($0.17) per contract when the contra-side is all other market participants (*i.e.,* MIAX Sapphire Market Maker, Away Market Maker, Non-Member Broker-Dealer, and Firm).

Next, the Exchange proposes to amend Sections 1)c)ii)–iii) of the Fee Schedule to reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Trading Floor. Currently, for Floor Brokers[16] entering Professional Customer orders for both QCC and cQCC transactions on the Trading Floor, the Exchange provides Floor Brokers the following rebates: ($0.07) per contract when the contra-side is a Priority Customer or where the Firm met the Firm Fee Cap;[17] ($0.17) per contract when the contra-side is a Professional Customer; and ($0.25) per contract when the contra-side is all other market participants (*i.e.,* Floor Market Maker, Away Market Maker, Broker-Dealer, and Firm), except for Firm origin orders where that Firm met the Firm Fee Cap. The Exchange now proposes to reduce these rebates. In particular, the Exchange proposes that for Floor Brokers entering Professional Customer orders for both QCC and cQCC transactions on the Trading Floor, the Exchange will provide Floor Brokers the following rebates: ($0.00) per contract when the contra-side is a Priority Customer or where the Firm met the Firm Fee Cap; ($0.00) per contract when the contra-side is a Professional Customer; and ($0.17) per contract when the contra-side is all other market participants (*i.e.,* Floor Market Maker, Away Market Maker, Broker-Dealer, and Firm), except for Firm origin orders where that Firm met the Firm Fee Cap.

The purpose of these changes is for business and competitive reasons. The Exchange believes that even with the proposal to remove the rebate payable to an EEM (or Floor Broker) entering a Professional Customer order as part of a QCC or cQCC transaction (electronic or on the Trading Floor) where the contra-side is a Priority Customer or Professional Customer, the Exchange's QCC and cQCC rebates remain competitive with those of other exchanges for Professional Customer orders.[18] The Exchange believes these changes will also align the Exchange's QCC and cQCC rebates with those of other exchanges for Professional Customer orders where the contra-side is a Priority Customer or Professional Customer.[19]

Proposal To Establish a Tiered Fee Structure for Away Market Makers Facilitation of Customer QFOs or cQFOs on the Trading Floor

Next, the Exchange proposes to amend Section 1)c)i) of the Fee Schedule to establish a tiered fee structure applicable to Trading Floor transactions where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes.

For background, the Exchange assesses fees and applies rebates to both executed sides of the paired QFO or cQFO on the Trading Floor. cQFO fees and rebates are per executed side per

[12] *See, e.g.,* BOX Exchange LLC (''BOX'') Fee Schedule, Section IV.D. (assessing professional customers $0.00 per contract for both the agency side and contra-side of QCC transactions); Nasdaq PHLX LLC (''PHLX''), Options 7: Pricing Schedule, Section 3, QCC Transaction Fee (providing that customers and professionals are not assessed a QCC transaction fee and that the QCC transactions fees apply to both electronic and floor QCC orders).

[13] ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[14] ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. *See* Exchange Rule 100, including Interpretation and Policy .01, and the Definitions section of the Fee Schedule.

[15] ''Market Maker'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[16] ''Floor Broker'' means an individual who is registered with the Exchange for the purpose, while on the Trading Floor, of accepting and handling options orders. A Floor Broker must be registered as a Floor Participant prior to registering as a Floor Broker. A Floor Broker may take into his own account, and subsequently liquidate, any position that results from an error made while attempting to execute, as Floor Broker, an order. *See* the Definitions section of the Fee Schedule and Exchange Rule 2015. ''Floor Participant'' means Floor Brokers as defined in Rule 2015 and Floor Market Makers as defined in Rule 2105(b). *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[17] *See* Fee Schedule Section 1)c)vii) for a description of the Firm Fee Cap.

[18] *See, e.g.,* NYSE American LLC (''NYSE American'') Options Fee Schedule, Section I.F. (providing no fee or rebate for customer and professional customer orders where the contra-side is a customer or professional customer in a QCC transaction and providing a rebate of ($0.12) per contract where a floor broker executes a customer or professional customer order where the contra-side is a market maker, firm or broker dealer in a QCC transaction); NYSE Arca Inc. (''NYSE Arca'') Options Fees and Charges, page 7 (providing no fee or rebate for QCC transactions involving all customers and providing a rebate of ($0.16) per contract when a customer order trades against a non-customer).

[19] *Id.*

leg. Floor Broker rebates are only payable on the Floor Brokers' billable sides. The rebates do not apply to Priority Customer, Professional Customer, Firm/Broker-Dealer Facilitating a Priority Customer or Professional Customer, competing Floor Broker orders, Floor Market Maker (sides) executions, and Firm (sides) executions where the Firm Fee Cap threshold has been met for the relevant Clearing Corporation [20] account in the relevant month. Fees for Floor Market Maker volume executed via a Floor Broker are assessed to the Floor Market Maker. Fees and rebates for Floor Broker volume, other than the executing Floor Broker's own orders, entered on behalf of a competing Floor Broker, are assessed to the competing Floor Broker.

Currently, the Exchange assesses a $0.25 per contract fee for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes, for Away Market Maker, Firm, and Broker-Dealer origins. The Exchange does not assess a fee (or provide a rebate) for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes, for Firm and Broker-Dealer origins that are facilitating a Priority Customer or Professional Customer order.

The Exchange now proposes to establish a new row in the table in Section 1)c)i) of the Fee Schedule that will apply to transactions for Away Market Maker facilitation of customer orders for the same Member firm. The Exchange proposes to specify in third explanatory paragraph below the table of fees in Section 1)c)i) of the Fee Schedule that the rates for Away Market Maker Facilitation will apply to any Trading Floor transaction where a Member firm directs a paired order to the Trading Floor, where the agency order is a customer of the Member firm, and where the contra-side of the transaction is the Away Market Maker of the Member firm. Further, the Away Market Maker firm must notify the Exchange for participation in the Away Market Maker Facilitation program.

The Exchange proposes to establish a new table at the end of the explanatory text in Section 1)c)i) of the Fee Schedule, which will be titled ''Away Market Maker Facilitation Breakup Table'' (referred to herein as the ''Breakup Table''). The Breakup Table will provide the proposed tiered fees for transactions where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on the following breakup percentages: 0 to 5% breakup will be assessed a per contract fee of $0.10; greater than 5% to 15% breakup will be assessed a per contract fee of $0.09; greater than 15% to 25% breakup will be assessed a per contract fee of $0.08; greater than 25% to 35% breakup will be assessed a per contract fee of $0.07; greater than 35% to 40% breakup will be assessed a per contract fee of $0.06; and greater than 40% breakup will be assessed a per contract fee of $0.05.

The Exchange also proposes to add the new note ''*'' to the Breakup Table and the corresponding note below table, which will provide as follows:

* These rates only apply to QFO or cQFO orders that are not part of a QCC, cQCC or Strategy transaction. For QFO volume to qualify these rates, the Away Market Maker must facilitate at least 1,000 initiating sides. For cQFO volume to qualify for these rates, the smallest leg must be at least 1,000 initiating sides.

The Exchange also proposes to amend the second sentence in the first paragraph of explanatory text below the tables in Section 1)c)i) of the Fee Schedule to specify that Floor Brokers will not be entitled to receive rebates from Away Market Maker Facilitation transactions. This concept is not new or novel as the Exchange does not provide the otherwise applicable rebate where a Firm or Broker-Dealer facilitates a Priority Customer or Professional Customer QFO or cQFO.[21]

The purpose of these changes is for business and competitive reasons. The Exchange believes that the proposed changes may encourage Members to submit more customer orders to the Trading Floor where the contra-side is the Away Market Maker of the Member firm in order to be assessed the lower tiered fees than would otherwise apply to such transactions. The Exchange believes that this may, in turn, increase open outcry participation, which may promote increased executions on the Trading Floor to the benefit of all Floor Participants. The Exchange also notes that this concept is not new or novel. The Exchange currently offers Firms and Broker-Dealers the opportunity to not be assessed a fee when a Firm or Broker-Dealer facilitates a Priority Customer or Professional Customer QFO or cQFO on the Trading Floor.[22]

The proposed changes are effective beginning August 1, 2026.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[23] in general, and furthers the objectives of Section 6(b)(5) of the Act,[24] in particular, in that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal is consistent with Section 6(b)(4) of the Act [25] because it represents an equitable allocation of reasonable dues, fees and other charges among its Members or issuers using its facilities.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [26]

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based and singly-listed options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of June 2026.[27] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 3.85% of executed volume of multiply-listed equity options for the month of June 2026.[28]

Proposal To Reduce Initiating and Contra-Side Fees for Professional Customer Orders for QCC and cQCC Transactions

The Exchange believes its proposal to reduce the initiating and contra-side fees applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor is reasonable, equitable and not unfairly discriminatory because it may further incentivize Professional

[20] The term ''Clearing Corporation'' means The Options Clearing Corporation. *See* Exchange Rule 100.

[21] *See* Fee Schedule, Section 1)c)i).

[22] *See* Fee Schedule, Section 1)c)i).

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

[25] 15 U.S.C. 78f(b)(4).

[26] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[27] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/* (last visited July 29, 2026).

[28] *See id*.

Customer orders to be submitted as QCC and cQCC transactions. The Exchange believes that this may, in turn, encourage Members to submit more Professional Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange believes the proposed changes are equitable and not unfairly discriminatory because the reduced fees will apply equally to all market participants who provide Professional Customer orders as part of QCC and cQCC transactions either electronically or via the Exchange's Trading Floor. The Exchange also believes the proposed changes are reasonable because the changes will align the Exchange's fee for such transactions with the similar fee structures in place at other exchanges for both electronic and trading floor QCC (and/or cQCC) transactions for professional customer orders.[29]

Proposal To Reduce Rebates Applicable to Professional Customer Orders for QCC and cQCC Transactions

The Exchange believes its proposal to reduce the rebates applicable to Professional Customer orders for QCC and cQCC transactions on the Exchange's Electronic Book and Trading Floor is reasonable, equitable and not unfairly discriminatory because the changes are for business and competitive reasons. The Exchange believes that even with the proposal to remove the rebate payable to an EEM (or Floor Broker) entering a Professional Customer order as part of a QCC or cQCC transaction (electronic or on the Trading Floor) where the contra-side is a Priority Customer or Professional Customer, the Exchange's QCC and cQCC rebates remain competitive with those of other exchanges.[30] The Exchange believes these changes are reasonable because they will align the Exchange's QCC and cQCC rebates with those of other exchanges for Professional Customer orders where the contra-side is a Priority Customer or Professional Customer.

Proposal To Establish a Tiered Fee Structure for Trading Floor Transactions for Away Market Makers Facilitation of Customer Orders

The Exchange believes its proposal to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes is reasonable, equitable and not unfairly discriminatory because these changes are for business and competitive reasons. The Exchange believes that the proposed changes may encourage Members to submit more customer orders to the Trading Floor where the contra-side is the Away Market Maker of the Member firm in order to be assessed the lower tiered fees than would otherwise apply to such transactions. The Exchange believes that this may, in turn, increase open outcry participation, which may promote increased executions on the Trading Floor to the benefit of all Floor Participants. The Exchange believes this proposal is equitably allocated and not unfairly discriminatory because it is open to all Members of the Trading Floor and is not limited to a particular customer segment. Members may submit paired any combination of a paired QFO or cQFO where the contra-side is an Away Market Maker of that Member firm in order to receive the tiered reduced fees, so long as the minimum size threshold is met.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule changes will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposed changes do not impose an undue burden on inter-market competition. The Exchange believes the proposed changes to reduce the fees and rebates applicable to initiating and contra-side Professional Customer orders entered as part of a QCC or cQCC transaction do not impose any burden on inter-market competition because other exchanges have similar fee structures for similar transactions.[31] The Exchange believes the proposed changes to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes does not impose any burden on inter-market competition because other exchanges that offer trading floors can offer similar incentives to their market participants.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The Exchange believes that the proposed changes reflect this competitive environment because the changes modify the Exchange's fees and rebates in a manner designed to continue to incent participants to direct trading interest to the Exchange (both electronically and on the Trading Floor), to provide liquidity and to attract additional order flow. To the extent that Away Market Makers are encouraged to facilitate more Priority Customer and Professional Customer QFOs and cQFOs, all Exchange market participants stand to benefit from the improved market quality and increased opportunities for price improvement. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

Intra-Market Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional QCC and cQCC liquidity from Professional Customers (both electronically and on the Trading Floor), thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders.

The proposed change to establish a tiered fee structure where a Member firm directs a paired QFO or cQFO to the Trading Floor, the agency order is a customer of the Member firm, and the contra-side of the transaction is the Away Market Maker of the Member firm, depending on certain breakup percentages and minimum sizes is

[29] *See supra* note 12.

[30] *See supra* note 18.

[31] *See supra* notes 12 and 18.

designed to attract additional customer order flow to the Trading Floor. Greater liquidity benefits all market participants on the Exchange and increased order flow would increase opportunities for execution of other trading interest. The proposed changes would apply and be available to all similarly-situated market participants that execute open outcry on the Trading Floor, and, accordingly, the proposed changes would not impose a disparate burden on competition among market participants on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[32] and Rule 19b–4(f)(2)[33] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2026–31 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2026–31. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–SAPPHIRE–2026–31 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16693 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

[32] 15 U.S.C. 78s(b)(3)(A)(ii).

[33] 17 CFR 240.19b–4(f)(2).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106107; File No. SR–EMERALD–2026–21]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Emerald Options Exchange Fee Schedule Regarding the Routing Fee Table

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Emerald Options Exchange Fee Schedule (''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/emerald-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the exchange grouping of options exchanges within the routing fee table in Section 1)b) of the Fee Schedule, Fees for Customer Orders Routed to Another Options Exchange, to add applicable Member[3] orders routed to MX2 LLC (''MX2'') and Investors Exchange LLC (''IEX''), in anticipation of the launch of MX2 Options and IEX Options, the new options trading facilities of MX2 and IEX.[4] The Exchange also proposes to update the routing fee table to reflect the name change of ''Nasdaq BX Options'' to ''Nasdaq Texas Options.''[5]

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Securities Exchange Act Release Nos. 104152 (September 30, 2025), 90 FR 47867 (October 2, 2025) (SR–MX2–2025–01) (Self-Regulatory Organizations; MX2 LLC; Order Granting Approval to a Proposed Rule Change To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called MX2 Options); 103998 (September 18, 2025), 90 FR 45861 (September 23, 2025)(SR–IEX–2025–02)(Self-Regulatory Organizations; Investors Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 3, To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called IEX Options).

[5] Nasdaq BX, Inc. (''Nasdaq BX'') recently converted from a corporation organized under the

Continued

Additionally, the Exchange proposes to update the exchange groupings of options exchanges within the routing fee table, specifically to remove ''MIAX Pearl'' from the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.25 fee tier and amend the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.40 fee tier to add ''MIAX Pearl.''

Currently, the Exchange assesses routing fees based upon (i) the origin type of the order; (ii) whether or not it is an order for standard option classes in the Penny Interval Program [6] (''Penny classes'') or an order for standard option classes which are not in the Penny Interval Program (''Non-Penny classes'') (or other explicitly identified classes); and (iii) to which away market it is being routed. This assessment practice is identical to the routing fees assessment practice currently utilized by the Exchange's affiliates, Miami International Securities Exchange, LLC (''MIAX''), MIAX PEARL, LLC (''MIAX Pearl''), and MIAX Sapphire, LLC (''MIAX Sapphire''). This is also similar to the methodology utilized by the Cboe BZX Exchange, Inc. (''Cboe BZX Options''), a competing options exchange, in assessing routing fees. Cboe BZX Options has exchange groupings in its fee schedule, similar to those of the Exchange, whereby several exchanges are grouped into the same category, dependent upon the order's origin type and whether it is a Penny or Non-Penny class.[7]

In anticipation of the launch of the options trading facilities of MX2 and IEX in the second half of 2026, the Exchange has determined to amend the exchange groupings of options exchanges within the routing fee table to include MX2 and IEX and the anticipated associated costs of routing customer orders to MX2 and IEX for execution. In determining to amend its routing fee table to determine which category MX2 and IEX belong to the Exchange took into account anticipated transaction fees and rebates assessed by the away markets to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market.

The Exchange's proposal to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is a conforming and non-substantive change in nature designed to ensure that the Exchange's Fee Schedule accurately reflects the name of the away market orders are being routed to and executed on.

As a result of conducting a periodic review of the current transaction fees charged by away markets the Exchange has determined to remove ''MIAX Pearl'' from the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.25 fee tier and amend the ''Routed, Public Customer that is not a Priority Customer, Non-Penny Program'' $1.40 fee tier to add ''MIAX Pearl.'' This change is being made as MIAX Pearl recently amended its fee schedule and increased the transaction fee per contract for orders in Non-Penny classes in Professional capacities which remove liquidity.[8]

The impact of these proposed changes will be increased routing options for Members, a clearer Fee Schedule, and a Fee Schedule that better reflects the associated costs. The Exchange notes that routing through the Exchange is optional and that Members will continue to be able to choose where to route applicable Member orders. Under this proposed change, the Exchange will not amend the fees associated with the exchange groupings. This proposal merely seeks to add MX2 and IEX to the exchange groupings, amend the name of a market, and amend the exchange groupings as described in the routing fee table below.

According, with the proposed change, the routing fee table will be as follows:

Description	Fees
Routed, Priority Customer, Penny Program, to: NYSE American, Cboe, Cboe EDGX Options, Nasdaq PHLX (except SPY), Nasdaq MRX, MIAX Sapphire	$0.15
Routed, Priority Customer, Penny Program, to: BOX	0.30
Routed, Priority Customer, Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, Nasdaq ISE, NOM, Nasdaq PHLX (SPY only), MIAX Emerald, MIAX Pearl, Nasdaq Texas Options, MEMX, MX2, IEX Options	0.65
Routed, Priority Customer, Non-Penny Program, to: NYSE American, BOX, Cboe, Cboe EDGX Options, Nasdaq PHLX, Nasdaq MRX, MIAX Sapphire	0.15
Routed, Priority Customer, Non-Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, MIAX Pearl, Nasdaq GEMX, NOM, Nasdaq Texas Options, Nasdaq ISE, MEMX, MX2, IEX Options	1.00
Routed, Public Customer that is not a Priority Customer, Penny Program, to: NYSE American, NYSE Arca Options, Cboe BZX Options, BOX, Cboe, Cboe C2, Cboe EDGX Options, Nasdaq GEMX, Nasdaq ISE, Nasdaq MRX, MIAX, MIAX Pearl, NOM, Nasdaq PHLX, Nasdaq Texas Options, MEMX, MIAX Sapphire, MX2, IEX Options	0.65
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: MIAX, NYSE American, Cboe, Nasdaq PHLX, Cboe EDGX Options, NOM	1.00
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe C2, BOX, MIAX Sapphire	1.15
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE Arca Options, Nasdaq GEMX, Nasdaq MRX	1.25
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe BZX Options, Nasdaq ISE, Nasdaq Texas Options, MEMX, MX2, IEX Options, MIAX Pearl	1.40

The purpose of the proposal is to adjust and amend the routing fee groups for orders routed to other exchanges to better reflect the associated costs for that routed execution in Penny and Non-Penny classes as determined by the fees

laws of the state of Delaware to a limited liability company (''LLC'') organized under the laws of the state of Texas and changed its name to ''Nasdaq Texas, LLC.'' (''Nasdaq Texas''). *See* Securities Exchange Act Release No. 104736 (January 29, 2026), 91 FR 4980 (February 3, 2026) (SR–BX–2026–005) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Repeal the Restated Certificate of Incorporation and Adopt a Certificate of Formation and Company Agreement.).

[6] *See* Exchange Rule 510(b).

