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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 989

[Doc. No. AMS–SC–23–0039; 23–J–0080]

Raisins Produced From Grapes Grown in California; Order Amending Marketing Order No. 989

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends Marketing Order No. 989, which regulates the handling of raisins produced from grapes grown in California. The Department of Agriculture approves and adopts amendments proposed by the Raisin Administrative Committee (Committee) after due consideration of a public hearing record, and after California raisin producers voted in favor of such amendments in a referendum. This rule reduces the Committee membership size from 47 to 21, removes producer district representation and adds an unaffiliated producer member seat, eliminates the designated cooperative bargaining association member seat, and lowers quorum requirements from 25 to 14; removes the requirement for separate member and alternate member position nominations for independent and small cooperative producers; removes factor 4 and part of factor 5 for establishing marketing policy and adds language clarifying the quality of reconditioned raisins; and adds authority to accept voluntary contributions and language regarding ownership of intellectual property. In addition, this action makes necessary changes to the marketing order to conform to the amendments adopted.

DATES: This rule is effective November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Christy Pankey, Marketing Specialist, or

Matthew Pavone, Chief, Rulemaking Services Branch, Market Development Division, Specialty Crops Program, AMS, USDA; telephone: (202) 720–8085, or email: Christy.Pankey@usda.gov or Matthew.Pavone@usda.gov.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: a Notice of Hearing published in the January 12, 2024, issue of the **Federal Register** (89 FR 2178); a Recommended Decision and Opportunity to File Written Exceptions published in the September 13, 2024, issue of the **Federal Register** (89 FR 74851); and a Secretary's Decision and Referendum Order published in the December 11, 2025, issue of the **Federal Register** (90 FR 57384).

This action is governed by the provisions of sections 556 and 557 of title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Orders 12866 and 14192.

Notice of this rulemaking action was provided to Tribal Governments through the USDA Office of Tribal Relations.

Preliminary Statement

This action finalizes amendments to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Order No. 989, as amended (7 CFR part 989), regulating the handling of raisins produced from grapes grown in California. Part 989 (referred to as the "Order") is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act." The final rule was formulated on the record of a public hearing held at the office of the Raisin Administrative Committee (Committee), 2445 Capitol Street, Suite 200, Fresno, California 93721, on February 13 and 14, 2024. The hearing was conducted pursuant to the provisions of the Act, and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900). Notice of this hearing was published in the **Federal Register** on January 12, 2024 (89 FR 2178) and provided an outline of each of the four amendatory proposals to the Order.

Upon the basis of evidence introduced at the hearing and the record thereof, on September 16, 2024, the Administrator of the Agricultural Marketing Service (AMS) filed with the

Hearing Clerk, USDA, a Recommended Decision and Opportunity to File Written Exceptions thereto by October 15, 2024. AMS published a copy of the Recommended Decision and Opportunity to File Written Exceptions in the **Federal Register** on September 13, 2024 (89 FR 74851). Three exceptions were filed. These exceptions opposed the removal of the designated cooperative bargaining association seat from the Committee membership.

AMS published the Secretary's Decision and Referendum Order in the **Federal Register** on December 11, 2025 (90 FR 57384), directing that a referendum be conducted during the period of January 12 through January 30, 2026, among eligible California raisin growers to determine whether they favored the amendments to the Order. To become effective, per the Order, the proposed amendments noted below required approval by at least two-thirds of producers voting, or by at least two-thirds of the volume of raisins represented by voters voting in the referendum.

The amendments to reduce the Committee membership size from 47 to 21, remove producer district representation and add an unaffiliated producer member seat, eliminate the designated cooperative bargaining association member seat, and lower quorum requirements from 25 to 14 were favored by 76.25 percent of the growers voting in the referendum, representing 82.66 percent of the total volume of raisins produced by those voting.

The amendment to remove the requirement for separate member and alternate member position nominations for independent and small cooperative producers was favored by 67.50 percent of the growers voting in the referendum, representing 81.65 percent of the total volume of raisins produced by those voting.

The amendments to remove factor 4 and part of factor 5 from the Committee's considerations for establishing marketing policy and add language to clarify the quality of reconditioned raisins as standard raisins were favored by 81.25 percent of the growers voting in the referendum, representing 91.99 percent of the total volume of raisins produced by those voting.

The amendments to add authority to accept voluntary contributions and add language regarding ownership of intellectual property were favored by 72.97 percent of the growers voting in the referendum, representing 87.75 percent of the total volume of raisins produced by those voting.