[7] *See* Cboe U.S. Options Fee Schedules, BZX Options, effective July 1, 2026 ''Fee Codes and Associated Fees,'' at *https://www.cboe.com/us/options/membership/fee_schedule/bzx/.*

[8] *See* MIAX Pearl Options Exchange Fee Schedule (effective July 1, 2026), Transaction Fees, *available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Options_Fee_Schedule_07012026.pdf*; *see also* Securities Exchange Act Release No. 105894 (July 13, 2026), 91 FR 43694 (July 16, 2026) (SR–PEARL–2026–34) (Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule To Amend Certain Fees and Rebates Applicable to Transactions in Non-Penny Classes for All Origins).

and rebates at the executing exchange. In determining to adjust and amend its groupings, the Exchange took into account anticipated transaction fees assessed by the away market to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market. The Exchange uses unaffiliated routing brokers to route orders to the away markets; the costs associated with the use of these services are included in the routing fees specified in the Fee Schedule. This routing fees structure is not only similar to the Exchange's affiliates, MIAX, MIAX Pearl, and MIAX Sapphire, but is also comparable to the structure in place at Cboe BZX Options,[9] a competing options exchange. The Exchange's routing fee structure approximates the Exchange's anticipated costs associated with routing orders to away markets. The per-contract transaction fee amount associated with each grouping closely approximates the Exchange's all-in cost (plus an additional, non-material amount) [10] to execute that corresponding contract(s) at that corresponding exchange. The Exchange notes that in determining whether to include certain exchanges in a certain groupings of options exchanges in the routing fee table, the Exchange considered the transaction fees and rebates assessed by away markets, and determined to amend the grouping of exchanges that assess transaction fees for routed orders within a similar range. This same logic and structure applies to all of the groupings in the routing fee table. By utilizing the same structure that is utilized by the Exchange's affiliates, MIAX, MIAX Pearl, and MIAX Sapphire, the Exchange's Members will be assessed routing fees in a similar manner. The Exchange believes that this structure will minimize any confusion as to the method of assessing routing fees between the three exchanges. The Exchange notes that its affiliates, MIAX, MIAX Pearl, and MIAX Sapphire, will file to make the same proposed routing fee changes contained herein.

[9] The Cboe BZX Options fee schedule is similar to the Exchange's Fee Schedule in that it has exchange groupings, whereby several exchanges are grouped into the same category. *See supra* note 7.

[10] This amount is to cover de minimis differences/changes to away market fees (*i.e.,* minor increases or decreases) that would not necessitate a fee filing by the Exchange to re-categorize the away exchange into a different grouping. Routing fees are not intended to be a profit center for the Exchange and the Exchange's target regarding routing fees and expenses is to be as close as possible to net neutral.

Implementation

The proposed rule changes will become effective on August 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [11] in general, and furthers the objectives of Section 6(b)(4) of the Act [12] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [13] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the routing fee table of exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed change seeks to recoup costs that will be incurred by the Exchange when routing customer orders to MX2 and IEX on behalf of Members and does so in the same manner to all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees and rebates assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed additions of MX2 and IEX to the exchange groupings would increase the routing options available to Members. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) to execute the corresponding contract at the corresponding exchange.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4).

[13] 15 U.S.C. 78f(b)(5).

The Exchange believes that the proposed change is equitable and not unfairly discriminatory because all Members' orders in Penny classes and Non-Penny classes routed to MX2 and IEX will be uniformly assessed the corresponding fee.

The proposed non-substantive change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Act and comply and enforce compliance with the provisions of the Act by its Members and persons associated with its Members, because it would ensure that the Exchange's Fee Schedule accurately reflects the correct name of the away market to which orders are being routed to and executed on and therefore contribute to the orderly operation of the Exchange by adding clarity and transparency. In addition, the proposed change would reduce potential investor and market participant confusion and therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that investors and market participants can more easily navigate and understand the Exchange's Fee Schedule. The proposed change would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased transparency and clarity, thereby reducing potential confusion.

The Exchange believes that the proposed changes to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed changes to the routing fee table exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed changes seek to recoup costs that are incurred by the Exchange when routing orders for Public Customers that are not Priority Customers to away markets on behalf of Members and does so in the same manner for all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily

includes transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed re-categorization of certain exchange groupings would enable the Exchange to better reflect the costs and fees associated with routing orders to other exchanges for execution.

The Exchange places away markets in the fee tier grouping that best approximates the Exchange's costs and fees to route the orders in that segment to that away market. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) [14] to execute the corresponding contract at the corresponding exchange. The Exchange believes its tier structure represents the best approach to reflect the costs and fees associated with routing and executing orders on other exchanges. As noted above, this routing fee structure is comparable to the structure in place on at least one other competing options exchange, Cboe BZX Options.[15]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed changes to add MX2 and IEX to the routing fee table will impose any burden on intramarket competition. Rather, the Exchange believes that the proposal will promote competition by increasing the available away markets to which Members can route orders to.

The proposed change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is not intended to address competitive issues but rather is concerned solely with updating the Exchange's Fee Schedule to reflect the name change of Nasdaq BX to Nasdaq Texas.

The Exchange's proposed re-categorization of certain exchange groupings is intended to enable the Exchange to recover the costs it incurs to route orders to away markets. The costs to the Exchange to route orders to away markets for execution primarily includes the transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange does not believe that this proposal imposes any unnecessary burden on competition because it seeks to better reflect the costs and fees incurred by the Exchange when routing orders to away markets on behalf of Members and notes that at least one other options exchange has a similar routing fee structure.[16]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[17] and Rule 19b–4(f)(2) [18] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–EMERALD–2026–21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–EMERALD–2026–21. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–EMERALD–2026–21 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

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[14] *See supra* note 10.

[15] *See supra* notes 7 and 9.

[16] *See supra* note 7.

[17] 15 U.S.C. 78s(b)(3)(A)(ii).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36297; File No. 812–16052]

Northern Lights Fund Trust and Ocean Park Asset Management, LLC

August 13, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 18(f)(1), 18(i), 22(d) and 22(e) of the Act and rule 22c–1 under the Act and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

SUMMARY OF APPLICATION: Applicants request an order (''Order'') that would permit a registered open-end management investment company to offer one class of exchange-traded shares that operates as an exchange-traded fund (an ''ETF Class,'' and such shares, ''ETF Shares'') and one or more classes of shares that are not exchange-traded (each such class, a ''Mutual Fund Class,'' and such shares, ''Mutual Fund Shares,'' and each such fund, a ''Multi-Class ETF Fund''). The Order would provide Multi-Class ETF Funds with two broad categories of relief: (i) the relief necessary to permit standard

exchange-traded fund (''ETF'') operations consistent with Rule 6c-11 under the Act (''ETF Operational Relief'') and (ii) the relief necessary for a fund to offer an ETF Class and one or more Mutual Fund Classes (''ETF Class Relief'').

APPLICANTS: Northern Lights Fund Trust and Ocean Park Asset Management, LLC.

FILING DATES: The application was filed on July 8, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on September 8, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Timothy Burdick, Northern Lights Fund Trust, 225 Pictoria Drive, Suite 450, Cincinnati, OH 45246; Andrew Davalla, Esq., Thompson Hine LLP, *andrew.davalla@thompsonhine.com.*

FOR FURTHER INFORMATION CONTACT: Thomas Ahmadifar, Branch Chief, or Deepak T. Pai, Senior Counsel at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' application, filed July 8, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system.

The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.* You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16765 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106091; File No. SR–MIAX–2026–32]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule To Modify Certain Volume Thresholds for the Priority Customer Rebate Program

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Options Exchange Fee Schedule (''Fee Schedule'') to amend the Priority Customer Rebate Program (''PCRP'') (defined below) table to modify certain volume thresholds.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 1)a)iii) of the Fee Schedule to modify the PCRP table to amend certain volume thresholds.

Background

Pursuant to the PCRP, the Exchange credits each Member [3] the per contract amount set forth in the PCRP table in Section 1)a)iii) of the Fee Schedule, as applicable, resulting from each Priority Customer [4] order transmitted by that Member which is executed electronically on the Exchange in all multiply-listed option classes (with certain exclusions described below), provided the Member meets certain percentage thresholds in a month as described in the PCRP table. The volume thresholds are calculated based on the percentage of national customer volume in multiply-listed options classes listed on MIAX entered and executed over the course of the month but does not include, in simple or complex as applicable, QCC [5] and cQCC Orders,[6] Priority Customer-to-Priority Customer Orders, C2C [7] and cC2C

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Exchange Rule 100.

[5] A Qualified Contingent Cross Order is comprised of an originating order to buy or sell at least 1,000 contracts, that is identified as being part of a qualified contingent trade, as that term is defined in Interpretations and Policies .01, coupled with a contra-side order or orders totaling an equal number of contracts. *See* Exchange Rule 516(j).

[6] A Complex Qualified Contingent Cross or ''cQCC'' Order is comprised of an originating complex order to buy or sell where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, as defined in Rule 516, Interpretations and Policies .01, coupled with a contra-side complex order or orders totaling an equal number of contracts. Trading of cQCC Orders is governed by Rule 515(h)(4). *See* Exchange Rule 518(b)(6).

[7] A Customer Cross Order is comprised of a Priority Customer Order to buy and a Priority

Continued

Orders,[8] PRIME[9] and cPRIME[10] AOC Responses, PRIME and cPRIME Contra-side Orders, PRIME and cPRIME Orders for which both the Agency and Contra-side Order are Priority Customers, and executions related to contracts that are routed to one or more exchanges in connection with the Options Order Protection and Locked/Crossed Market Plan referenced in MIAX Rule 1400.[11]

Pursuant to the PCRP, Priority Customer volume for transactions in simple, PRIME Agency, complex, and cPRIME Agency are aggregated to determine the appropriate volume tier threshold applicable to each transaction. Volume is recorded for, and credits are delivered to, the Member that submits the order to the Exchange. All fees and rebates are per contract per leg. MIAX aggregates the contracts resulting from Priority Customer Orders[12] transmitted and executed electronically on MIAX from Members and Affiliates[13] for purposes of the thresholds described in the PCRP table.

Further, the Exchange established the cPRIME Agency Order Break-up Table in Section 1)a)iii) of the Fee Schedule which provides a tiered agency credit rate for cPRIME Agency Orders for Priority Customers dependent upon the break-up percentage, unless the Member is eligible to receive the alternative cPRIME Agency Order Credit amount for cPRIME Agency Orders in Tier 4 of the PRCP, in which case those orders will earn a credit of $0.12 per contract.[14]

The cPRIME Agency Order Break-up Table provides a per contract agency credit based upon the break-up percentage of the order. Specifically, orders with a break-up % of 0–10% earn a credit of $0.05 per contract; orders with a break-up percentage greater than 10% to, and including 20%, earn a per contract credit of $0.06; orders with a break-up percentage greater than 20% to, and including 30%, earn a per contract credit of $0.07; orders with a break-up percentage greater than 30% to, and including 40%, earn a per contract credit of $0.08; orders with a break-up percentage greater than 40% will earn a per contract credit of $0.10, unless the Member is eligible to receive the alternative cPRIME Agency Order Credit amount for cPRIME Agency Orders in Tier 4 of the PCRP, in which case the order will earn a per contract credit of $0.12.

Proposal

Currently, the PCRP table provides the following volume thresholds applicable to Priority Customer Orders, which are based on a percentage of national customer volume in multiply-listed options classes listed on MIAX during the relevant month: 0.00% to 0.50% in tier 1; above 0.50% to 1.50% in tier 2; above 1.50% to 2.00% in tier 3; above 2.00% to 3.50% in tier 4; and above 3.50% in tier 5.[15] The Exchange now proposes to amend the PCRP table to modify the volume thresholds in tiers 3 and 4. With the proposed changes, the volume threshold applicable to tier 3 will now be above 1.50% to 1.90% and the volume threshold applicable to tier 4 will now be above 1.90% to 3.50%. The Exchange does not propose to amend any of the rebates applicable to the PCRP or any other volume thresholds.

The purpose of the proposed changes to certain volume thresholds for the PCRP is for business and competitive reasons in order to attract additional Priority Customer volume from Members. The Exchange believes that the proposed change to reduce the minimum volume threshold in tier 4 of the PCRP may encourage Members to submit more Priority Customer Orders to achieve the higher rebates in tier 4, which may lead to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

Implementation

The proposed changes are effective beginning August 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[16] in general, and furthers the objectives of Section 6(b)(4) of the Act[17] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[18] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Commission has repeatedly expressed its preference for competition

Customer Order to sell at the same price and for the same quantity. *See* Exchange Rule 516(i).

[8] A Complex Customer Cross or ''cC2C'' Order is comprised of one Priority Customer complex order to buy and one Priority Customer complex order to sell at the same price and for the same quantity. Trading of cC2C Orders is governed by Rule 515(h)(3). *See* Exchange Rule 518(b)(5).

[9] PRIME is a process by which a Member may electronically submit for execution (''Auction'') an order it represents as agent (''Agency Order'') against principal interest, and/or an Agency Order against solicited interest. *See* Exchange Rule 515A(a).

[10] A Complex Prime or ''cPRIME'' Order is a complex order (as defined in Rule 518(a)(5)) that is submitted for participation in a cPRIME Auction. *See* Exchange Rule 518(b)(7).

[11] *See* Fee Schedule, Section 1)a)iii).

[12] The term ''Priority Customer Order'' means an order for the account of a Priority Customer. *See* Exchange Rule 100.

[13] For purposes of the MIAX Options Fee Schedule, the term ''Affiliate'' means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, (''Affiliate''), or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An ''Appointed Market Maker'' is a MIAX Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an ''Appointed EEM'' is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Market Maker) that has been appointed by a MIAX Market Maker, pursuant to the following process. A MIAX Market Maker appoints an EEM and an EEM appoints a MIAX Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to *membership@miaxglobal.com* no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange's acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. *See* Fee Schedule, Section 1)a)i), note 1.

[14] Under the PCRP, any Member or its Affiliate that qualifies for Priority Customer Rebate Program tier 4 and executes Priority Customer standard, non-paired complex volume at least equal to or greater than three (3) times their Priority Customer cPRIME Agency Order volume, on a monthly basis, will receive a credit of $0.12 per contract for cPRIME Agency Orders. *See* Fee Schedule, Section 1)a)iii), note ''**''.

[15] The Exchange added tier 5 to the PCRP pursuant to a rule filing with the Securities and Exchange Commission, which filing was made effective for July 1, 2026. *See* Securities Exchange Act Release No. 105906 (July 14, 2026), 91 FR 44924 (July 17, 2026) (SR–MIAX–2026–30). The Exchange now proposes a minor non-substantive edit to footnote ''**'' in Section 1)a)iii) of the Fee Schedule to add the words ''or higher'' following the words ''tier 4.'' The purpose of this change is to take into account the new tier 5 of the PCRP such that Members that achieve tier 4 or higher (*i.e.,* tier 5) would also be able to achieve the higher $0.12 per contract rebate pursuant to the cPRIME Agency Order Break-up Table.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78f(b)(5).

over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [19]

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based and singly-listed options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of June 2026.[20] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 8.28% of executed volume of multiply-listed equity options for the month of June 2026.[21]

The Exchange believes its proposal to amend certain volume thresholds in the PCRP is reasonable, equitable and not unfairly discriminatory because it may further incentivize Priority Customer Orders to the Exchange by lowering the minimum volume threshold in tier 4. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer Orders for Members to achieve the higher tier 4 rebates, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange believes the proposed change to the PCRP is equitable and not unfairly discriminatory because it will apply equally to all market participants who provide Priority Customer Orders in various segments.

The Exchange believes its proposal to amend footnote ''**'' in Section 1)a)iii) of the Fee Schedule to add the words ''or higher'' following the words ''tier 4'' is reasonable, equitable and not unfairly discriminatory. This is a non-substantive change to take into account the new tier 5 of the PCRP, which was added for July 1, 2026, such that Members that achieve tier 4 or higher (*i.e.,* tier 5) would also be able to achieve the higher $0.12 per contract rebate pursuant to the cPRIME Agency Order Break-up Table.[22] This proposed change will add clarity to the Fee Schedule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposal will impose any burden on intra-market competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange believes its proposal to amend certain volume threshold in the PCRP will not impose any burden on intra-market competition. Instead, the Exchange believes this proposed change will promote competition because it will further incentivize Priority Customer Orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer Orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

Inter-Market Competition

The Exchange does not believe that the proposed changes will impose any burden on inter-market competition and the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of June 2026.[23] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 8.28% of executed volume of multiply-listed equity options for the month of June 2026.[24]

In such an environment, the Exchange must continually adjust its rebates and tiers to remain competitive with other options exchanges. Because competitors are free to modify their own fees and tiers in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's tiers in a manner that encourages market participants to continue to provide liquidity and to send order flow to the Exchange.

* * * * *

The Exchange believes its proposal to amend footnote ''**'' in Section 1)a)iii) of the Fee Schedule to add the words ''or higher'' following the words ''tier 4'' will not impose any burden on intra-market or inter-market competition because the proposed change is not intended to address any competitive issue; rather it is to add clarity to the Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[25] and Rule 19b–4(f)(2) [26] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or

[19] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[20] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/* (last visited July 29, 2026).

[21] *See id.*

[22] *See* supra note 15.

[23] *See supra* note 20.

[24] *See id.*

[25] 15 U.S.C. 78s(b)(3)(A)(ii).

[26] 17 CFR 240.19b–4(f)(2).

• Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2026–32 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2026–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2026–32 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16692 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106108; File No. SR–PEARL–2026–35]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule Regarding the Routing Fee Table

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Pearl Options Exchange Fee Schedule (''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the exchange grouping of options exchanges within the routing fee table in Section (1)(b) of the Fee Schedule, Fees for Customer Orders Routed to Another Options Exchange, to add applicable Member[3] orders routed to MX2 LLC (''MX2'') and Investors Exchange LLC (''IEX''), in anticipation of the launch of MX2 Options and IEX Options, the new options trading facilities of MX2 and IEX.[4] The Exchange also proposes to update the routing fee table to reflect the name change of ''Nasdaq BX Options'' to ''Nasdaq Texas Options.''[5]

Currently, the Exchange assesses routing fees based upon (i) the origin type of the order; (ii) whether or not it is an order for standard option classes in the Penny Interval Program[6] (''Penny classes'') or an order for standard option classes which are not in the Penny Interval Program (''Non-Penny classes'') (or other explicitly identified classes); and (iii) to which away market it is being routed. This assessment practice is identical to the routing fees assessment practice currently utilized by the Exchange's affiliates, Miami International Securities Exchange, LLC (''MIAX''), MIAX Emerald, LLC (''MIAX Emerald''), and MIAX Sapphire, LLC (''MIAX Sapphire''). This is also similar to the methodology utilized by the Cboe BZX Exchange, Inc. (''Cboe BZX Options''), a competing options exchange, in assessing routing fees. Cboe BZX Options has exchange groupings in its fee schedule, similar to those of the Exchange, whereby several exchanges are grouped into the same category, dependent upon the order's origin type and whether it is a Penny or Non-Penny class.[7]

In anticipation of the launch of the options trading facilities of MX2 and IEX in the second half of 2026, the Exchange has determined to amend the exchange groupings of options exchanges within the routing fee table to include MX2 and IEX and the anticipated associated costs of routing customer orders to MX2 and IEX for execution. In determining to amend its routing fee table to determine which category MX2 and IEX belong to the Exchange took into account anticipated transaction fees and rebates assessed by the away markets to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market.

[27] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[4] *See* Securities Exchange Act Release Nos. 104152 (September 30, 2025), 90 FR 47867 (October 2, 2025) (SR–MX2–2025–01) (Self-Regulatory Organizations; MX2 LLC; Order Granting Approval to a Proposed Rule Change To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called MX2 Options); 103998 (September 18, 2025), 90 FR 45861 (September 23, 2025)(SR–IEX–2025–02)(Self-Regulatory Organizations; Investors Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 3, To Adopt Rules To Govern the Trading of Options on the Exchange for a New Facility Called IEX Options).

[5] Nasdaq BX, Inc. (''Nasdaq BX'') recently converted from a corporation organized under the laws of the state of Delaware to a limited liability company (''LLC'') organized under the laws of the state of Texas and changed its name to ''Nasdaq Texas, LLC.'' (''Nasdaq Texas''). *See* Securities Exchange Act Release No. 104736 (January 29, 2026), 91 FR 4980 (February 3, 2026) (SR–BX–2026–005) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Repeal the Restated Certificate of Incorporation and Adopt a Certificate of Formation and Company Agreement.).

[6] *See* Exchange Rule 510(c).

[7] *See* Cboe U.S. Options Fee Schedules, BZX Options, effective July 1, 2026 ''Fee Codes and Associated Fees,'' at *https://www.cboe.com/us/options/membership/fee_schedule/bzx/.*

The Exchange's proposal to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is a conforming and non-substantive change in nature designed to ensure that the Exchange's Fee Schedule accurately reflects the name of the away market orders are being routed to and executed on.

The impact of these proposed changes will be increased routing options for Members, a clearer Fee Schedule, and a Fee Schedule that better reflects the associated costs. The Exchange notes that routing through the Exchange is optional and that Members will continue to be able to choose where to route applicable Member orders. Under this proposed change, the Exchange will not amend the fees associated with the exchange groupings. This proposal merely seeks to add MX2 and IEX to the exchange groupings, amend the name of a market, and amend the exchange groupings as described in the routing fee table below.

According, with the proposed change, the routing fee table will be as follows:

Description	Fees
Routed, Priority Customer, Penny Program, to: NYSE American, Cboe, Cboe EDGX Options, Nasdaq PHLX (except SPY), Nasdaq MRX, MIAX Sapphire	$0.15
Routed, Priority Customer, Penny Program, to: BOX	0.30
Routed, Priority Customer, Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, Nasdaq ISE, NOM, Nasdaq PHLX (SPY only), MIAX Emerald, Nasdaq Texas Options, MEMX, MX2, IEX Options	0.65
Routed, Priority Customer, Non-Penny Program, to: NYSE American, BOX, Cboe, Cboe EDGX Options, MIAX, Nasdaq PHLX, Nasdaq MRX, MIAX Sapphire	0.15
Routed, Priority Customer, Non-Penny Program, to: NYSE Arca Options, Cboe BZX Options, Cboe C2, Nasdaq GEMX, NOM, MIAX Emerald, Nasdaq [BX]Texas Options, Nasdaq ISE, MEMX, MX2, IEX Options	1.00
Routed, Public Customer that is not a Priority Customer, Penny Program, to: NYSE American, NYSE Arca Options, Cboe BZX Options, BOX, Cboe, Cboe C2, Cboe EDGX Options, Nasdaq GEMX, Nasdaq ISE, Nasdaq MRX, MIAX Emerald, MIAX, NOM, Nasdaq PHLX, Nasdaq Texas Options, MEMX, MIAX Sapphire, MX2, IEX Options	0.65
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE American, MIAX, Cboe, Nasdaq PHLX, Cboe EDGX Options, NOM	1.00
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe C2, BOX, MIAX Sapphire	1.15
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: NYSE Arca Options, Nasdaq GEMX, Nasdaq MRX, MIAX Emerald	1.25
Routed, Public Customer that is not a Priority Customer, Non-Penny Program, to: Cboe BZX Options, Nasdaq ISE, Nasdaq Texas Options, MEMX, MX2, IEX Options	1.40

The purpose of the proposal is to adjust and amend the routing fee groups for orders routed to other exchanges to better reflect the associated costs for that routed execution in Penny and Non-Penny classes as determined by the fees and rebates at the executing exchange. In determining to adjust and amend its groupings, the Exchange took into account anticipated transaction fees assessed by the away market to which the Exchange routes orders, as well as the Exchange's anticipated clearing costs, administrative, regulatory, and technical costs associated with routing orders to an away market. The Exchange uses unaffiliated routing brokers to route orders to the away markets; the costs associated with the use of these services are included in the routing fees specified in the Fee Schedule. This routing fees structure is not only similar to the Exchange's affiliates, MIAX, MIAX Emerald, and MIAX Sapphire, but is also comparable to the structure in place at Cboe BZX Options,[8] a competing options exchange. The Exchange's routing fee structure approximates the Exchange's anticipated costs associated with routing orders to away markets. The per-contract transaction fee amount associated with each grouping closely approximates the Exchange's all-in cost (plus an additional, non-material amount) [9] to execute that corresponding contract(s) at that corresponding exchange. The Exchange notes that in determining whether to include certain exchanges in a certain groupings of options exchanges in the routing fee table, the Exchange considered the transaction fees and rebates assessed by away markets, and determined to amend the grouping of exchanges that assess transaction fees for routed orders within a similar range. This same logic and structure applies to all of the groupings in the routing fee table. By utilizing the same structure that is utilized by the Exchange's affiliates, MIAX, MIAX Emerald, and MIAX Sapphire, the Exchange's Members will be assessed routing fees in a similar manner. The Exchange believes that this structure will minimize any confusion as to the method of assessing routing fees between the three exchanges. The Exchange notes that its affiliates, MIAX, MIAX Emerald, and MIAX Sapphire, will file to make the same proposed routing fee changes contained herein.

Implementation

The proposed rule changes will become effective on August 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [10] in general, and furthers the objectives of Section 6(b)(4) of the Act [11] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [12] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the exchange groupings of options exchanges within

[8] The Cboe BZX Options fee schedule is similar to the Exchange's Fee Schedule in that it has exchange groupings, whereby several exchanges are grouped into the same category. *See supra* note 7.

[9] This amount is to cover de minimis differences/changes to away market fees (*i.e.,* minor increases or decreases) that would not necessitate a fee filing by the Exchange to re-categorize the away exchange into a different grouping. Routing fees are not intended to be a profit center for the Exchange and the Exchange's target regarding routing fees and expenses is to be as close as possible to net neutral.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78f(b)(5).

the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed change to add the new options facilities of MX2 and IEX to the routing fee table of exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed change seeks to recoup costs that will be incurred by the Exchange when routing customer orders to MX2 and IEX on behalf of Members and does so in the same manner to all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees and rebates assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed additions of MX2 and IEX to the exchange groupings would increase the routing options available to Members. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) to execute the corresponding contract at the corresponding exchange.

The Exchange believes that the proposed change is equitable and not unfairly discriminatory because all Members' orders in Penny classes and Non-Penny classes routed to MX2 and IEX will be uniformly assessed the corresponding fee.

The proposed non-substantive change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' would enable the Exchange to continue to be so organized as to have the capacity to carry out the purposes of the Act and comply and enforce compliance with the provisions of the Act by its Members and persons associated with its Members, because it would ensure that the Exchange's Fee Schedule accurately reflects the correct name of the away market to which orders are being routed to and executed on and therefore contribute to the orderly operation of the Exchange by adding clarity and transparency. In addition, the proposed change would reduce potential investor and market participant confusion and therefore remove impediments to and perfect the mechanism of a free and open market and a national market system by ensuring that investors and market participants can more easily navigate and understand the Exchange's Fee Schedule. The proposed change would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from the increased transparency and clarity, thereby reducing potential confusion.

The Exchange believes that the proposed changes to the exchange groupings of options exchanges within the routing fee table furthers the objectives of Section 6(b)(4) of the Act and is reasonable, equitable and not unfairly discriminatory because the proposed change will continue to apply in the same manner to all Members that are subject to routing fees. The Exchange believes the proposed changes to the routing fee table exchange groupings furthers the objectives of Section 6(b)(5) of the Act and is designed to promote just and equitable principles of trade and is not unfairly discriminatory because the proposed changes seek to recoup costs that are incurred by the Exchange when routing orders for Public Customers that are not Priority Customers to away markets on behalf of Members and does so in the same manner for all Members that are subject to routing fees. The costs to the Exchange to route orders to away markets for execution primarily includes transaction fees assessed by the away markets to which the Exchange routes orders, in addition to the Exchange's clearing costs, administrative, regulatory and technical costs. The Exchange believes that the proposed re-categorization of certain exchange groupings would enable the Exchange to better reflect the costs and fees associated with routing orders to other exchanges for execution.

The Exchange places away markets in the fee tier grouping that best approximates the Exchange's costs and fees to route the orders in that segment to that away market. The per-contract transaction fee amount associated with each grouping approximates the Exchange's all-in cost (plus an additional, non-material amount) [13] to execute the corresponding contract at the corresponding exchange. The Exchange believes its tier structure represents the best approach to reflect the costs and fees associated with routing and executing orders on other exchanges. As noted above, this routing fee structure is comparable to the structure in place on at least one other competing options exchange, Cboe BZX Options.[14]

[13] *See supra* note 9.

[14] *See supra* notes 7 and 8.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed changes to add MX2 and IEX to the routing fee table will impose any burden on intramarket competition. Rather, the Exchange believes that the proposal will promote competition by increasing the available away markets to which Members can route orders to.

The proposed change to rename ''Nasdaq BX Options'' to ''Nasdaq Texas Options'' is not intended to address competitive issues but rather is concerned solely with updating the Exchange's Fee Schedule to reflect the name change of Nasdaq BX to Nasdaq Texas.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[15] and Rule 19b–4(f)(2) [16] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments:

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

• Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2026–35 on the subject line.

Paper Comments:

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2026–35. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2026–35 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16699 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36295; File No. 812–16048]

Stone Point Credit Income Fund and Stone Point Credit Income Adviser LLC

August 12, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from Sections 18(a)(2), 18(c), 18(i), and 61(a) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end investment companies that have elected to be regulated as business development companies to issue multiple classes of shares with varying sales loads and asset-based distribution and/or service fees.

APPLICANTS: Stone Point Credit Income Fund and Stone Point Credit Income Adviser, LLC.

FILING DATES: The application was filed on July 1, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on September 7, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Brian J. Rooder, c/o Stone Point Credit, 20 Horseneck Lane, Greenwich, Connecticut 06830, with copies to: William J. Bielefeld and Matthew J. Carter, Dechert LLP, 1900 K Street, Northwest, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Rachel Loko, Senior Special Counsel at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' Application, dated July 1, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.* You may also call the SEC's Office of Investor Education and Advocacy at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16700 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106095; File No. SR–PEARL–2026–36]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule To Amend Certain Fees and Rebates Applicable to Transactions in Non-Penny Classes for Certain Origins

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 31, 2026, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Pearl Options Exchange Fee Schedule (''Fee Schedule'') to amend certain fees and rebates applicable to transactions in non-Penny Classes (defined below) for certain origins.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 1(a) of the Fee Schedule to: (1) amend the MIAX Pearl Market Maker [3] origin table to reduce Maker rebates in certain tiers in non-Penny Classes and increase Taker fees in all tiers in non-Penny Classes; and (2) amend the Non-Priority Customer, Firm, BD, and Non-MIAX Pearl Market Maker origin (collectively referred to herein as the ''Professional origin'') [4] table to reduce Maker rebates in certain tiers in non-Penny Classes and increase Taker fees in all tiers in non-Penny Classes.

Background

The Exchange currently assesses transaction rebates and fees to all market participants which are based upon the total monthly volume executed by the Member [5] on MIAX Pearl in the relevant, respective origin type (not including Excluded Contracts) [6] (as the numerator) expressed as a percentage of (divided by) TCV [7] (as the denominator). In addition, the per contract transaction rebates and fees are applied retroactively to all eligible volume for that origin type once the respective threshold tier has been reached by the Member. The Exchange aggregates the volume of Members and their Affiliates.[8] Members that place resting liquidity, *i.e.,* orders resting on the Book [9] of the MIAX Pearl System,[10] are paid the specified ''maker'' rebate (each a ''Maker''), and Members that execute against resting liquidity are assessed the specified ''taker'' fee (each a ''Taker''). For opening transactions and ABBO [11] uncrossing transactions, per contract transaction rebates and fees are waived for all market participants. Finally, Members are assessed lower transaction fees and receive lower rebates for order executions in standard option classes in the Penny Interval Program [12] (''Penny Classes'') than for order executions in standard option classes which are not in the Penny Interval Program (''non-Penny Classes''), where Members are assessed higher transaction fees and receive higher rebates.

Proposal To Amend the Market Maker Origin Table To Reduce Maker Rebates in Certain Tiers and Increase Taker Fees in All Tiers in Non-Penny Classes

The Exchange proposes to amend the Market Maker origin table to reduce the Maker rebates in certain tiers and increase the Taker fees in all tiers for Market Maker orders in non-Penny Classes that trade against all origins. Currently, pursuant to the Market Maker origin table, Market Makers qualify for the Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 1 for non-Penny Classes if the Market Maker executes above 0.00% to at least 0.20% of TCV. Market Makers can qualify for the Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 2 for non-Penny Classes by achieving at least one of the following three volume calculations: (i) if the Market Maker executes above 0.20% to at least 0.50% of TCV; or (ii) if the Market Maker executes above 0.55% in SPY/QQQ/IWM classes; or (iii) if the Market Maker executes above 0.30% in SPY/QQQ/IWM classes when adding liquidity to the Exchange.[13]

[3] The term ''Market Maker'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[4] The Exchange notes that certain terms are not specifically defined in the Rulebook, including away Non-Priority Customer, Firm, BD, and Non-MIAX Pearl Market Make.

[5] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[6] The term ''Excluded Contracts'' means any contracts routed to an away market for execution. *See* the Definitions section of the Fee Schedule.

[7] The term ''TCV'' means total consolidated volume calculated as the total national volume in those classes listed on MIAX Pearl for the month for which the fees apply, excluding consolidated volume executed during the period time in which the Exchange experiences an ''Exchange System Disruption'' (solely in the option classes of the affected Matching Engine (as defined below)). *See* the Definitions section of the Fee Schedule. The term ''Exchange System Disruption'' means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hours or more, during trading hours. *Id.* A ''Matching Engine'' is a part of the MIAX Pearl electronic system that processes options orders and trades on a symbol-by-symbol basis. Some Matching Engines will process option classes with multiple root symbols, and other Matching Engines may be dedicated to one single option root symbol (for example, options on SPY may be processed by one single Matching Engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated Matching Engine. A particular root symbol may not be assigned to multiple Matching Engines. *Id.* The Exchange believes that it is reasonable and appropriate to select two consecutive hours as the amount of time necessary to constitute an Exchange System Disruption, as two hours equates to approximately 1.4% of available trading time per month. The Exchange notes that the term ''Exchange System Disruption'' and its meaning have no applicability outside of the Fee Schedule, as it is used solely for purposes of calculating volume for the threshold tiers in the Fee Schedule.

[8] The term ''Affiliate'' means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An ''Appointed Market Maker'' is a MIAX Pearl Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an ''Appointed EEM'' is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Pearl Market Maker) that has been appointed by a MIAX Pearl Market Maker, pursuant to the following process. A MIAX Pearl Market Maker appoints an EEM and an EEM appoints a MIAX Pearl Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to *membership@miaxglobal.com* no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange's acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. *See* the Definitions section of the Fee Schedule.

[9] The term ''Book'' means the electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[10] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[11] The term ''ABBO'' means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Exchange Rule 1400(g)) and calculated by the Exchange based on market information received by the Exchange from OPRA. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[12] *See* Securities Exchange Act Release No. 88992 (June 2, 2020), 85 FR 35142 (June 8, 2020) (SR–PEARL–2020–06).

[13] In tier 2 for the Market Maker origin, the alternative volume criteria (above 0.55% in SPY/QQQ/IWM) is calculated based on the total monthly volume executed by the Market Maker collectively in SPY, QQQ, and IWM options on MIAX Pearl in the relevant origin type, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY/QQQ/IWM TCV (as the denominator). In Tier 2 for the Market Maker origin, the alternative volume criteria (above 0.30% in SPY/QQQ/IWM when adding liquidity) is calculated based on the total monthly volume that added liquidity executed by the Market Maker collectivity in SPY, QQQ, and IWM options on MIAX Pearl in the relevant origin type, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY/QQQ/IWM TCV (as the denominator). *See* Fee Schedule, Section (1)(a) (explanatory notes section below the tables).

Market Makers can qualify for the Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 3 for non-Penny Classes by achieving at least one of the following two volume calculations: (i) if the Market Maker executes above 0.50% to at least 0.85% of TCV; or (ii) if the Market Maker executes above 1.10% in SPY when adding liquidity.[14] Market Makers can qualify for the Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 4 for non-Penny Classes by achieving at least one of the following two volume calculations: (i) if the Market Maker executes above 0.85% to at least 1.25% of TCV; or (ii) if the Market Maker executes above 2.50% in SPY.[15] Market Makers can qualify for the Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 5 for non-Penny Classes if the Market Maker executes above 1.25% to at least 1.40% of TCV. Finally, Market Makers can qualify for the Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 6 if the Market Maker executes above 1.40% of TCV.

The Exchange now proposes to amend the Market Maker origin table to: (i) reduce the Maker rebates from ($0.80) to ($0.55) per contract for tiers 1 and 2 for Market Maker orders in non-Penny Classes that trade against all origins; (ii) reduce the Maker rebate from ($0.80) to ($0.60) per contract for tier 3 for Market Maker orders in non-Penny Classes that trade against all origins; (iii) reduce the Maker rebate from ($0.80) to ($0.65) per contract for tier 4 for Market Maker orders in non-Penny Classes that trade against all origins; (iv) reduce the Maker rebate from ($0.80) to ($0.70) per contract for tier 5 for Market Maker orders in non-Penny Classes that trade against all origins; and (v) increase the Taker fees from $1.21 to $1.23 per contract for all tiers for Market Maker orders in non-Penny Classes that trade against all origins. The Exchange does not propose to amend any of the volume threshold criteria.

The purpose of the proposed changes to the Market Maker origin Maker rebates and Taker fees for non-Penny Classes is for business and competitive reasons. The Exchange believes that even with the proposed decrease to the Maker rebates for Market Maker orders in non-Penny Classes in certain tiers and the proposed increase to the Taker fees for Market Maker orders in non-Penny Classes in all tiers, the Exchange's Maker rebates and Taker fees for Market Maker orders in non-Penny Classes will remain competitive with the rebates offered and fees assessed by other exchanges for similar transactions.[16]

Proposal To Amend the Professional Origin Table To Decrease Maker Rebates in Certain Tiers and Increase Taker Fees in All Tiers in Non-Penny Classes

The Exchange proposes to amend the Professional origin table to decrease the Maker rebates in certain tiers for Professional orders in non-Penny Classes that trade against all origins and increase the Taker fees in all tiers for Professional orders in non-Penny Classes that trade against all origins. The Professional origin table provides certain volume criteria thresholds for all tiers that are based upon the total monthly volume executed in all option classes by a Professional on MIAX Pearl as a percentage of TCV. Currently, Professionals can qualify for the following rebates and fees for transactions in non-Penny Classes: (i) Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 1 if the Professional executes above 0.00% to at least 0.20% of TCV; (ii) Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 2 if the Professional executes above 0.20% to at least 0.50% of TCV; (iii) Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 3 if the Professional executes above 0.50% to at least 0.85% of TCV; (iv) Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 4 if the Professional executes above 0.85% to at least 1.25% of TCV; (v) Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 5 if the Professional executes above 1.25% to at least 1.50% of TCV; and (vi) Maker rebate of ($0.80) per contract or Taker fee of $1.21 per contract in tier 6 if the Professional executes above 1.50%.

The Exchange now proposes to amend the Professional origin table to: (i) decrease the Maker rebates from ($0.80) to ($0.55) per contract for tiers 1 and 2 for Professional orders in non-Penny Classes that trade against all origins; (ii) decrease the Maker rebate from ($0.80) to ($0.60) per contract for tier 3 for Professional orders in non-Penny Classes that trade against all origins; (iii) decrease the Maker rebate from ($0.80) to ($0.65) per contract for tier 4 for Professional orders in non-Penny Classes that trade against all origins; (iv) decrease the Maker rebate from ($0.80) to ($0.70) per contract for tier 5 for Professional orders in non-Penny Classes that trade against all origins; and (v) increase the Taker fees from $1.21 to $1.23 per contract for all tiers for Professional orders in non-Penny Classes that trade against all origins. The Exchange does not propose to amend any of the volume threshold criteria.

The purpose of the proposed changes to the Professional origin Maker rebates and Taker fees for non-Penny Classes is for business and competitive reasons. The Exchange believes that even with the proposed decrease to the Maker rebates for Professional orders in non-Penny Classes in certain tiers and proposed increase to the Taker fees for Professional orders in non-Penny Classes in all tiers that the Exchange's Maker rebates and Taker fees will remain competitive with the rebates offered and fees assessed by at least one other exchange for similar transactions.[17]

Implementation

The proposed changes are effective beginning August 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend the Fee Schedule is consistent with Section 6(b) of the Act[18] in general, and furthers the objectives of

[14] In tier 3 for the Market Maker origin, the alternative volume criteria (above 1.10% in SPY when adding liquidity) is calculated based on the total monthly volume that added liquidity executed by the Market Maker solely in SPY options on MIAX Pearl, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY TCV (as the denominator). Market Makers that do not qualify for the alternative volume criteria in tier 3 will receive the tier 3 rates in the Market Maker origin table in Penny Classes and non-Penny Classes. Members will receive the highest tier based on the thresholds achieved. *See* Fee Schedule, Section (1)(a), footnote ✦.

[15] In tier 4 for the Market Maker origin, the alternative volume criteria (above 2.50% in SPY) is calculated based on the total monthly volume executed by the Market Maker solely in SPY options on MIAX Pearl in the relevant origin type, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY TCV (as the denominator). *See* Fee Schedule, Section 1)a) (explanatory notes section below the tables).

[16] *See* Cboe BZX Exchange, Inc. (''BZX'') Options Fee Schedule, Transactions fee section (providing market makers a rebate ranging from ($0.40) to ($0.88) per contract for adding liquidity to BZX Options in non-penny classes); *see also* The Nasdaq Stock Market LLC (''Nasdaq''), Options 7: Pricing Schedule, Section 2, Nasdaq Options Market—Fees and Rebates (assessing NOM Market Makers a fee of $1.25 per contract for removing liquidity from Nasdaq in non-penny classes).

[17] *See* BZX Options Fee Schedule, Transactions fee section (providing professionals, firms/BDs/JBOs, and away market makers a rebate ranging from ($0.30) to ($0.65) per contract for adding liquidity to BZX Options in non-penny classes); *see also* Nasdaq Texas, LLC (''Nasdaq Texas''), Options 7: Section 2 NTX Options Market Fees and Rebates (assessing non-customers and firms a fee of $1.25 per contract for removing liquidity from Nasdaq Texas in non-penny classes).