All proposed amendments exceeded the two-thirds requirement. Accordingly, the amendments favored by voters included in this final rule will reduce Committee membership size from 47 to 21, remove producer district representation, add an unaffiliated producer member seat, eliminate the designated cooperative bargaining association seat, and lower quorum requirements from 25 to 14; remove the requirement for separate member and alternate member position nominations for independent and small cooperative producers; remove factor 4 and part of factor 5 for establishing marketing policy, and add language clarifying the quality of reconditioned raisins; and add authority to accept voluntary contributions and add language regarding ownership of intellectual property.

AMS also recommended necessary changes to the Order to conform to the amendments adopted or to correct minor inconsistencies and typographical errors. Specifically, AMS revised § 989.129 to replace the word “ballot” with “vote.” AMS revised § 989.129 to revert the regulatory text to its original form prior to the 2018 amendment (October 26, 2018; 83 FR 53965), which separated nomination procedures for independent producers or producers affiliated with small cooperative marketing associations. This conforming change aligns with the Committee’s proposal to remove the requirement that independent and small cooperative producers must be nominated separately for either a member or alternate member position. In addition, witnesses at the hearing testified in support of the amendment to remove separate nominations for small cooperative and independent producers, stating that separate nomination procedures discouraged participation rather than encouraged it, and that the separate nominations would no longer be necessary with a smaller Committee size. The regulatory text included in this final rule reflects this conforming change.

The amended marketing agreement was subsequently mailed to all raisin handlers in the production area for their approval. The amended marketing agreement was not approved by handlers representing more than 50 percent of the volume of raisins handled

by all handlers during the August 1, 2024, through July 31, 2025, representative period. Consequently, a companion handler agreement will not be established.

Small Business Considerations

Pursuant to the 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, and the rules issued thereunder, are unique in that they are brought about through group action of typically small entities acting on their own behalf.

According to the hearing transcript, there are approximately 1,500 producers of California raisins. According to the National Agricultural Statistical Service (NASS) data presented at the hearing, the total value of production for the 2022–2023 crop year of raisins was \$381,780,000. Taking the total value of production for raisins and dividing it by the total number of raisin producers provides a return per producer of \$254,520 (\$381,780,000 production volume divided by 1,500 producers). Small agricultural producers of raisins are defined by the Small Business Administration (SBA) as those having annual receipts equal to or less than \$4 million (NAICS code 111332, Grape Vineyards) (13 CFR 121.201). Therefore, a majority of raisin producers would be considered small entities under SBA’s standards.

According to the hearing record, there were 17 handlers for the 2022–2023 crop year. Small agricultural service firms are defined as those whose annual receipts are equal to or less than \$34 million (NAICS code 115114, Postharvest Crop Activities) (13 CFR 121.201). To make a similar computation for handlers, the first step is to estimate a representative handler price received per pound for packaged raisins. Recent USDA purchases under the Commodity Procurement Program provide such an estimate. For the most recent raisin crop year used by the Committee, the 2022–2023 crop year average price paid for packaged raisins purchased by the USDA for food assistance programs was \$1.56 per pound. The annual receipts for handlers can be calculated by taking the USDA average purchase price and multiplying it by the total number of shipments as

reported by the Committee for the 2022–2023 crop year (\$1.56 multiplied by 414,898,000 pounds) which equals \$647,240,880. Taking the calculation for the annual receipts by handlers and dividing by the number of handlers provides an estimated annual receipt per handler (\$647,240,880 divided by 17 handlers), which equals \$38,072,993. Based on the SBA definition of an agricultural service firm having less than \$34 million in annual receipts, there is a mix of both large and small raisin handlers.

The production area regulated under the Order covers the State of California. Acreage devoted to raisin production in the production area has declined in recent years. According to data presented at the hearing, bearing acreage for raisins reached a high of 280,000 acres during the 2000–2001 crop year. Since then, bearing acreage for raisins has decreased almost 53 percent to 133,000 acres in 2021–2022. Total production of raisins reached a high during the 2000–2001 crop year of 2,921,000 tons (green tons) but has decreased 65 percent to a total production of raisins of 1,010,000 tons in 2021–2022.

During the hearing held on February 13 and 14, 2024, interested persons were invited to present evidence on the probable regulatory and informational impact of the proposed amendments to the Order on small businesses. The evidence presented at the hearing showed that none of the proposed amendments would have any burdensome effects on small agricultural producers or firms.

Material Issues

This action amends the Order to reduce the Committee membership size from 47 to 21, remove producer district representation and add an unaffiliated producer member seat, eliminate the designated cooperative bargaining association member seat, and lower quorum requirements from 25 to 14; remove the requirement for separate member and alternate member position nominations for independent and small cooperative producers; remove factor 4 and part of factor 5 for establishing marketing policy and add language clarifying the quality of reconditioned raisins; and add authority to accept voluntary contributions and language regarding ownership of intellectual property. In addition, this action makes necessary changes to the Order to conform to the amendments adopted.