[18] 15 U.S.C. 78f(b).

Section 6(b)(4) of the Act,[19] in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange Members and issuers and other persons using its facilities, and 6(b)(5) of the Act,[20] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based and singly-listed options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of June 2026.[22] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 1.84% of executed volume of multiply-listed equity options for the month of June 2026.[23]

Proposals To Amend the Market Maker and Professional Origins To Decrease Maker Rebates in Certain Tiers and Increase Taker Fees in All Tiers in Non-Penny Classes

The Exchange believes the proposal to amend the Market Maker and Professional origins to reduce the Maker rebates in certain tiers in non-Penny Classes is reasonable, equitably allocated, and not unfairly discriminatory because the purpose of the proposed changes to the Maker rebates is for business and competitive reasons. Even with the proposed decrease, the Exchange believes the proposed Maker rebates will not discourage Market Maker and Professional order flow. The Exchange notes that despite the changes proposed herein, the Exchange's proposed Maker rebates for the Market Maker and Professional origin for tiers 1, 2, 3, 4, and 5 in non-Penny Classes remains competitive with the Maker rebates for similar executions that are charged by other equity options exchanges.[24]

The Exchange believes the proposal to amend the Market Maker and Professional origins to increase Taker fees to $1.23 per contract in all tiers in non-Penny Classes is reasonable, equitably allocated, and not unfairly discriminatory because the purpose of the proposed changes to the Taker fees is for business and competitive reasons. Even with the proposed increase, the Exchange believes the proposed Taker fees will not discourage Market Maker and Professional order flow. The Exchange notes that despite the changes proposed herein, the Exchange's proposed Taker fee of $1.23 per contract for the Market Maker and Professional origin for all tiers in non-Penny Classes remains competitive with (and lower than) the Taker fee for similar executions that are charged by other equity options exchanges.[25]

The Exchange believes that even with the proposed decrease to the Maker rebates for Market Maker and Professional orders in non-Penny Classes in certain tiers and proposed increase to the Taker fees for Market Maker and Professional orders in non-Penny Classes in all tiers, the Exchange's Maker rebates and Taker fees for Market Maker and Professional transactions in non-Penny Classes will continue to encourage such market participants to trade on the Exchange. In turn, this should continue to contribute to a deep and liquid market to the benefit of all market participants and allow the Exchange to maintain its attractiveness as a trading venue. The Exchange further believes the proposed decreased Maker rebates and increased Taker fees are equitable and not unfairly discriminatory because the proposed decreased rebates and increased fees will apply equally to all Market Makers and Professionals transacting in non-Penny Classes.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that any of the proposed changes will impose any burden on intra-market competition. The Exchange believes that its proposal to reduce Maker rebates in certain tiers and increase Taker fees in all tiers for Market Maker and Professional transactions in non-Penny Classes will not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because these changes are for business and competitive reasons. The Exchange notes that despite the changes proposed herein, the Exchange's rebates and fees remain competitive with the maker rebates offered and the taker fees assessed by other exchanges for similar executions in non-penny classes by those exchanges for their market maker and professional customers.[26]

Inter-Market Competition

The Exchange does not believe that the proposed changes will impose any burden on inter-market competition and the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of June 2026.[27] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 1.84% of executed volume of multiply-listed equity options for the month of June 2026.[28]

In such an environment, the Exchange must continually adjust its rebates and tiers to remain competitive with other options exchanges. Because competitors are free to modify their own fees and tiers in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely

[19] 15 U.S.C. 78f(b)(4).

[20] 15 U.S.C. 78f(b)(1) and (b)(5).

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[22] *See* the ''Market Share'' section of the Exchange's website, *https://www.miaxglobal.com/* (last visited July 29, 2026).

[23] *See id.*

[24] *See supra* notes 16 and 17.

[25] *See supra* notes 16 and 17.

[26] *See supra* notes 16 and 17.

[27] *See supra* note 22.

[28] *See id.*

limited. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's fees and rebates in a manner that encourages market participants to continue to provide liquidity and to send order flow to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[29] and Rule 19b–4(f)(2)[30] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2026–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2026–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2026–36 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

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[29] 15 U.S.C. 78s(b)(3)(A)(ii).

[30] 17 CFR 240.19b–4(f)(2).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106078; File No. SR–CBOE–2026–068]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

August 12, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2026, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Fees Schedule to amend certain transaction fees for Cboe Magnificent 10 Index options (''MGTN options''), amend certain LMM Incentive Programs, and eliminate certain other LMM Incentive Programs. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/options/regulation/rule_filings/cone/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule, effective August 3, 2026.

MGTN Option Transaction Fee Changes

The Exchange proposes to amend certain fees for transactions in options on the Cboe Magnificent 10 Index (''MGTN options'') as follows:

- Fee code GO, appended to all Customer orders in MGTN options, assess a fee of $0.16 per contract. The Exchange proposes to decrease this fee to $0.10 per contract to these orders.
- Fee code GW, appended to all Market-Maker orders in MGTN options contra Customer that add liquidity and that are executed electronically, currently assesses no fee per contract. The Exchange proposes to assess a fee of $0.10 per contract to these orders.

Amend GTH VIX/VIXW LMM Incentive Program

The Exchange proposes to amend its Fees Schedule in connection with the GTH VIX/VIXW LMM Incentive Program by generally decreasing the quote width requirements. By way of background, the GTH VIX/VIXW LMM Incentive Program provides a rebate to Trading Permit Holders with an LMM appointment to the incentive program that meet certain quoting standards in a month. The Exchange notes that meeting or exceeding the quoting standards (both current and as proposed) in VIX and VIXW series to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

receive the applicable rebate is optional for LMMs appointed to the program. Particularly, an LMM appointed to the incentive program is eligible to receive the corresponding rebate if it satisfies the applicable quoting standards, which the Exchange believes encourages appointed LMMs to provide liquidity in VIX and VIXW during GTHs. The Exchange may consider other exceptions to the program's quoting standards based on demonstrated legal or regulatory requirements or other mitigating circumstances. In calculating whether an LMM appointed to the incentive program meets the program's quoting standards each month, the Exchange excludes from the calculation in that month the business day in which the LMM missed meeting or exceeding the quoting standards in the highest number of series.

The current GTH VIX/VIXW LMM Incentive Program provides that, if the appointed LMM provides continuous electronic quotes during GTH (*i.e.,* from 7:15 p.m. CST to 8:25 a.m. CST the next day) that meet or exceed the VIX and VIXW quoting standards [3] in at least 95% of each of the VIX and VIXW series, 90% of the time in a given month, the LMM will receive a rebate for that month in the amount of $30,000 for VIX and $5,000 for VIXW (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month) for that month. The Exchange proposes to amend the minimum percentage of series in which an appointed LMM must provide continuous electronic quotes during GTH that meet or exceed the basic quoting standards in a given month to receive a rebate for that month, from 95% to 90%.

Amend GTH SPX LMM Incentive Programs

The Exchange proposes to amend the GTH1 and GTH2 SPX/SPXW LMM Incentive Programs. By way of background, each of the GTH1 and GTH2 SPX/SPXW LMM Incentive Program provides a rebate to Trading Permit Holders with an LMM appointment to the incentive program that meet certain quoting standards in a month. The Exchange notes that meeting or exceeding the quoting standards (both current and as proposed) in each program to receive the applicable rebate is optional for LMMs appointed to the program. Particularly, an LMM appointed to each incentive program is eligible to receive the corresponding rebate if it satisfies the applicable quoting standards, which the Exchange believes encourage appointed LMMs to provide liquidity in SPX and SPXW during GTH. The Exchange may consider other exceptions to the program's quoting standards based on demonstrated legal or regulatory requirements or other mitigating circumstances. In calculating whether an LMM appointed to the incentive program meets the program's quoting standards each month, the Exchange excludes from the calculation in that month the business day in which the LMM missed meeting or exceeding the quoting standards in the highest number of series.

The GTH1 SPX/SPXW LMM Incentive Program provides that if the appointed LMM provides continuous electronic quotes during GTH from 7:15 p.m. CST to 2:00 a.m. CST (''GTH1'') that meet or exceed the program's quoting standards [4] in at least 85% of the SPX and SPXW series 90% of the time in a given month, the LMM will receive a rebate for that month in the amount of $25,000 (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month). Separately, an LMM may earn an additional $15,000 compensation for satisfying the Mid Term (23 days to 37 days to expiry) quoting requirements.

Similarly, the GTH2 SPX/SPXW LMM Incentive Program provides that if the appointed LMM provides continuous electronic quotes during GTH from 2:00 a.m. CST to 8:25 a.m. CST (''GTH2'') that meet or exceed the program's quoting standards [5] in at least 85% of the SPX and SPXW series 90% of the time in a given month, the LMM will receive a rebate for that month in the amount of $25,000 (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month). Separately, an LMM may earn an additional $15,000 compensation for satisfying the Mid Term (23 days to 37 days to expiry) quoting requirements

The Exchange proposes to adopt a new set of quoting standards for the GTH1 SPX/SPXW LMM Incentive Program as follows (new proposed widths are denoted with an asterisk).

Premium level	Expiring		Near Term		Mid Term		Mid-Long Term		Long Term	
	7 days or less		8 days to 22 days		23 days to 37 days		38 to 180 days		181 to 500 days	
	Width	Size	Width	Size	Width	Size	Width	Size	Width	Size
VIX Value at Prior Close < 20										
$0.00—$5.00	*$0.30	15	$0.40	15	*$0.30	10	*$0.50	5	*$1.00	5
$5.01—$15.00	*0.50	15	0.70	15	*0.45	10	*1.00	5	*2.00	5
$15.01—$50.00	*1.00	10	*1.20	15	*1.00	10	*1.50	5	*3.00	5
$50.01—$100.00	*5.00	5	*2.50	10	*2.00	5	*2.50	5	*3.50	5
$100.01—$200.00	*12.00	1	6.00	5	3.00	5	*3.00	5	*5.00	5
Greater than $200.00	*18.00	1	10.00	1	10.00	1	12.00	1	*30.00	1
VIX Value at Prior Close ≥ 20 and < 30										
$0.00—$5.00	*0.40	10	*0.50	10	*0.50	5	*0.60	5	*1.50	5
$5.01—$15.00	*0.60	10	*0.80	10	*0.80	5	*1.20	5	*3.00	5
$15.01—$50.00	*2.00	10	*2.00	10	*2.00	5	*2.00	5	*4.00	5
$50.01—$100.00	*5.00	5	*3.00	5	*3.00	5	*3.00	5	*6.00	5
$100.01—$200.00	*10.00	1	*8.00	1	*4.00	1	*5.00	5	*10.00	5
Greater than $200.00	*20.00	1	12.00	1	12.00	1	*15.00	1	*40.00	1
VIX Value at Prior Close ≥ 30										
$0.00—$5.00	2.000 [sic]	5	1.20	5	1.00	5	1.00	5	3.00	5
$5.01—$15.00	3.00	5	2.70	5	2.20	5	3.00	5	5.00	5
$15.01—$50.00	5.00	5	5.50	5	4.00	5	4.00	5	8.00	5
$50.01—$100.00	*8.00	5	12.00	5	8.00	5	5.00	3	10.00	1
$100.01—$200.00	20.00	1	15.00	5	10.00	5	15.00	1	18.00	1
Greater than $200.00	*25.00	1	*25.00	1	20.00	1	30.00	1	*50.00	1

[3] Located in the ''GTH VIX/LMM Incentive Program'' table in the Exchange's Fees Schedule.

[4] Located in the ''GTH1 SPX/SPXW LMM Incentive Program'' table in the Fees Schedule.

[5] Located in the ''GTH2 SPX/SPXW LMM Incentive Program'' table in the Fees Schedule.

The Exchange also proposes to adopt a new set of quoting standards for the GTH2 SPX/SPXW LMM Incentive Program as follows (new proposed widths are denoted with an asterisk):

Premium level	Expiring		Near Term		Mid Term		Mid-Long Term		Long Term	
	7 days or less		8 days to 22 days		23 days to 37 days		38 to 180 days		181 to 500 days	
	Width	Size	Width	Size	Width	Size	Width	Size	Width	Size
VIX Value at Prior Close < 20										
$0.00—$5.00	*$0.25	25	$0.40	15	$0.25	15	*$0.40	5	$1.00	5
5.01—15.00	*0.50	20	*0.50	20	0.40	15	*1.00	10	1.50	5
15.01—50.00	*1.00	15	*1.00	15	*0.80	10	*1.50	10	2.00	5
50.01—100.00	*5.00	10	*2.00	10	*1.50	5	*2.00	10	3.00	5
100.01—200.00	*10.00	1	5.00	5	3.00	5	*2.50	5	5.00	5
Greater than 200.00	*15.00	1	8.00	1	8.00	1	*10.00	1	30.00	1
VIX Value at Prior Close ≥ 20 and < 30										
0.00—5.00	*0.40	15	*0.50	10	*0.50	10	*0.60	5	*1.50	5
5.01—15.00	*0.60	15	*0.80	15	0.80	10	*1.20	5	3.00	5
15.01—50.00	*2.00	10	*2.00	10	*2.00	5	*2.00	5	*4.00	5
50.01—100.00	*5.00	10	*3.00	10	*3.00	5	*3.00	5	*6.00	5
100.01—200.00	*10.00	1	8.00	5	*4.00	1	*5.00	5	10.00	5
Greater than 200.00	*18.00	1	*10.00	1	10.00	1	*15.00	1	*40.00	1
VIX Value at Prior Close ≥ 30										
0.00—5.00	0.90	10	1.00	10	0.80	5	1.00	5	3.00	5
5.01—15.00	2.50	10	2.50	10	2.00	5	3.00	5	4.00	5
15.01—50.00	4.00	10	5.00	10	3.50	5	4.00	5	8.00	5
50.01—100.00	*8.00	5	10.00	5	8.00	5	4.50	3	10.00	1
100.01—200.00	*12.00	1	12.00	5	10.00	5	15.00	1	18.00	1
Greater than 200.00	25.00	1	25.00	1	20.00	1	30.00	1	*50.00	1

The Exchange also proposes to increase the rebate offered by each of the GTH1 and GTH2 SPX/SPXW LMM Incentive Program for meeting the heightened quoting standards in a given month from $25,000 to $35,000.

Eliminate Certain LMM Incentive Programs

The Exchange proposes to eliminate the RTH XSP LMM Incentive Program, the GTH1 XSP LMM Incentive Program, and the GTH2 XSP LMM Incentive Program (the ''XSP LMM Incentive Programs'') from the Fees Schedule. By way of background, each XSP LMM Incentive Program provides a rebate to TPHs with LMM appointments to the respective incentive program that meet certain quoting standards in the applicable series in a month. Meeting or exceeding the quoting standards in an XSP LMM Incentive Program to receive the applicable rebate is optional for an LMM appointed to a program. An LMM appointed to an incentive program is eligible to receive the corresponding rebate if it satisfies the applicable quoting standards. The Exchange is not required to offer the XSP LMM Incentive Programs and no longer desires to do so, as of August 3, 2026. As such, the Exchange proposes deleting each of the XSP LMM Incentive Program details set forth in the Fees Schedule.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

MGTN Option Transaction Fee Changes

The Exchange believes the proposed changes to certain transaction fees for MGTN options are reasonable, equitable, and not unfairly discriminatory. The proposed fees are within the range of amounts assessed for the Exchange's other index products. Additionally, the Exchange believes it is reasonable to charge different fee amounts to different user types in the manner proposed because the proposed fees are consistent with the price differentiation that exists today for MGTN options and other index products. The proposed fees are also less than fees for these user types of index options listed for trading on other exchanges.[9]

Amend GTH VIX/VIXW LMM Incentive Program

The Exchange believes the proposed change to the percentage of series in which an appointed LMM must provide continuous electronic quotes of VIX and VIXW series during GTH that meet or exceed the quoting standards for at least 90% of the time in a given month is reasonable. The proposed quoting standards are overall reasonably designed to continue to encourage LMMs appointed to the incentive programs to provide significant liquidity in these options, which benefits investors overall by providing more trading opportunities, tighter spreads, and added market transparency and price discovery. The proposed reduced percentage of series required to meet or exceed the quoting standards does not represent a significant departure from the current percentage threshold. The Exchange believes the slight easing of the standard for appointed LMMs to satisfy the requirements to receive the

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] *See, e.g.,* Nasdaq ISE, LLC (''ISE'') Options 7, Section 5 (which imposes a transaction fee of $0.75 for Market-Maker orders and $0.50 or $0.75 for Market-Maker orders).

rebate continues to incentivize quoting activity in VIX/VIXW during GTH and may possible incentive increased quoting activity. Particularly, by slightly reducing the percentage of series in which LMMs must meet or exceed the quoting standards, the Exchange believe the proposed change will encourage appointed LMMs to post more aggressive quotes in VIX/VIXW options in order to meet the quoting standards and receive the rebate offered under the incentive program, resulting in tighter spreads and increased liquidity to the benefit of investors. The Exchange believes the proposed reduced percentage of series requirement remains generally aligned with that of other LMM Incentive Programs, as the required series percentage is only marginally changed to incentive an increase in quoting activity.

The Exchange believes that the proposed change to the GTH VIX/VIX LMM Incentive Program is equitable and not unfairly discriminatory. Specifically, the proposed changes will apply equally to any TPHs with LMM appointments to the GTH VIX/VIXW LMM Incentive Program that seek to meet the program's quoting standards in order to receive the rebates offered under each respective program. The Exchange notes that meeting or exceeding the quoting standards (both current and as proposed) in VIX and VIXW series to receive the applicable rebate is optional for LMMs appointed to the program. The Exchange additionally notes that, if an LMM appointed to the GTH VIX/VIXW LMM Incentive Program does not satisfy the corresponding heightened quoting standard for any given month, then it simply will not receive the rebate offered by the respective program for that month.

Regarding the GTH VIX/VIXW LMM Incentive Program, generally, the Exchange believes it is reasonable, equitable, and not unfairly discriminatory to continue to offer these financial incentives, including as amended, to LMMs appointed to the program, because it benefits all market participants trading in the corresponding products during GTH. This incentive program encourages the LMMs appointed to the program to satisfy the quoting standards, which may increase liquidity and provide more trading opportunities and tighter spreads. Indeed, the Exchange notes that these LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade VIX/VIXW options during GTH, which can lead to increased volume, providing for robust markets. The Exchange ultimately offers the LMM Incentive Program, as amended, to sufficiently incentivize the appointed LMMs to provide key liquidity and active markets in VIX/VIXW during the GTH session. The Exchange further believes this incentive program, as amended, will continue to encourage increased quoting to add liquidity in VIX/VIXW, thereby protecting investors and the public interest. The Exchange also notes that an LMM appointed to an incentive program may undertake added costs each month to satisfy that heightened quoting standards, such as having to purchase additional logical connectivity.

Amend GTH SPX LMM Incentive Programs

The Exchange believes it is reasonable to amend the quoting standards for each of the GTH SPX LMM Incentive Programs. The proposed quoting standards are overall reasonably designed to continue to encourage LMMS appointed to the incentive programs to provide significant liquidity in these options, which benefits investors overall by providing more trading opportunities, tighter spreads, and added market transparency and price discovery. The proposed changes adopt generally tighter width standards for each program. The Exchange believes that by adopting tighter width standards, the proposed rule change offers LMMs appointed to the programs a more challenging opportunity, thus further incentive, to strive to meet the quoting standards to receive the rebate on their SPX/SPXW options orders. As noted above, the proposed quoting standards are overall reasonably designed to continue to encourage LMMs appointed to the incentive programs to provide significant liquidity in these options, which benefits investors overall by providing more trading opportunities, tighter spreads, and added market transparency and price discovery. The Exchange also notes that the proposed amended quoting standards do not represent a significant departure from each program's current quote width and size standards and remain generally aligned with the current heightened standards in the programs.

The Exchange believes the proposed rule change to increase the amount of the rebate paid to an appointed LMM in each of the GTH SPX LMM Incentive Programs if the LMM satisfies the quoting standards is reasonable. The Exchange notes that LMMs appointed to the respective programs will continue to receive a monthly rebate. The Exchange believes the proposed rebate amounts are reasonably designed to continue to incentivize an LMM appointed to the respective program to meet the applicable quoting standards for SPX and SPXW options during the applicable GTH session, thereby providing liquid and active markets, which facilitates tighter spreads, increased trading opportunities, and overall enhanced market quality to the benefit of all market participants. The Exchange further believes the proposed increase rebate is reasonable and equitable because the amount continues to be in-line with the amounts of other rebates the Exchange offers through other LMM Incentive Programs. Additionally, the Exchange believes the increased rebate amount is reasonable and equitable given the proposed changes described above to generally tighten the widths for SPX and SPXW will make it more challenging for an LMM to meet the quoting standards to receive the rebate. The Exchange believes the proposed increase in the rebate amount may provide LMMs appointed to the programs with further incentive to strive to meet the narrower quote widths to receive the rebate, which benefits investors overall by providing more trading opportunities, tighter spreads, and added market transparency and price discovery.

The Exchange believes that the proposed changes to the GTH SPX LMM Incentive Programs are equitable and not unfairly discriminatory. Specifically, the proposed changes will apply equally to any TPHs with LMM appointments to the GTH SPX LMM Incentive Programs, as applicable, that seek to meet the programs' quoting standards to receive the rebates offered under each respective program. The Exchange additionally notes that, if an LMM appointed to either of the GTH SPX LMM Incentive Programs does not satisfy the corresponding quoting standard for any given month, then it simply will not receive the rebate offered by the respective program for that month.

Regarding the GTH SPX LMM Incentive Programs, generally, the Exchange believes it is reasonable, equitable, and not unfairly discriminatory to continue to offer these financial incentives, including as amended, to LMMs appointed to the programs, because it benefits all market participants trading in the corresponding products during GTH1 and GTH2. These incentive programs encourage the LMMs appointed to such programs to satisfy the applicable quoting standards, which may increase liquidity and provide more trading opportunities and tighter spreads.

Indeed, the Exchange notes that these LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade SPX/SPXW options during GTH, which can lead to increased volume, providing for robust markets. The Exchange ultimately offers the GTH SPX LMM Incentive Programs, as amended, to sufficiently incentivize the appointed LMMs to provide key liquidity and active markets in SPX/SPXW during the applicable GTH session. The Exchange further believes these incentive programs, as amended, will continue to encourage increased quoting to add liquidity in SPX/SPXW, thereby protecting investors and the public interest. The Exchange also notes that an LMM appointed to an incentive program may undertake added costs each month to satisfy that heightened quoting standards, such as having to purchase additional logical connectivity.

Eliminate Certain LMM Incentive Programs

The Exchange believes the proposed rule change to eliminate the XSP LMM Incentive Programs is reasonable, equitable, and not unfairly discriminatory. As noted above, the Exchange is not required to offer the XSP LMM Incentive Programs and no longer desires to do so. The proposed change is reasonable, as the Exchange wishes to reallocate resources to its other pricing programs and potentially develop other pricing programs that may benefit market participants. The Exchange also believes the proposed change is equitable and is not unfairly discriminatory because it applies to all Market-Makers equally. While no Market-Maker will be or continue to be eligible for the eliminated XSP LMM Incentive Programs, all Market-Makers remain eligible to participate in the Exchange's other pricing programs, including other LMM Incentive Programs offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

MGTN Option Transaction Fee Changes

The Exchange does not believe that the proposed changes to certain MGTN option transaction fees will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed MGTN transaction fees for the separate types of market participants will be assessed automatically and uniformly to all such market participants, as applicable. As discussed above, while different fees are assessed to different market participants in some circumstances, these different market participants have different obligations and different circumstances as discussed above. For example, preferential pricing to Customers is a long-standing options industry practice which serves to enhance Customer order flow, thereby attracting Market-Makers to facilitate tighter spreads and trading opportunities to the benefit of all market participants. The Exchange does not believe the proposed changes to certain MGTN option transaction fees will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes apply to products exclusively listed on the Exchange. As noted above, the proposed fees are within the range of amounts assessed for the Exchange's other index products, excluding Underlying Symbol List A and are also less than fees for these user types of index options listed for trading on other exchanges.[10]

Amend GTH LMM Incentive Programs

The Exchange does not believe the proposed changes to the GTH LMM Incentive Programs will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because these changes will apply to all LMMs appointed to the applicable program in a uniform manner. The Exchange notes that meeting or exceeding the quoting standards (both current and as proposed) in a GTH LMM Incentive Program to receive the applicable rebate is optional for LMMs appointed to the program. If an LMM appointed to a GTH LMM Incentive Program does not satisfy the corresponding quoting standard for any given month, then the LMM simply will not receive the rebate offered by the respective program for that month. As noted above, to the extent the LMMs appointed to an incentive program receive a benefit that other market participants do not, these LMMs in their role as Market-Makers on the Exchange have different obligations and are held to different standards. For example, Market-Makers play a crucial role in providing active and liquid markets in their appointed products, thereby providing a robust market which benefits all market participants. Such Market-Makers also have obligations and regulatory requirements that other participants do not have. The Exchange also notes that an LMM appointed to a GTH LMM Incentive Program may undertake added costs each month to satisfy that heightened quoting standards, such as having to purchase additional logical connectivity. The Exchange also notes that the LMM Incentive Programs are designed to attract additional order flow to the Exchange, wherein greater liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [11]

The Exchange does not believe that the proposed rule changes to the GTH LMM Incentive Programs will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change applies only to products exclusively listed on the Exchange. As noted above, the incentive programs are designed to attract additional order flow to the Exchange, wherein greater liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity. To the extent that the proposed changes make the Exchange a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become Exchange market participants. Other exchanges are welcome to offer similar programs with respect to products exclusively listed on their markets.

Eliminate Certain LMM Incentive Programs

Finally, the Exchange does not believe the proposed rule change to eliminate the LMM Incentive Programs will

[10] *See, e.g.,* Nasdaq ISE, LLC (''ISE'') Options 7, Section 5 (which imposes a transaction fee of $0.75 for Market-Maker orders and $0.50 or $0.75 for Market-Maker orders).

[11] *See* Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act proposed rule change because it applies to all Market-Makers equally. While no Market-Maker will be or continue to be eligible for the eliminated LMM Incentive Programs, all Market-Makers remain eligible to participate in the Exchange's other pricing programs, including other LMM Incentive Programs offered by the Exchange. The Exchange does not believe the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as it applies only to fees and programs applicable to transactions in products that are exclusively listed on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and paragraph (f) of Rule 19b–4 [13] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CBOE–2026–068 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CBOE–2026–068. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CBOE–2026–068 and should be submitted on or before September 8, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16689 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0026]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension: Form N–2

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. § 3501 *et seq.*), the Securities and Exchange Commission (SEC or ''Commission'') is soliciting comments on the proposed collection of information described below.

Form N–2 (17 CFR 239.14 and 274.11a–1) is the form used by closed-end management investment companies (''registered closed-end funds'') to register under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act''), and to register their securities under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (''Securities Act''). Form N–2 is also used by business development companies (''BDCs''), which are closed-end management investment companies that do not register under the Investment Company Act (but instead elect to be subject to certain provisions of the Investment Company Act (15 U.S.C. 80a–2(a)(48)) to register and offer their securities under the Securities Act.

Section 5 of the Securities Act (15 U.S.C. 77e) requires the filing of a registration statement prior to the offer of securities to the public and that the statement be effective before any securities are sold. The primary purpose of the registration process is to provide disclosure of financial and other information to current and potential investors for the purpose of evaluating an investment in a security. Section 5(b) of the Securities Act requires that investors be provided with a prospectus containing the information required in a registration statement prior to the sale, or at the time of confirmation or delivery, of the securities. A closed-end management investment company (that is not a BDC) is required to register as an investment company under Section 8(a) of the Investment Company Act (15 U.S.C. 80a–8(a)). Form N–2 permits a registered closed end fund and a BDC to provide investors with a prospectus covering essential information about the fund when the fund makes an initial or additional offering of its securities. More-detailed information is available to interested investors in the Statement of Additional Information, which is provided to investors upon request and without charge.

The purpose of Form N–2 is to meet the filing and disclosure requirements of the Securities Act and the Investment Company Act and to enable funds to provide investors with information necessary to evaluate an investment in a registered closed-end fund or BDC. The information filed with the Commission permits the verification of compliance with securities law requirements and assures the public availability and dissemination of the information. A registered closed-end fund or BDC must file a registration statement on Form N–2 only when making initial or additional offerings of securities under the Securities Act, or when amending its registration statement. Compliance with the disclosure requirements of Form N–2 is mandatory. Responses to the disclosure

requirements will not be kept confidential.

We estimate that approximately 427 respondents file Form N–2 annually, with 1 response annually per respondent at 344 hours per response, including the time and the cost of preparing and reviewing disclosure, filing documents, and retaining records, for a total annual time burden of 146,888 hours. In addition, we estimate the total annual external cost burden associated with Form N–2 to be $9,914,940, based on 30 hours of outside services at a wage rate of $774 per hour for an attorney in the securities industry ($23,220 per response times 427 respondents).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the SEC, including whether the information will have practical utility; (b) the accuracy of the SEC's estimate of the burden imposed by the proposed collection of information, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic collection techniques or other forms of information technology.

Please direct your written comments on this 60-Day Collection Notice to Austin Gerig, Director/Chief Data Officer, Securities and Exchange Commission, c/o Tanya Ruttenberg via email to *PaperworkReductionAct@sec.gov* by October 16, 2026.

Dated: August 12, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–16704 Filed 8–14–26; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Delegation of Authority No. 628]

Delegation of Authority to the Assistant Secretary of Economic, Energy, and Business Affairs To Review and Deny Requests for Reconsideration of Sanctions Designations

By virtue of the authority vested in the Secretary of State by the laws of the United States, including 22 U.S.C. 2651a(a)(4), I hereby delegate to the Assistant Secretary for Economic, Energy, and Business Affairs (EEB), to the extent authorized by law, the authority to review and deny requests for reconsideration of sanctions imposed pursuant to a determination by the Secretary of State pursuant to the following executive orders: E.O. 14404, E.O. 14203, E.O. 14078, E.O. 14024, E.O. 13894, and E.O. 13846.

With respect to sanctions imposed pursuant to E.O. 14404 and E.O. 14024, the Assistant Secretary for EEB shall coordinate decisions on denial of requests for reconsideration with the Assistant Secretary for Arms Control and Nonproliferation, as appropriate.

Any authority covered by this delegation may also be exercised by the Secretary, the Deputy Secretary, the Deputy Secretary for Management and Resources, and the Under Secretary for Economic Growth, Energy, and the Environment. This delegation does not repeal or modify any other delegation currently in effect. Any reference in this delegation of authority to any executive order shall be deemed to be a reference to such executive order as amended from time to time.

This delegation of authority shall be published in the **Federal Register**.

Dated: August 4, 2026.

Marco Rubio,

Secretary of State, U.S. Department of State.

[FR Doc. 2026–16759 Filed 8–14–26; 8:45 am]

BILLING CODE 4710–07–P

DEPARTMENT OF STATE

[Public Notice: 13101]

Notice of Determinations; Culturally Significant Objects Being Imported for Conservation, Scientific Research, and Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects, constituting a sculpture entitled ''Satyr and Hermaphrodite,'' being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary conservation, scientific research, and exhibition or display at The J. Paul Getty Museum at the Getty Villa, Pacific Palisades, California, and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary conservation, scientific research, and exhibition or display within the United States as aforementioned are in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). Themailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Sherry C. Keneson-Hall,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2026–16745 Filed 8–14–26; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2026–7360]

Agency Information Collection Activities: Requests for Comments; Clearance for Renewal of Information Collection: Privacy International Civil Aviation Organization (ICAO) Address

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for an information collection renewal. The collection involves an aircraft operator's request for a privacy ICAO address through a web-based application process. The information to be collected is necessary to qualify for the authorized use of the privacy ICAO address services and for monitoring to support continued airworthiness and enforcement activities.

DATES: Written comments should be submitted by August 25, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Mr. Jamal A. Wilson, Surveillance and Broadcast Services, AJM 42, PIA Program Manager at *jamal.wilson@faa.gov* or at (202) 267–4301.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0779.

Title: Privacy International Civil Aviation Organization (ICAO) Address Program.

Form Numbers: Not applicable.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on 25 June 2026 (FR Doc. 2026–13035). In 2010, the FAA issued a final rule mandating equipage requirements and performance standards for Automatic Dependent Surveillance-Broadcast (ADS–B) Out avionics on aircraft operating in certain airspace after December 31, 2019. Aircraft operators must be equipped with ADS–B Out to fly in most controlled airspace. Federal Regulations 14 CFR 91.225 and 14 CFR 91.227 contain requirement details. Each registered aircraft is assigned an aircraft registration number and an ICAO 24-bit aircraft address. This is also referred to as a ''Mode S Code'' in some FAA documents and websites, including the FAA Aircraft Registry. Where a 1090-MHz Extended Squitter (1090ES) transponder is required for ADS–B Out compliance, this ICAO 24-bit aircraft address, based on current transponder avionics standards, is openly broadcasted on the 1090 MHz frequency in transponder replies and ADS–B messages. Subsequently, the nature of openly broadcasting makes the identity of the aircraft publicly available. Industry stakeholders have long suggested that FAA develop a process for aircraft operators who seek anonymity such that their aircraft movements and identity cannot be traced or seen by privately owned sensors that monitor the 1090 MHz frequency and combine this with other downlinked ADS–B and Mode S data being disseminated using the internet. The FAA intends to develop a process for operators who wish to mask their aircraft movements and identity for a period while flying within the sovereign airspace of the United States. Participation in the assignment of privacy ICAO Code addresses is voluntary. Only U.S. registered aircraft can be assigned a privacy ICAO aircraft address. No operator can use a privacy ICAO aircraft address for a U.S.-registered aircraft unless that operator is authorized to use a third-party flight identification for that same aircraft. No unique privacy ICAO address will be assigned to more than one U.S.-registered aircraft at any given time. Once approved, the operator will be assigned a privacy ICAO address. The operator will be required to notify the FAA when their avionics have been loaded with the assigned temporary ICAO 24-bit aircraft address. Owners and operators must verify that the ICAO 24-bit aircraft address (Mode S code) broadcast by their ADS–B equipment matches the assigned privacy ICAO address for their aircraft. Operators can verify what ICAO 24-bit aircraft address is being broadcast by their aircraft by visiting: *https://adsbperformance.faa.gov/PAPRRequest.aspx.* For monitoring privacy ICAO address use, the information will be downloaded by the FAA and entered into the FAA's ADS–B Performance Monitor [Docket No. FAA–2017–1194 published in **Federal Register**, December 20, 2017, as Document Number: 2017–27202].

Respondents: Intended for operators who seek anonymity such that their aircraft movements and identity cannot be easily traced or seen by privately owned sensors that monitor the 1090 MHz frequency. FAA estimates up to 15,000 respondents.

Frequency: Frequency will be occasional based on specific scenarios. An operator can change privacy ICAO aircraft addresses, but no more often than once every 20 days. In the event real-world security concerns become evident, an operator can elect to change their PIA address sooner than 20 days.

Estimated Average Burden per Response: Approximately 15 minutes per application.

Estimated Total Annual Burden: 12,563 hours.

Issued in Washington, DC, on August 13, 2026.

Jamal A. Wilson,

Privacy ICAO Address (PIA) Program Manager, In-Service Performance and Sustainment (AJM–4220), Federal Aviation Administration.

[FR Doc. 2026–16754 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Tennessee

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by FHWA that are final. The actions relate to a proposed highway project, Interstate I–24, from I–40 in Nashville to I–840 near Murfreesboro, in Davidson County and Rutherford County, Tennessee, for approximately 26 miles. Those actions grant licenses, permits, and approvals for the project. The FHWA's Finding of No Significant Impact (FONSI) provides details on the Selected Alternative for the proposed improvements.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the listed highway project will be barred unless the claim is filed on or before January 14, 2027. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Boday Borres, P.E., Division Administrator; FHWA, Tennessee Division Office; 404 BNA Drive, Building 200, Suite 508; Nashville, Tennessee, 37217; (615) 781–5770; *Boday.Borres@dot.gov.*

The FHWA, Tennessee Division Office's normal business hours are 7:30 a.m. to 4:00 p.m. (Central Time). For the Tennessee Department of Transportation (TDOT): Paige Heintzman, P.E., Public-Private Partnerships Director, TDOT; 312 Rosa L. Parks Avenue, 14th Floor, Nashville, Tennessee 37243; (615) 253–8314; *paige.heintzman@tn.gov.* The TDOT

Public-Private Partnerships Division's normal business hours are 8:00 a.m. to 5:00 p.m. (Central Time).

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency actions by issuing a FONSI for the following highway project in the State of Tennessee: I–24 Southeast Choice Lanes project, PIN 134727.01. TDOT is proposing improvements to approximately 26 miles of I- 24 between I–40 and I–840 in Davidson and Rutherford counties, Tennessee. The proposed Project includes widening the existing interstate to accommodate the addition of two price-managed lanes (Choice Lanes) in each direction, adding additional interchange and access points, and interchange improvements throughout the corridor. The proposed Project would use the Public-Private Partnership (P3) model, under which TDOT would partner with a private entity responsible for the design, construction, financing, operation, and maintenance of the proposed Choice Lanes. The P3 model would also leverage the potential for innovations in design and flexibility during construction, as well as the revenue-generating mechanism of price-managed Choice Lanes, enabling accelerated project delivery.

The FHWA's actions and the laws under which such actions were taken are described in the Environmental Assessment (EA) for the project, approved on January 30, 2026, and the FONSI, approved on June 16, 2026, and in other documents in the project file. The EA, FONSI, and other project records are available by contacting the FHWA or TDOT at the addresses provided above. In addition, these documents can be viewed and downloaded from the project website at: *https://www.tn.gov/tdot/projects/region-3/interstate-24-choice-lanes-.html.*

This notice applies to all Federal agency decisions that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C.4321 *et seq.*]; Federal-Aid Highway Act (23 U.S.C. 109, 139, and 128).

2. *Air:* Clean Air Act [42 U.S.C. 7401–767l(q)].

3. *Noise:* Federal-Aid Highway Act of 1970, Public Law 91–605 [84 Stat. 1713]; 23 U.S.C. 109(h) and (i)].

4. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310].

5. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 306108 *et seq.*]; Archaeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)-470(mm)]; Archaeological and Historic Preservation Act [54 U.S.C. 312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

7. *Social and Economic:* American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, Section 319) (33 U.S.C. 1251–1387); Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3901, 3921]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(14)]; Flood Disaster Protection Act [42 U.S.C. 4012a, 4106].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*]; Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Environment; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

(Authority: 23 U.S.C. 139(*l*)(1).)

Boday Borres,

Division Administrator, Tennessee Division, Federal Highway Administration.

[FR Doc. 2026–16746 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Project in Hawaii

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions.

SUMMARY: This notice announces actions taken by FHWA, U.S. Fish and Wildlife Service (USFWS), and National Oceanic and Atmospheric Administration, National Marine Fisheries Service (NMFS) that are final. The actions relate to a proposed bridge project, the Ala Wai Bridge Project, which crosses the Ala Wai Canal, Waikiki, City and County of Honolulu, State of Hawaii. These actions grant licenses, permits, and approvals for the project.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139*(l)(*1). A claim seeking judicial review of the Federal agency actions on the listed bridge project will be barred unless the claim is filed on or before January 14, 2027. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Richelle Takara, Division Administrator, Federal Highway Administration, 300 Ala Moana Boulevard, Box 50206, Honolulu, Hawaii 96850, Telephone: (808) 541–2700. For HDOT: Robin Shishido, Deputy Director for Highways, State of Hawaii Department of Transportation, 869 Punchbowl Street, Honolulu, Hawaii 96813, Telephone: (808) 587–2220. For City and County of Honolulu: J. Roger Morton, Director of Transportation Services, City and County of Honolulu Department of Transportation Services, 711 Kapiolani Boulevard, Suite 1600, Honolulu, Hawaii 96813, Telephone: (808) 768–8303.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA, USFWS, and NMFS have taken final agency actions subject to 23 U.S.C. 139(*l)*(1) by issuing licenses, permits, and approvals for the following bridge project in the State of Hawaii: The Ala Wai Bridge Project includes a bridge spanning the Ala Wai Canal to provide safe and comfortable pedestrian and bicycle access and connecting the Waikiki, McCully, and Moiliili neighborhoods.

These actions by the Federal agencies, and the laws under which such actions

were taken, are described in the combined Final Environmental Assessment (FEA) and Finding of No Significant Impact (FONSI) for the project, approved on August 12, 2026 and in other documents in the project records. The FEA/FONSI and other project records are available by contacting City and County of Honolulu Department of Transportation Services, the Hawaii Department of Transportation, or FHWA at the addresses provided above. The FEA/FONSI can be viewed and downloaded from the project website at *https://www.honolulu.gov/dts/ala-pono/* or obtained from any contact listed above.

This notice applies to all Federal agency decisions on the project that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (42 U.S.C. 4321 *et seq.*); Federal-Aid Highway Act (23 U.S.C. 109, 139, and 128).

2. Air: Clean Air Act, as amended (42 U.S.C. 7401–7671q).

3. Noise: Noise Control Act of 1972 (42 U.S.C. 4901–4918); Procedures for Abatement of Highway Traffic Noise and Construction Noise (23 U.S.C. 109(h), 109(i)); 42 U.S.C. 4331, 4332; sec. 339(b), Public Law 04–59, 109 Stat. 568, 605.

4. Land: Section 4(f) of the Department of Transportation Act of 1966 (49 U.S.C. 303;23 U.S.C. 138); Landscaping and Scenic Enhancement (Wildflowers) (23 U.S.C. 319).

5. Wildlife: Endangered Species Act (16 U.S.C. 1531–1544 and 1536); Marine Mammal Protection Act (16 U.S.C. 1361–1423h); Fish and Wildlife Coordination Act (16 U.S.C. 661–667(d)); Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703–712); Magnuson-Stevens Fishery Conservation and Management Act of 1976, as amended (16 U.S.C. 1801 *et seq.*), with Essential Fish Habitat requirements (16 U.S.C. 1855(b)(2)).

6. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended (54 U.S.C. 306108 *et seq.*); Archaeological Resources Protection Act of 1977 (16 U.S.C. 470(aa)-470(mm)); Archaeological and Historic Preservation Act (54 U.S.C. 312501–312508); Native American Grave Protection and Repatriation Act (NAGPRA) (25 U.S.C. 3001 *et seq.*).

7. Social and Economic: American Indian Religious Freedom Act (42 U.S.C. 1996); Farmland Protection Policy Act (FPPA) (7 U.S.C. 4201–4209); the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (42 U.S.C. 4601 *et seq.,* as amended by the Uniform Relocation Act Amendments of 1987 (Pub. L. 100–17)).

8. Wetlands and Water Resources: Coastal Zone Management Act (16 U.S.C. 1451–1464); Land and Water Conservation Fund Act (16 U.S.C. 4601–4604); Safe Drinking Water Act (SDWA) (42 U.S.C. 300(f)–300(j)–26); Rivers and Harbors Act of 1899 (33 U.S.C. 401–406); Wetlands Mitigation (23 U.S.C. 119(g) and 133(b)(14)); Flood Disaster Protection Act (42 U.S.C. 4012a, 4106).

9. The analysis pertaining to any applicable Executive Order considered during the environmental review process to the extent such analysis may be challenged in court. Such Executive Orders may include: E.O. 11990 Protection of Wetlands; E.O. 11988 and 13690, Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

Authority: 23 U.S.C. 139 *(l)(*1).

Richelle Takara,

Division Administrator, Honolulu, HI.

[FR Doc. 2026–16719 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2026–1750]

Denial of Motor Vehicle Defect Petition, DP26002

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of a petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a defect petition (DP26002) submitted by Mr. Bhupinder Dhadda. The petition requested that the Agency initiate a safety defect investigation into wheel fastening practices on heavy-duty vehicles and vehicles utilizing 10–285.75 mm bolt circle wheels, with the focus of the investigation being the absence of a redundant mechanical wheel fastener mechanism. After conducting a technical review of the petition and other information, NHTSA's Office of Defects Investigation has concluded that the issues raised by the petition do not warrant a defect investigation at this time. Accordingly, the Agency has denied the petition.

FOR FURTHER INFORMATION CONTACT: Andrew Brady, Medium and Heavy-Duty Vehicle Defect Division, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202–751–5800. Email: *andrew.brady@dot.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

Interested persons may petition NHTSA requesting that the Agency initiate an investigation to determine whether a motor vehicle or an item of replacement equipment does not comply with an applicable motor vehicle safety standard or contains a defect that relates to motor vehicle safety. 49 U.S.C. 30162(a)(2); 49 CFR 552.1. Upon receipt of a properly filed petition, the Agency conducts a technical review of the petition, material submitted with the petition, and any additional information. 49 U.S.C. 30162(a)(2); 49 CFR 552.6. The technical review may consist solely of a review of information already in the possession of the Agency, or it may include the collection of information from a motor vehicle manufacturer or other sources. After conducting the technical review and considering appropriate factors, which may include, but are not limited to, the nature of the complaint, allocation of Agency resources, Agency priorities, the likelihood of uncovering sufficient evidence to establish the existence of a defect, and the likelihood of success in any necessary enforcement litigation, the Agency will grant or deny the petition. *See* 49 U.S.C. 30162(a)(2); 49 CFR 552.8.

Background Information

The Office of Defects Investigation (ODI) received a petition on November 21, 2025, requesting a defect investigation to ''determine whether the absence of a redundant mechanical wheel fastener locking mechanism constitutes a safety-related defect in motor vehicles and motor-vehicle equipment'' in the heavy-vehicle sector. On March 4, 2026, NHTSA opened Defect Petition DP26002 to evaluate the petitioner's request. The petition itself can be reviewed at *NHTSA.gov* under ODI number 11703245.

Summary of Petition

The petition alleges that heavy-vehicle wheel fasteners can loosen once a vehicle is placed into service due to real-world stresses such as thermal

cycling, vibration, dynamic loads, embedment relaxation, and joint fatigue. The petitioner requested that NHTSA initiate a defect investigation to determine whether the absence of a redundant mechanical wheel fastener locking mechanism constitutes a safety-related defect in the heavy-vehicle sector.

Office of Defects Investigation Analysis

The petition focused on all vehicles utilizing the 10–285.75 mm bolt wheels, also known as 10 Hole 22.5″ Hub Pilot Wheels. ODI conducted a comprehensive search of Vehicle Owner Questionnaires (VOQ) and Early Warning Reporting (EWR) data for vehicles equipped with the subject wheels. Furthermore, ODI reviewed six months of the Federal Motor Carrier Safety Administration's Motor Carrier Management Information System (MCMIS) violation data for commercial vehicles cited for loose or missing wheel fasteners. After reviewing this data, ODI has found insufficient evidence to support the petitioner's claim that a safety-related defect exists.

The data indicates that instances of loose or missing fasteners typically occur at higher mileages following fleet maintenance activities, rather than because of an inherent vehicle manufacturing or design defect. Furthermore, commercial motor vehicle operators are required to conduct daily pre-trip inspections to detect and mitigate loose fasteners before operation. Given the lack of evidence establishing a systemic safety defect, ODI is denying this petition.

The denial of this petition does not foreclose the Agency from taking further action if warranted or making a future finding that a safety-related defect exists based upon additional information the Agency may receive.

Authority: 49 U.S.C. 30162(d) and 49 CFR part 552; delegation of authority at 49 CFR 1.95(a).[1]

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2026–16749 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–59–P

[1] The authority to determine whether to approve or deny defect petitions under 49 U.S.C. 30162(d) and 49 CFR part 552 has been further delegated to the Associate Administrator for Enforcement.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2026–1651]

New Car Assessment Program (NCAP); Removal of Dynamic Rollover Resistance Test and Side Air Bag Out-of-Position Testing; Updates to NCAP's 10-Year Roadmap

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Request for comments (RFC).

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) is requesting public comment on a proposal to remove two legacy test procedures from its signature consumer information program, the New Car Assessment Program (NCAP): the Dynamic Rollover Resistance Test (specifically, the ''Fishhook'' maneuver) and the Side Air Bag Out-of-Position (SAB–OOP) testing protocols. The Agency believes these program elements have achieved their original safety goals. This notice also proposes updates to both the mid- and long-term components of the 10-year roadmap established for future NCAP upgrades. These proposed changes are intended to modernize NCAP, focus resources on crash scenarios and technologies with the greatest potential for injury reduction, and ensure the program continues to provide the most impactful safety information to the public.

DATES: Comments should be submitted no later than October 16, 2026.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by one of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Suite W58–213, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9826 or (202) 366–9317 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Taryn Rockwell, Office of Crashworthiness Standards by email at *taryn.rockwell@dot.gov,* or by phone at 202–366–1810. Address: National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

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I. Background

NCAP was established in 1978 to provide consumers with comparative information on the safety performance of new vehicles, thereby incentivizing safety improvements that extend beyond the established Federal Motor Vehicle Safety Standards (FMVSS). The program uses a 5-Star Safety Rating System to communicate vehicle safety performance in three key areas: frontal crash protection, side crash protection, and rollover resistance. Separately, the program also conducts testing to assess the performance of advanced driver assistance systems (ADAS), pedestrian protection, the protection afforded by side air bags to out of position occupants, and child seat usability.

To maintain NCAP's effectiveness as a driver of safety innovation and consumer awareness, NHTSA periodically reviews its test procedures to ensure they accurately reflect the current vehicle fleet and provide data that assists consumers in their

purchasing decisions. This request for comments (RFC) notice focuses on streamlining NCAP by proposing to remove tests (dynamic rollover resistance and the SAB–OOP tests) that are redundant with existing regulations and thus no longer effectively incentivize safety improvements.

On December 3, 2024, NHTSA published a 10-year roadmap [1] setting forth NHTSA's plans to upgrade NCAP, with mid-term plans spanning 2024 through 2028 and long-term plans spanning 2024 through 2033. NHTSA noted that it plans to update the roadmap every 2 to 4 years.[2] Accordingly, this RFC proposes updates to the program's mid- and long-term components of the NCAP roadmap to align with NHTSA's current research and priorities.

A. Legislative and Administrative History

The inclusion of the specific programs and tests discussed in this notice—Dynamic Rollover and SAB–OOP—stems from a combination of Congressional mandates and Agency-led safety initiatives authorized under the Motor Vehicle Information and Cost Savings Act of 1972 (15 U.S.C. 1942 *et seq.*).

1. Dynamic Rollover Testing

NCAP's current rollover rating system was established in response to Section 12 of the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act of 2000 (Pub. L. 106–414). Congress directed the Secretary of Transportation to ''develop a dynamic test on rollovers by motor vehicles for the purposes of a consumer information program, and carry out a program for conducting such tests'' and to ''conduct a rulemaking to determine how best to disseminate these test results to the public.'' Applicability was limited to those passenger cars, multipurpose passenger vehicles, and trucks having a gross vehicle weight rating (GVWR) of 4,536 kilograms (10,000 pounds) or less (referred as light vehicles in this notice). This mandate, codified at 49 U.S.C. 30117, led to the adoption of the dynamic Fishhook maneuver test in NCAP in 2003,[3] which supplemented the Static Stability Factor (SSF) assessment adopted for the program in 2001.[4] The rollover risk for a vehicle, accounting for the vehicle's SSF and its performance in the Fishhook maneuver test, has been provided on NHTSA's website since 2004.

The Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) Act of 2005 (Pub. L. 109–59) further reinforced this testing regimen. Section 10307 required that automobile [5] manufacturers present rollover resistance ratings on the side window sticker at the point-of-sale, and Section 10309 [6] expanded the applicability of NCAP rollover assessments to include 15-passenger vans due to the unique safety risks and high fatality rates associated with rollovers in this vehicle class when fully loaded.[7] In response to SAFETEA–LU, NHTSA has included a rollover risk rating in terms of stars on the Monroney label (vehicle window sticker) since 2007.[8] NHTSA also tests 12- and 15-passenger vans with GVWR less than or equal to 4,536 kilograms (light vehicles) for rollover propensity using the Fishhook maneuver.

2. SAB–OOP Testing

Unlike the dynamic rollover test, SAB–OOP testing was not a direct Congressional mandate but rather an Agency-adopted protocol to monitor a voluntary industry commitment. In the late 1990s and early 2000s, the rapid introduction of side air bags raised concerns regarding the potential risk of injury to out-of-position [9] children and small adults from deploying side air bags. In response, the Side Airbag Out-of-Position Technical Working Group (TWG)—a consortium of automotive manufacturers and safety organizations [10]—developed the ''Recommended Procedures for Evaluating Occupant Injury Risk from Deploying Side Airbags.'' [11] NHTSA subsequently incorporated these procedures into NCAP in 2003 [12] to verify that vehicles with side air bags met these voluntary safety guidelines and thus would not pose unreasonable risks to children and small adults.

3. NCAP 10-Year Roadmap

NHTSA published its first 10-year roadmap for upgrading NCAP on December 3, 2024 [13] in response to Section 24213(c) of the Infrastructure, Investment, and Jobs Act of 2021 (IIJA) (Pub. L. 117–58), codified at 49 U.S.C. 32310. The provision directed the Secretary of Transportation to establish a roadmap for implementing NCAP that spans a term of ten years, with a five-year mid-term component and a five-year long-term component. The IIJA provision further specifies that the roadmap be updated at least once every four years to reflect new Agency interests and diverse stakeholder input. As mandated, the December 2024 10-year roadmap includes phased upgrades to NCAP and, where possible and appropriate, takes steps to harmonize these upgrades with existing consumer information rating programs.

II. Proposed Removals From NCAP

A. Dynamic Rollover Testing

The current NCAP rollover resistance rating is derived from a statistical combination of a vehicle's SSF and its performance in the dynamic rollover test.

The SSF, which measures a vehicle's propensity to roll over based on its geometry, is designed to represent tripped rollovers (*e.g.,* those caused by curbs, soft soil, potholes, guard rails, or by wheel rims digging into the pavement). Tripped rollovers constitute the majority of rollover crashes. The SSF for a vehicle is calculated as a ratio of one half its track width divided by the height of its center of gravity above ground. Generally, trucks and sports utility vehicles have lower SSF values than passenger cars because of their higher center of gravity. While the SSF addresses tripped rollover events, a dynamic rollover test is utilized to address untripped rollover events (*e.g.,* those caused by high-speed turning or cornering, or by jerking the steering wheel to swerve to avoid a braking vehicle ahead or a hazard in the roadway).

Historically, NCAP utilized a dynamic rollover test, termed the Fishhook Maneuver, which evaluates a vehicle's

[1] *https://www.nhtsa.gov/sites/nhtsa.gov/files/2024-11/NCAP-Roadmap-11182024-web.pdf.*

[2] 89 FR 96078.

[3] 68 FR 59250.

[4] 66 FR 3388.

[5] The Automobile Information Disclosure Act (15 U.S.C. 1231) defines the term ''automobile'' to include any passenger car or station wagon. NHTSA interpreted this to mean all passenger vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or less.

[6] 49 U.S.C. 30117 note.

[7] 15-passenger vans were defined as vehicles that seat 10 to 14 passengers, not including the driver. SAFETEA–LU's expanded applicability of NCAP rollover assessments to include 15-passenger vans is subject to the weight limit in 49 U.S.C. 30117(c)(3) of a GVWR of 4,536 kilograms (10,000 pounds) or less.

[8] 71 FR 53572.

[9] ''Out-of-Position'' refers to a situation where a passenger or driver is not seated in the standard, upright posture that safety restraint systems such as seat belts and air bags are designed to protect.

[10] Namely, the Alliance of Automobile Manufacturers (Alliance), the Association of International Automobile Manufacturers (AIAM), the Automotive Occupant Restraints Council (AORC), and the Insurance Institute for Highway Safety (IIHS).

[11] *Available at https://www.iihs.org/media/020f855e-79e2-4f5c-b560-3ccc991bdfb2/0tCvYA/Ratings/Protocols/current/twg_final_procedures.pdf* (last accessed June 3, 2026).

[12] Docket No. NHTSA–1999–5098.

[13] 89 FR 95916.

susceptibility to on-road, untripped rollovers during an aggressive, evasive steering maneuver. However, the Agency mandated the use of the more-aggressive Sine-with-Dwell maneuver as part of FMVSS No. 126, ''Electronic stability control systems for light vehicles,'' as a dynamic assessment of a vehicle's lateral stability and rollover resistance for all light vehicles manufactured on or after September 1, 2011.[14]

Untripped rollovers represent less than five percent of all rollover events. In untripped rollovers, the tire/road interface friction is the only external force acting on the vehicle to cause the rollover. The Fishhook maneuver approximates the steering a driver acting in panic might use in an effort to regain lane position after swerving to avoid an obstacle in the road. The rapid steering input followed by an over-correction is representative of a general loss of control situation. Performance in the dynamic test is determined by whether a vehicle's inside wheels simultaneously lift two or more inches from the test surface during the maneuver. Vehicles exhibiting a simultaneous wheel lift of two or more inches are said to have ''tipped-up.''

The Agency utilizes two distinct logistic regression equations to calculate the risk of rollover, with each using SSF as a covariate. The equation selected for risk determination is based on whether the vehicle ''tips up'' during the dynamic maneuver:

$$No\ tip-up\ in\ dynamic\ test: Rollover\ risk = \frac{1}{1+e^{2.8891+1.1686\times Ln(SSF-0.9)}} \quad (1)$$

$$Tip-up\ in\ dynamic\ test:\ Rollover\ risk = \frac{1}{1+e^{2.6968+1.1686\times Ln(SSF-0.9)}} \quad (2)$$

$$where\ SSF = static\ stability\ factor$$

Figure 1 presents the risk of vehicle rollover as a function of vehicle SSF for the two conditions (1) no tip-up and (2) tip-up in the Fishhook maneuver test using Equations 1 and 2, respectively. The difference in the risk of rollover for a given SSF for a vehicle that has a tip-up compared to a vehicle that does not tip-up in the dynamic test varies from 1.6 percent for vehicles with high SSF values to 4.8 percent for vehicles with low SSF values.

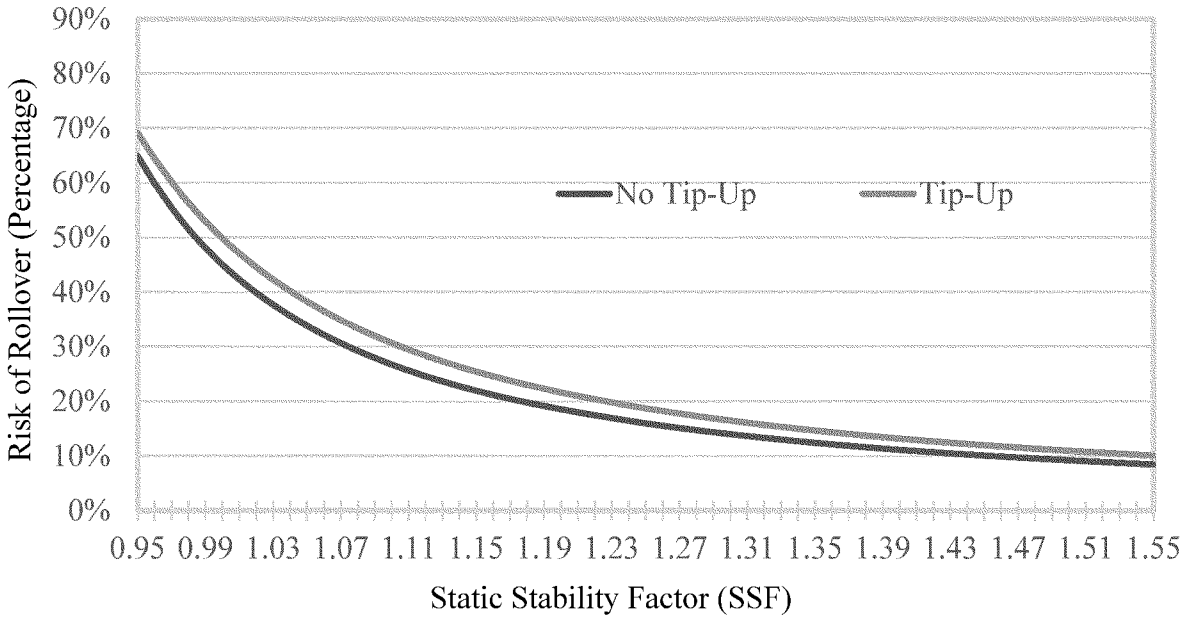

Figure 1. Risk of rollover as a function of vehicle SSF and whether the vehicle tips-up in the dynamic Fishhook maneuver test.

[14] The requirements for electronic stability control systems in light vehicles were phased in over a three-year period starting on September 1, 2008. A manufacturer's light vehicle production in a specified period required to comply with FMVSS No. 126 was as follows: September 1, 2008 to August 31, 2009—55 percent; September 1, 2010 to August 31, 2010—75 percent; September 1, 2010 to August 31, 2011—95 percent.

NHTSA proposes transitioning away from the NCAP Fishhook maneuver because the rigorous requirements of FMVSS No. 126 already provide the necessary safeguards to ensure dynamic stability to prevent untripped rollovers and therefore additional NCAP testing is unnecessary. When the dynamic rollover test using the Fishhook maneuver was introduced in NCAP, electronic stability control (ESC) was an emerging technology, and the test was effective in identifying vehicles with poor dynamic stability. However, with the full implementation of FMVSS No. 126 since 2012, virtually all light vehicles in the U.S. fleet are now equipped with robust ESC systems.

Unlike the Fishhook maneuver utilized in NCAP that evaluates on-road untripped rollover susceptibility, the Sine-with-Dwell maneuver, utilized in FMVSS No. 126, incites yaw motion and evaluates the responsiveness of ESC systems to mitigate oversteer and maintain lateral stability. The ESC systems meeting FMVSS No. 126 requirements assist the driver in keeping the vehicle on the road during impending loss-of control situations and thereby mitigate exposure of vehicles to off-road tripping mechanisms, in addition to ESC's primary function of preventing untripped rollovers.

Electronic stability control, as the name implies, is designed to improve vehicle stability when the system detects a loss of traction or steering control. In such situations, the system is designed to apply the brakes to wheels automatically and individually, such as to the outer front wheel to counter oversteering or the inner rear wheel to counter understeering, to help regain control and steer the vehicle where the driver intends to go.

Agency data indicates that modern ESC systems are highly effective at preventing the loss of control situations and wheel lift occurrences [15] the Fishhook maneuver was designed to provoke; all ESC-equipped vehicles tested by NCAP have passed the ''no tip-up'' criteria. Consequently, the Fishhook maneuver test has ceased to be a discerning metric. The test no longer distinguishes between superior and inferior performers, as the vast majority of the fleet performs identically under these specific test conditions.

Furthermore, the NCAP dynamic rollover test no longer serves its original purpose of incentivizing ESC adoption. This is true even for 12- and 15-passenger vans, which have historically presented a higher rollover risk compared to other light vehicle types. All 12- and 15-passenger vans tested by NCAP since 2015 were equipped with not only ESC but oftentimes roll stability control (RSC) as well.[16] Accordingly, NHTSA observed no tip-ups for these vehicles during NCAP's dynamic rollover testing. NHTSA notes that 12- and 15-passenger vans with a GVWR greater than 4,536 kilograms are not required to have ESC and are not subject to dynamic rollover testing using the sine-with-dwell or the Fishhook maneuvers, as they exceed the weight threshold established for the program by the TREAD Act (codified at 49 U.S.C. 30117(c)).[17] The Agency is aware of only one 2026 model, the Ford Transit 15-passenger T–350 HD with dual rear wheel configuration, that has a minimum GVWR that exceeds 4,536 kilograms. Therefore, all other 12- and 15-passenger vans would be required to have ESC as standard equipment, and based on past NHTSA testing, would be expected not to tip-up during NCAP's dynamic rollover assessment.

Regarding the 2026 Ford Transit 15-passenger T–350 HD with dual rear wheel configuration, NCAP has not conducted a dynamic rollover test for this vehicle model because it exceeds the established weight threshold (as explained above). However, NHTSA has no reason to believe this model would tip-up during such an assessment since it is equipped with both ESC (though not required) and RSC, and its dual rear wheels contribute to a wider track width and lower center of gravity. The addition of RSC and dual rear wheels to this higher weight configuration suggests manufacturers are exercising due diligence to ensure adequate safety is afforded for all passenger van configurations irrespective of requirements imposed by Federal standards. Therefore, NHTSA does not believe removal of the dynamic rollover test from NCAP will generate a safety gap for consumers or organizations choosing to purchase 12- or 15-passenger vans, regardless of whether the associated GVWR for the procured models falls below or exceeds 4,536 kilograms.

The fact that no tip-ups have been observed during NCAP testing since ESC's full adoption in the vehicle fleet demonstrates that the SSF has been the primary differentiator for rollover risk since 2012. This should not be viewed as a detriment to safety, however; as a geometric measurement, the SSF provides a repeatable and reliable indicator of a vehicle's fundamental rollover susceptibility and has proven to correlate highly with actual crash statistics. Though ESC improves lateral stability and resistance to untripped rollovers, ESC may not provide the needed stability and prevent rollover after a vehicle has driven off the road. In such conditions, the SSF of a vehicle is correlated to the propensity of vehicle rollover. Since most real-world vehicle rollovers are tripped rollover events, rollover risk of a vehicle, determined by the equations 1 and 2 and presented in Figure 1, is mainly influenced by the vehicle's SSF. Therefore, the Agency believes that removing the dynamic rollover test while continuing to evaluate SSF measurements in NCAP should sufficiently ensure real-world rollover risk remains low. The Agency continues to fulfill its dynamic rollover testing mandate through the Sine-with-Dwell maneuver as required in FMVSS No. 126.

Regarding the mandate in 49 U.S.C. 30117(c)(1) requiring NHTSA to ''develop a dynamic test on rollovers by motor vehicles for the purposes of a consumer information program'' and to ''carry out a program for conducting such tests[,]'' NHTSA has developed both the Fishhook maneuver and the Sine-with-Dwell maneuver tests. While this RFC proposes to discontinue conducting the Fishhook maneuver test in NCAP, the Agency is not abandoning dynamic rollover testing. Rather, NHTSA will continue to conduct regular compliance testing of light vehicle models using the Sine-with-Dwell maneuver to ensure adherence to FMVSS No. 126, thereby maintaining a dynamic assessment program that satisfies the requirements of 49 U.S.C. 30117. Because a non-compliance carries significant consequences, vehicle manufacturers ensure their light vehicles comply with FMVSS No. 126. All light vehicles subject to FMVSS No. 126 would not tip-up in the Fishhook

[15] ESC systems meeting the FMVSS No. 126 sine-with dwell test requirements not only address on-road untripped rollovers as assessed by the Fishhook maneuver test, but also address loss of control events. This added feature of FMVSS No. 126 compliant ESC systems results in a large reduction in single vehicle crashes, untripped vehicle rollovers, and tripped vehicle rollovers by keeping the vehicle on the road. ESC is 50 percent effective in reducing single vehicle fatal crashes and about 70 percent effective in reducing first-event rollover crashes involving passenger cars and light trucks and vans; DOT HS 811 486 and DOT HS 812 391.

[16] RSC systems utilize a specialized roll rate sensor and driving situation specific control algorithms, in addition to the sensors and control strategy used by conventional ESC systems, to predict and respond more accurately to a potential rollover during sharp turns or emergency maneuvers.

[17] The Fishhook and sine-with-dwell test procedures were specifically developed for vehicles with a GVWR 4,536 kilograms or less in accordance with 49 U.S.C § 30117. Therefore, the Fishhook maneuver test is conducted on 12- and 15-passenger vans with a GVWR 4,536 kilograms or less.

maneuver tests, as evidenced by no tip-ups in the NCAP tests in the past 15 years.

To fulfill the mandate in 49 U.S.C. 30117(c)(2) to ''disseminate the dynamic rollover test results to the public[,]'' NHTSA will continue to provide rollover rating of light vehicles based on SSF (Equation 1) for the no tip-up condition on its website and on the Monroney label.

Streamlining the program by removing the redundant Fishhook maneuver will allow NHTSA to redirect significant resources (*e.g.,* funding and staff) toward developing and incorporating more contemporary safety assessments, such as enhanced crashworthiness and ADAS evaluations.

In light of the aforementioned considerations, the Agency tentatively believes it is appropriate to remove the Fishhook maneuver from NCAP at this time, relying instead on the Sine-with-Dwell maneuver requirements of FMVSS No. 126 starting with model year 2027 vehicles.

Questions

- Do commenters agree with the Agency's assessment that the Dynamic Rollover Test (Fishhook maneuver) no longer provides relevant consumer information due to the prevalence of FMVSS No. 126-compliant ESC systems, and that the Sine-with-Dwell maneuver serves as a sufficient replacement?
- Do commenters agree with the Agency's assessment that the Dynamic Rollover Test is no longer needed in NCAP for 12- and 15-passenger vans since these vehicles are equipped with FMVSS No. 126-compliant ESC systems?

B. SAB–OOP Testing

NCAP's SAB–OOP testing was implemented in 2003 to assess the potential injury risk to occupants, particularly smaller adults and children, who are in an abnormal, out-of-position posture relative to a deploying side air bag. As mentioned, this testing was adopted preemptively to ensure that early-generation side air bags did not induce injuries due to aggressive deployment.

Under the TWG procedures, a 5th percentile female side impact test dummy (SID–IIs), a Hybrid III (HIII) three-year-old child test dummy, and a HIII six-year-old child test dummy are placed in several positions close to a vehicle's side air bag systems. Any side air bags that deploy from vehicle seat backs (seat-mounted), from the door or rear quarter panel, typically just below the windowsill (side-mounted), or from the roof rail above the door (roof-mounted) can be assessed. After the dummy is positioned as specified in the procedures, the air bag is deployed statically, and the dummy injury measures stemming from the deployment of the air bag are recorded. The measured forces are compared to established Injury Assessment Reference Values (IARVs), which are very similar to those in FMVSS No. 208, ''Occupant crash protection,'' for out-of-position testing of frontal air bags. Unlike FMVSS No. 208 out-of-position testing, however, the SAB–OOP does not include objective test procedures that yield reliable results.

NHTSA is proposing to remove the SAB–OOP tests from NCAP because the specific, extreme out-of-position scenarios included in the TWG test protocol have not demonstrated a correlation with real-world injury data. A critical responsibility of any regulatory agency is to perform retrospective analysis of its programs to ensure that they further their intended goals. While the Agency generally observes approximately two SAB–OOP test failures per year during its testing of the vehicle fleet, to date, not a single failure could be related to real-world incidents for those specific vehicle models. Conversely, NHTSA identified a real-world crash where an occupant sustained injuries resulting from side air bag deployment in a vehicle model that passed all the TWG SAB–OOP tests.

NHTSA has also found that even minor deviations in dummy positioning have shown vastly different injury readings, thus challenging the objectivity of the TWG test procedures. Furthermore, because the TWG test procedures allow for adjustments to test positions on a case-by-case basis to ascertain the ''worst-case'' scenario, the Agency has found it difficult to repeat and reproduce test results. Therefore, NHTSA has been unable to issue recall proceedings for any failures observed during testing. These difficulties also raise questions as to whether the testing itself provides meaningful, actionable information to consumers and manufacturers or merely diverts testing resources away from true safety-enhancing activities and provides consumers with a false sense of security.

In addition, conducting TWG SAB–OOP tests in NCAP is burdensome for both vehicle manufacturers and NHTSA. For NCAP's TWG SAB–OOP procedure, manufacturers are asked to submit data for up to 30 test positions per vehicle,[18] and NCAP staff spot-checks performance for approximately 30 to 40 percent of crash-tested models. NHTSA tentatively concludes that discontinuing SAB–OOP testing in NCAP will eliminate this burden and allow the program's emphasis to shift toward evaluating new technologies and crash scenarios that present the most significant current safety risk for real-world occupants.

Questions

- Do commenters agree with the Agency's assessment that it is now appropriate to remove the SAB–OOP assessments from NCAP?
- What specific data, if any, is available regarding the residual real-world safety benefit of NCAP SAB–OOP testing in vehicles equipped with current-generation side air bag systems?

III. Proposed Updates to NCAP's 10-Year Roadmap

In December 2024, NHTSA established a 10-year roadmap for NCAP to modernize the program and provide a clear, long-term vision for vehicle safety in the U.S.[19] By outlining plans a decade in advance, NHTSA provides manufacturers and suppliers the lead time necessary for research, development, and product planning, ensuring that safety innovations reach the market faster.

The published roadmap was divided into mid-term (2024–2028) and long-term (2029–2033) initiatives focused on four core areas: Crashworthiness, Crash Avoidance, Vulnerable Road User (VRU) safety, and Vehicle Safety Ratings. Included items were evaluated and selected based on four prerequisites: (1) the update to the program would address a safety need, (2) there are, or may soon be, system designs that can mitigate the safety problem, (3) existing or new system designs have the potential to improve safety, and (4) a performance-based objective test procedure exists that can assess system performance.

The mid-term updates in the roadmap included actions that met the four prerequisites and for which the Agency could reasonably anticipate start and completion times. For the crash avoidance program, these included: the adoption of enhanced automatic emergency braking (AEB), lane keeping

[18] Starting with model year 2026 vehicles and later, NHTSA only requires that manufacturers attest to passing/failing performance and provide the test report number(s) associated with their internal SAB–OOP testing. For any vehicles exhibiting a test failure during NHTSA testing, the Agency has the option to request that the manufacturer provide a copy of the associated test report so that the Agency may review the related test data.

[19] *https://www.nhtsa.gov/sites/nhtsa.gov/files/2024-11/NCAP-Roadmap-11182024-web.pdf.*

assistance (LKA), blind spot warning (BSW), and blind spot intervention (BSI), as well as the addition of rear automatic braking (RAB). For the crashworthiness program, mid-term roadmap items included: adding a new frontal oblique crash test in NCAP; using advanced 50th percentile male dummies (THOR–50M in frontal impact crash tests and the WorldSID–50M in side impact tests); testing with the 5th percentile female dummy, HIII–05F, in the driver seating position; and adding chest deflection measurements to the 5th percentile female side impact dummy, SID–IIs. The VRU safety program included the addition of pedestrian automatic emergency braking (PAEB), bicyclist and motorcyclist AEB, crashworthiness pedestrian protection, and unattended child alert system using direct sensing technologies. The mid-term component of the roadmap also included updating the crashworthiness rating system and adding crash avoidance and VRU safety rating systems, along with updates of the Monroney label.

The long-term updates comprised a variety of new technologies having safety potential, but which are not sufficiently mature, such that additional research, test procedure development, and product development, is necessary. For the crash avoidance program, these included: advanced lighting systems, intersection AEB, enhanced LKA, higher-speed AEB with additional scenarios, driver monitoring systems, and intelligent speed assist. For the crashworthiness program, roadmap items included: addition of the 5th percentile small female THOR dummy (THOR–05F) in front and rear seats of frontal crash tests, and adoption of the 5th percentile female WorldSID dummy (WorldSID–05F) in side impact crash tests. Finally, for the VRU safety program, adopted initiatives included: intersection AEB for bicyclists and motorcyclists; BSW and BSI technologies for motorcyclist and bicyclist protection; adoption of the advanced pedestrian legform, aPLI, for crashworthiness pedestrian protection; enhanced PAEB; and driver visibility.

NHTSA is proposing updates to the December 2024 mid-term and long-term components of NCAP's 10-year roadmap to align with the availability of resources, progress in research activities, and a better understanding of the state of technology. On September 22, 2025, NHTSA published a notice [20] announcing a delay in the implementation of the NCAP crashworthiness pedestrian protection program finalized in the November 25, 2024 final decision notice [21] and the upgrades to the crash avoidance program discussed in the December 3, 2024 final decision notice.[22] Items in the December 2024 roadmap that have already been implemented into NCAP have been removed in the proposed updated NCAP roadmap.[23]

The proposed updated NCAP roadmap spans the years 2026 to 2035, with the mid-term portion spanning 2026 to 2030 and the long-term portion spanning 2031 to 2035. The NCAP roadmap includes four phases for each NCAP initiative, along with a completion milestone for each phase. The four phases are: (1) Research phase, if applicable, (2) Request for comment (RFC) phase, (3) Final decision phase, and (4) Implementation phase. The planned updates to the NCAP roadmap are in the following three safety programs: crashworthiness, crash avoidance, and vulnerable road user safety. Updates are also planned for the vehicle safety rating category. A summary of the mid-term and long-term actions for the updated 10-year roadmap is presented in Tables 1 and 2, respectively. The timeframe shown for the research, RFC, and final decision phases is presented in calendar years. Figures 1 and 2 present the details of the proposed updated mid-term and long-term components of the 10-year roadmap, respectively.

Some of the items in the long-term component of the December 2024 NCAP roadmap have been moved to the mid-term component because the needed research has been completed. For example, NHTSA plans to initiate work on a request for comment notice on adaptive driving beam (ADB) and semi-automatic beam switching (SABS) in 2027. Other items moved from the long-term to the mid-term component are (1) use of aPLI [24] to evaluate pedestrian lower limb injuries and (2) BSW and BSI for motorcyclist and bicyclist protection.

Because the rulemaking process to standardize NHTSA's most advanced dummies, the THOR–50M and WorldSID–50M, is ongoing and because the Agency continues to conduct research to complete enhancements to its frontal and side test procedures to accommodate these dummies, incorporation of the THOR–50M and the frontal oblique crash test has been delayed by two years, and the incorporation of the WorldSID–50M into NCAP's side impact test has been moved to the long-term component. However, NHTSA plans to include in the mid-term component SID–IIs chest and abdominal deflection to assess overall injury potential in the side impact test program (both the moving deformable barrier (MDB) test and the side pole impact test).[25] Because of resource constraints, the proposed updates of the mid-term component also include a one-year delay in the implementation of a rating system for crash avoidance technologies and a two-year delay in an updated rating system for crashworthiness, VRU safety, and overall safety as well as a revised Monroney label.

NHTSA is adding a new item to the proposed mid-term component of the roadmap that was not included in the December 2024 NCAP roadmap. Specifically, the Agency is updating its Child Restraint System (CRS) Ease-of-Use rating program with proposed implementation in the fourth quarter of 2028. NHTSA established the CRS Ease-of-Use (EOU) program to help caregivers more easily select and properly use child restraints. Recognizing that correct use is critical to the safety performance of a CRS, the CRS EOU program evaluates and rates the clarity of instructions, labeling, and the usability of installation features. The CRS EOU program is being updated to improve objectivity of assessments and to align better with current CRS designs, features, and labeling.

The proposed long-term component of the roadmap has also been updated to reflect the state of research supporting upgrades to NCAP. The crash avoidance program upgrades in the long-term component of the roadmap are as follows:

- Enhanced LKA (Higher Speed, Curved Road and/or Road Edge Detection Scenarios): While substantial research on enhanced LKA has been completed,[26] further research may be needed due to complexity of the test conditions. As a result, the Agency is

[20] 90 FR 45463.

[21] 89 FR 93000.

[22] 89 FR 95916.

[23] Starting with model year 2026 vehicles, NHTSA provides information on vehicle models with an unattended child alert system that uses direct sensing technologies in the Safety Features section of the ratings web page.

[24] aPLI is the advanced pedestrian legform impactor. It assesses pedestrian injuries to the knee, upper leg, and lower leg in impacts with the front of vehicles.

[25] This is an interim upgrade to side impact protection for small-sized occupants until the advanced 5th percentile female side impact test dummy, WorldSID–05F, is included in NCAP (currently in the long-term component of the roadmap).

[26] Lane Keeping Assist System Confirmation Draft Research Test Procedure. *https://www.regulations.gov/document/NHTSA-2019-0102-0417.*

postponing initiating the request for comment process for enhanced LKA by two years.

• Driver Monitoring System for Drowsiness: NHTSA's driver monitoring system (DMS) research for drowsiness is underway with data collection planned to begin after NHTSA obtains approval under the Paperwork Reduction Act (PRA). The test procedure for confirmation of performance for DMS for drowsiness detection will be affected by challenges of assuring reliable results given the necessary involvement of humans or human surrogates in the test procedure. Because of these challenges, and to allow sufficient time to gather needed information to support inclusion of DMS for drowsiness in NCAP, this item's implementation into NCAP is now anticipated to start with model year 2036.

• Driver Monitoring System for Distraction: NHTSA's ongoing driver distraction research includes a multi-year research effort examining DMS for driver distraction mitigation that begins in 2026. Similar to drowsiness DMS, this effort will also be affected by substantial challenges in assuring reliable results given the necessary involvement of humans or human surrogates in the test procedure. Due to these challenges, and to allow sufficient time for PRA approval, the topic is not included in this proposed roadmap while NHTSA gathers needed information to support inclusion of DMS for driver distraction mitigation in NCAP.

• Intelligent Speed Assist: NHTSA's multi-year research on intelligent speed assist (ISA) began in 2024 and consists of three separate studies. The first study examines ISA enabling technologies (*e.g.,* camera perception, digital maps) and implementation approaches (*e.g.,* speed limit information function, warnings, speed management). The second study examines ISA user acceptance and effectiveness. The third study examines ISA system accuracy and test protocols. To permit sufficient time to complete all studies, including PRA approval, the Agency is proposing to revise the timeline for the completion of planned research to 2031 and implementation into NCAP in 2035.

NHTSA continues to prioritize activities related to the development of the advanced 5th percentile female frontal crash test dummy, THOR–05F. While NHTSA has already completed substantial required research,[27] this advanced dummy still needs to be standardized and included in regulation, and research on injury criteria applicable to this dummy needs to be completed. Therefore, expected implementation of this component remains unchanged from the December 2024 NCAP roadmap.

NHTSA's research on enhanced AEB for bicyclists and motorcyclists and enhanced PAEB with additional crash scenarios is ongoing and expected to be completed by the end of 2028. The Agency plans to implement enhanced AEB for bicyclists, motorcyclists, and pedestrians starting with model year 2034. NHTSA plans to complete test procedure development for assessing driver visibility in 2029. In 2030, NHTSA will conduct analysis to evaluate whether driver visibility meets the four prerequisites for inclusion in NCAP.

TABLE 1—PROPOSED UPDATED MID-TERM COMPONENT OF THE NCAP ROADMAP

[In calendar years]

Potential updates to NCAP evaluations	Research phase	RFC phase	Final decision phase	Implementation phase start in 4th quarter
Crash Avoidance Program				
Enhanced FCW, CIB, DBS	Completed	Completed	Completed	2026
LDW+LKA and BSW+BSI	Completed	Completed	Completed	2026
Rear Automatic Braking	Completed	2026	2027	2028
Adaptive Driving Beam and Semi-Automatic Beam Switching	Completed	2027	2028	2030
Crashworthiness Program				
THOR–50M in Frontal Crash Tests and HIII–05F in Driver Position in Frontal Rigid Barrier Crash Test	2026	2026	2027	2029
Frontal Oblique Crash Test with THOR–50M	2026	2026	2027	2029
Adding SID–IIs Rib Deflections for Injury Risk Assessment	.....	2026	2027	2029
Vulnerable Road User (VRU) Safety Program				
PAEB (day- and night-time)	Completed	Completed	Completed	2026
Crashworthiness Pedestrian Protection	Completed	Completed	Completed	2026
Adding a PLI to Crashworthiness Pedestrian Protection	2026	2027	2028	2030
Bicyclist and Motorcyclist AEB (along path scenarios)	Completed	2027	2028	2030
BSW and BSI for Bicyclist and Motorcyclist Protection	2026	2027	2028	2030
Update of Child Restraint Ease-of-Use Rating System	2026	2026	2027	2028
Vehicle Safety Rating				
Rating System for Crash Avoidance Technologies	.....	.....	2026	2028
Rating Systems for Crashworthiness, VRU Safety, and Overall Safety	.....	2027	2028	2029
Monroney Label Rulemaking—Crash Avoidance, Crashworthiness, VRU Safety, and Overall Safety Ratings	2026–2027	2027	2028	2029

[27] *www.regulations.gov,* Docket No., NHTSA–2019–0107, item 0007. *https://www.regulations.gov/document/NHTSA-2019-0107-0007.*

TABLE 2—PROPOSED UPDATED LONG-TERM COMPONENT OF THE NCAP ROADMAP

[In calendar years]

Potential updates to NCAP evaluations	Research phase	RFC phase	Final decision phase	Implementation phase start in 4th quarter
Crash Avoidance Program				
AEB for Intersection Crash Scenarios	2027	2028	2029	2031
Enhanced LKA (Higher Speed, Curved Road and/or Road Edge Detection Scenarios)	2027–2028	2029–2030	2030–2031	2033
Enhanced AEB (Speed and Additional Scenarios)	2027–2029	2029–2030	2030–2031	2033
Driver Monitoring Systems—Drowsy Driving	2027–2030	2031–2032	2032–2033	2035
Intelligent Speed Assist	2027–2031	2032–2033	2033–2034	2035
Crashworthiness Program				
THOR–05F in Frontal Rigid Barrier Crash Test in Driver and Rear Seating Positions	2027	2028	2029	2031
WorldSID–50M in Side Impact Tests	2027	2028	2029	2031
WorldSID–05F * in Side Impact Crash Tests	2027–2029	2030	2031	2033
VRU Safety Program				
Enhanced AEB for Bicyclists and Motorcyclists in Intersection Crashes	2027–2028	2029–2030	2030–2031	2033
Enhanced PAEB (Additional Scenarios)	2027–2028	2029–2030	2030–2031	2033
Driver Visibility	2027–2029	.....	.....	.....

* WorldSID–05F is an advanced 5th percentile female side impact crash test dummy.

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FIGURE 1— PROPOSED UPDATED MID-TERM COMPONENT OF THE NCAP ROADMAP (IN CALENDAR YEARS)

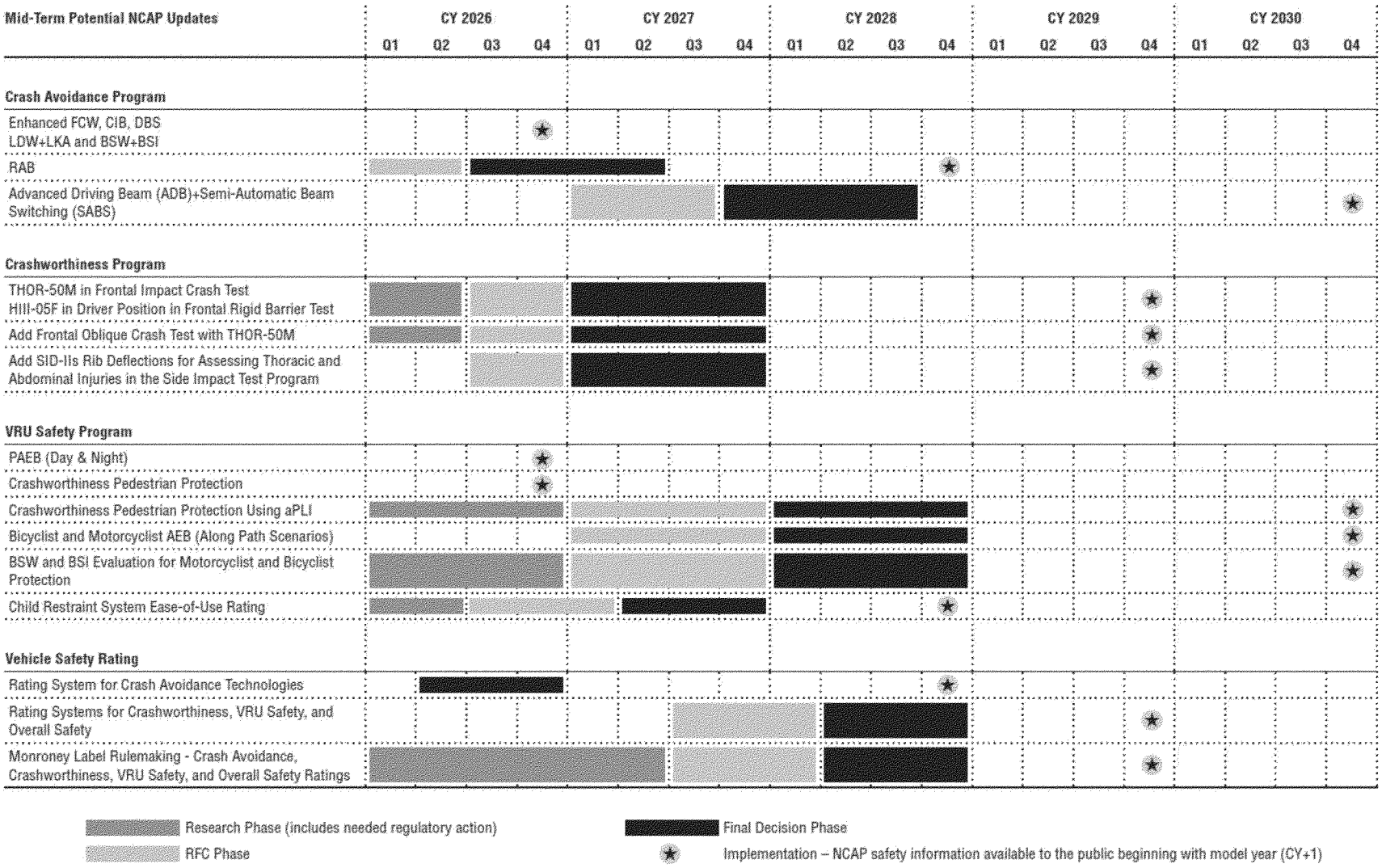
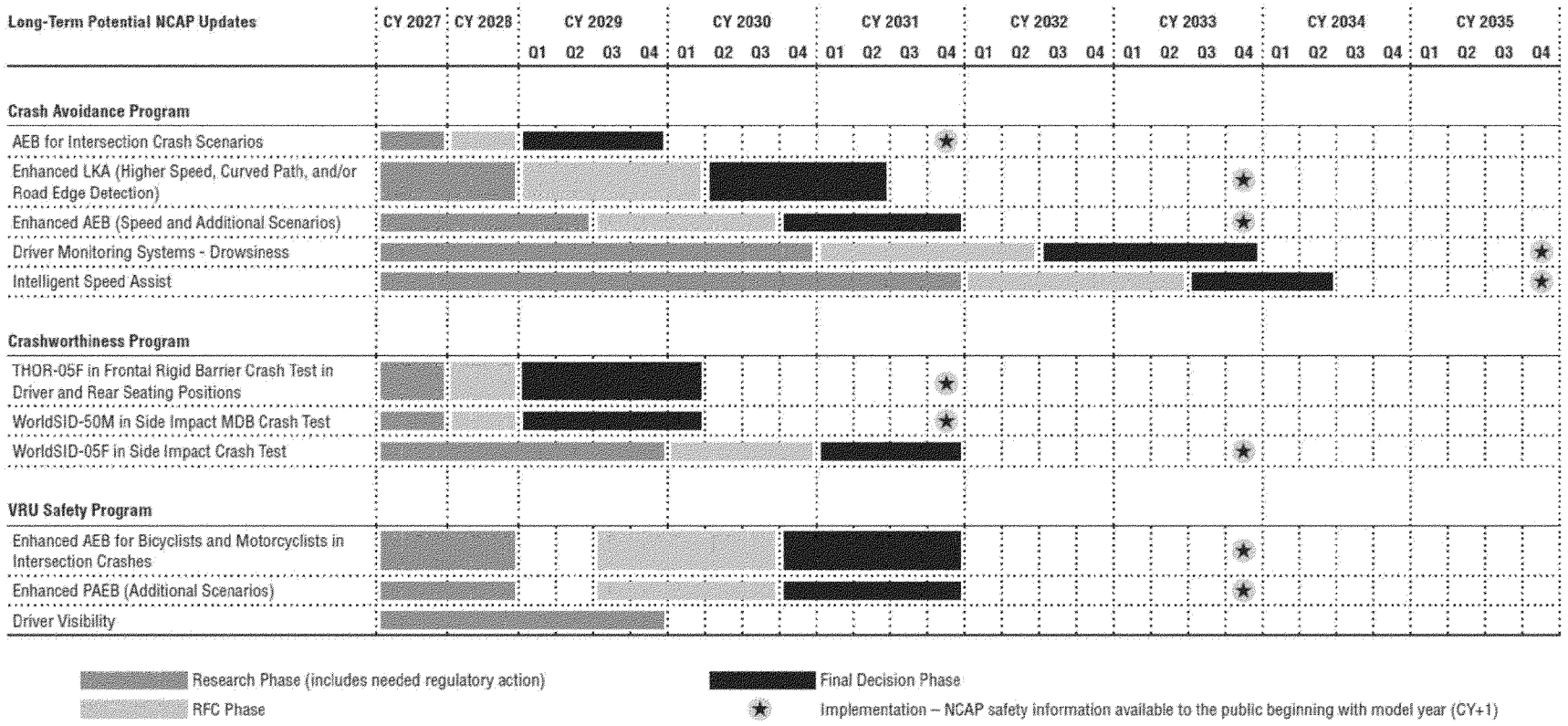


FIGURE 2— PROPOSED UPDATED LONG-TERM COMPONENT OF THE NCAP ROADMAP (IN CALENDAR YEARS)



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IV. Conclusion

NHTSA is committed to maintaining NCAP as a relevant and forward-looking consumer information program. The proposed removal of dynamic rollover and SAB–OOP testing is a strategic effort to reallocate resources toward more critical safety initiatives, such as the development of the statutorily mandated ADAS rating system, a requirement under Section 24322 of the Fixing America's Surface Transportation (FAST) Act of 2015 (Pub. L. 114–94) and Section 24213 of IIJA. In addition, the updates to NCAP's 10-year roadmap are intended to assist vehicle manufacturers in planning for future vehicle design improvements.

V. Public Participation

Interested parties are strongly encouraged to submit thorough and detailed comments relating to each of the relevant areas discussed in this notice. Please see Appendix A for a summarized list of specific questions that have been posed in this notice. Comments submitted will help NHTSA make informed decisions as it strives to advance NCAP by encouraging continuous safety improvements for new vehicles and enhancing consumer information.

How do I prepare and submit comments?

Your comments must be written in English. To ensure that your comments are correctly filed in the Docket, please include the docket number indicated in this document in your comments.

Your comments must not be more than 15 pages long (49 CFR 553.21). NHTSA established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

If you are submitting comments electronically as a PDF (Adobe) file, NHTSA asks that the documents submitted be scanned using an Optical Character Recognition (OCR) process, thus allowing NHTSA to search and copy certain portions of your submissions.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the Agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *https://www.transportation.gov/regulations/dot-information-dissemination-quality-guidelines.*

How do I submit confidential business information?

You should submit a redacted ''public version'' of your comment (including redacted versions of any additional documents or attachments) to the docket using any of the methods identified under **ADDRESSES**. This ''public version'' of your comment should contain only the portions for which no claim of confidential treatment is made and from which those portions for which confidential treatment is claimed has been redacted. See below for further instructions on how to do this.

You also need to submit a request for confidential treatment directly to the Office of Chief Counsel. Requests for confidential treatment are governed by 49 CFR part 512. Your request must set forth the information specified in Part 512. This includes the materials for which confidentiality is being requested (as explained in more detail below); supporting information, pursuant to § 512.8; and a certificate, pursuant to § 512.4(b) and part 512, Appendix A.

You are required to submit to the Office of Chief Counsel one unredacted ''confidential version'' of the information for which you are seeking confidential treatment. Pursuant to § 512.6, the words ''ENTIRE PAGE CONFIDENTIAL BUSINESS INFORMATION'' or ''CONFIDENTIAL BUSINESS INFORMATION CONTAINED WITHIN BRACKETS'' (as applicable) must appear at the top of each page containing information claimed to be confidential. In the latter situation, where not all information on the page is claimed to be confidential, identify each item of information for which confidentiality is requested within brackets: ''[ ].''

You are also required to submit to the Office of Chief Counsel one redacted ''public version'' of the information for which you are seeking confidential treatment. Pursuant to § 512.5(a)(2), the redacted ''public version'' should include redactions of any information for which you are seeking confidential treatment (*i.e.,* the only information that should be unredacted is information for which you are not seeking confidential treatment).

NHTSA is currently treating electronic submission as an acceptable method for submitting confidential business information to the Agency under Part 512. Please do not send a hard copy of a request for confidential treatment to NHTSA's headquarters. The request should be sent to Dan Rabinovitz in the Office of the Chief Counsel at *Daniel.Rabinovitz@dot.gov,* or you may contact him for a secure file transfer link. Manufacturers or any companies that already have a Confidential Business Information (CBI) Portal account or an Enterprise Account with NHTSA should use the CBI Portal for their submission. If you submit a CBI request, please also email a courtesy copy of the request to Taryn Rockwell at *taryn.rockwell@dot.gov.*

Will the Agency consider late comments?

We will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that the docket receives after that date. If the docket receives a comment too late for us to consider in developing a final decision (assuming that one is issued), we will consider that comment as an informal suggestion for future NCAP updates.

Issued under authority delegated in 49 CFR 1.95.

Jonathan Morrison,

Administrator.

[FR Doc. 2026–16735 Filed 8–14–26; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Extension of a Currently Approved Information Collection: Authorization Agreement for Preauthorized Payment (SF 5510)

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Standard Form 5510, ''Authorization Agreement for Preauthorized Payment''.

DATES: Written comments should be received on or before October 16, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information

to Bureau of the Fiscal Service, Bruce A. Sharp, T1–G, PO Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Authorization Agreement for Preauthorized Payment.

OMB Number: 1530–0015.

Form Number: SF 5510.

Abstract: The form is used to collect information from remitters (individuals and corporations) to authorize electronic fund transfers from accounts maintained at financial institutions to collect monies for government agencies.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit, individuals or households, Federal Government.

Estimated Number of Respondents: 100,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 25,000.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (1.) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2.) the accuracy of the agency's estimate of the burden of the collection of information; (3.) ways to enhance the quality, utility, and clarity of the information to be collected; (4.) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (5.) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 13, 2026.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2026–16726 Filed 8–14–26; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Extension of a Currently Approved Information Collection: Annual Financial Statement of Surety Companies—Schedule F

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Annual Financial Statement of Surety Companies–Schedule F.

DATES: Written comments should be received on or before October 16, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, T1–G, PO Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Annual Financial Statement of Surety Companies—Schedule F.

OMB Number: 1530–0008.

Form Number: FS Form 6314.

Abstract: The form provides information used to determine the amount of unauthorized reinsurance of Treasury approved Admitted Reinsurers. This computation is necessary to ensure the solvency of companies recognized by the Treasury to write Federal surety bonds, and their ability to carry out contractual requirements.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 317.

Estimated Time per Respondent: Varies from 1 hour to 40 hours.

Estimated Total Annual Burden Hours: 6,499.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 13, 2026.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2026–16725 Filed 8–14–26; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Taxpayer Experience Office Speaker Request

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Information Collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before October 16, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Control No. 1545–2320'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620–6008.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Taxpayer Experience Office Speaker Request.

OMB Control Number: 1545–2320.

Form number: 15424.

Abstract: If an organization would like a representative from Internal Revenue Service (IRS) Taxpayer Experience Office to speak at their event, they can complete the speaker request form. This form provides organizations with a more structured way of making the request. Also, the form streamlines the process by ensuring the IRS receives the necessary information in order to provide a speaker.

Current Actions: There is no change to the previously approved information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit, and not-for-profit institutions.

Estimated Number of Responses: 100.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 17.

Dated: August 11, 2026.

Jason M. Schoonmaker,

Tax Analyst.

[FR Doc. 2026–16717 Filed 8–14–26; 8:45 am]

BILLING CODE 4831–GV–P

FEDERAL REGISTER

Vol. 91 Monday,

No. 157 August 17, 2026

Part II

The President

Proclamation 11054—National Substance Use Primary Prevention Month, 2026

Federal Register
Vol. 91, No. 157
Monday, August 17, 2026

Presidential Documents

Title 3—

The President

Proclamation 11054 of August 12, 2026

National Substance Use Primary Prevention Month, 2026

By the President of the United States of America

A Proclamation

This National Substance Use Primary Prevention Month, we renew our pledge to safeguard our children, friends, families, and communities from the devastating reach of illicit drugs by stopping addiction before it ever begins.

Substance abuse remains among the gravest threats confronting our country, poisoning neighborhoods, shattering families, and destroying lives filled with promise. Our Nation's youth stand among the most targeted and vulnerable, susceptible at an impressionable age to influences that can draw them into a life-threatening cycle of dependency. Every young life claimed by this scourge represents a future torn from our national story, a tragedy whose grief echoes throughout households and hometowns.

My Administration has confronted this crisis with unwavering resolve to protect American lives. I proudly signed the HALT Fentanyl Act into law, permanently classifying fentanyl-related substances as Schedule I drugs, and I designated nearly a dozen cartels as foreign terrorist organizations. Our southern border now stands as the most secure in American history, stopping the flood of illegal aliens, deadly narcotics, and criminal traffickers before they can infiltrate our communities. These achievements sever the pipeline that delivers poison to our streets and our schools, forming one of the most powerful safeguards against substance abuse our Nation has ever known.

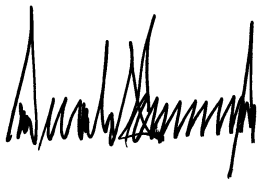
Stopping drug use before it starts remains the best path to spare families the crippling disease of addiction. For the first time in American history, my 2026 *National Drug Control Strategy* establishes a framework that places quality, evidence-based prevention at the center of our national response, uniting schools, communities, and houses of worship in a single mission. While radical lunatics pass out needles, my Administration is cleaning up our streets and preventing addiction before it starts. Education delivered through trusted voices—parents, teachers, coaches, pastors, and neighbors—is one of the strongest defenses against substance abuse, reaching young hearts and minds long before the dealers and their poisons ever can. Student drug abstention rates have already climbed to record-breaking levels under this historic effort, marking a major victory in our mission to protect young Americans.

America's youth embody the boundless promise of our Nation, a rising generation of patriots called to lead our Republic and carry the timeless values of faith, family, and freedom forward. We call on every family, every school, and every community to devote themselves to our sons and daughters, nurturing citizens that are strong, minds that are sharp, and spirits that are unshakable. Together, we will raise up a healthy, confident, and purposeful generation free from substance abuse—securing an even more glorious future where our Nation's brightest days lie forever ahead.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim August 2026 as National Substance Use Primary Prevention Month. I call upon all Americans to remain united in the same urgent mission of preventing drug use before

it begins so that our Nation's children can lead lasting and fulfilling lives free from the grip of addiction. By preventing drug use before it starts, we will protect our Nation's youth, strengthen American families, fortify communities across our country, and build a drug-free future for all.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of August, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



[FR Doc. 2026–16799
Filed 8–14–26; 11:15 am]
Billing code 3395–F4–P

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