The hearing record shows that the amendments will help reduce Committee vacancies, improve attendance, generate cost savings,

enhance administrative efficiency, ensure fair representation, and align Committee membership with the overall size of the California raisin industry. The record demonstrates that reducing the Committee membership size from 47 to 21 will make it easier to manage and fill Committee positions, thus improving attendance and lessening the likelihood of prolonged vacancies. This amendment, along with the other amendments to remove producer district representation, add an unaffiliated producer member seat, and eliminate the designated cooperative bargaining association member seat, ensure that the size and composition of the Committee align with the size and structure of the industry and that different stakeholders within the industry have a fair and equitable level of representation on the Committee. Further, with lower quorum requirements, the Committee can make decisions more easily and reduce meeting delays and rescheduling caused by low attendance, improving administrative efficiency and generating cost savings for the Committee.

The record further showed that removing the requirement for separate member and alternate member position nomination procedures for independent and small cooperative producers will enhance administrative efficiency by reducing administrative burden and streamlining the nomination process.

Additionally, removing factors for establishing marketing policy will improve administrative efficiency by removing unnecessary and outdated considerations, allowing the Committee to focus on more relevant matters. Further, the amendment to clarify the quality of reconditioned raisins will dispel negative impressions stemming from misconceptions and clarify the quality of reconditioned fruit, streamlining sales and contribute to improved administrative efficiencies.

Lastly, the addition of voluntary contribution authority and intellectual property language will generate cost savings, as voluntary contributions and revenue from intellectual property can provide additional funding, aside from assessments, that the Committee may use for other activities approved under the Order, such as research and promotion.

These amendments align the Order with current market-driven practices that result in a more efficient industry for producers and handlers of all sizes. AMS has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule. These amendments are intended to improve the operation and administration of the

Order and to assist in the marketing of California raisins.

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.

Paperwork Reduction Act

Current information collection requirements that are part of the Federal marketing order for California raisins (7 CFR part 989) are approved under OMB No. 0581–0178 Vegetables and Specialty Crops. Some minor changes in those requirements are anticipated as a result of this proceeding. Changes would remove information no longer applicable. Such changes would be submitted to OMB for approval.

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.

Civil Justice Reform

The amendments to the Order herein have been reviewed under Executive Order 12988, “Civil Justice Reform.” They are not intended to have retroactive effect. The amendments do not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with 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. A 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 no later than 20 days after the date of entry of the ruling.

Order Amending the Order Regulating the Handling of Raisin Produced From Grapes Grown in California¹

Findings and Determinations

The findings and determinations hereinafter set forth are supplementary to the findings and determinations that were previously made in connection with the issuance of the Order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) Findings and Determinations Upon the Basis of the Hearing Record

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure effective thereunder (7 CFR part 900), a public hearing was held upon proposed further amendment of Marketing Order No. 989, regulating the handling of raisins produced from grapes grown in California.

Upon the basis of the record, it is found that:

(1) The Order, as amended, and as hereby further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

(2) The Order, as amended, and as hereby further amended, regulates the handling of raisins produced from grapes grown in the production area in the same manner as, and is applicable only to, persons in the respective classes of commercial and industrial activity specified in the marketing order upon which a hearing has been held;

(3) The Order, as amended, and as hereby further amended, is limited in its application to the smallest regional production area that is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

(4) The Order, as amended, and as hereby further amended, prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of raisins produced from grapes grown in California; and

¹ This Order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

(5) All handling of raisins produced from grapes grown in the production area as defined in the Order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Order Relative To Handling

It is therefore ordered, that on and after the effective date hereof, all handling of raisins grown in California shall be in conformity to, and in compliance with, the terms and conditions of the said Order, as amended, and as hereby amended as follows:

The provisions of the proposed marketing order amending the Order contained in the Recommended Decision and Opportunity to File Written Exceptions published in the September 13, 2024, issue of the **Federal Register** (89 FR 74851), and in the Secretary's Decision and Referendum Order (December 11, 2025; 90 FR 57384), will be and are the terms and provisions of this order amending the Order and are set forth in full herein.

List of Subjects in 7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 7 CFR part 989 is amended as follows:

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for part 989 continues to read as follows:

Authority: 7 U.S.C. 601–674.

§ 989.22 [Removed and Reserved]

■ 2. Remove and reserve § 989.22.

■ 3. Amend § 989.24 by revising paragraph (b) to read as follows:

§ 989.24 Standard raisins, off-grade raisins, other failing raisins, and raisin residual material.

* * * * *

(b) *Off-grade raisins* means raisins which do not meet the then effective minimum grade and condition standards for natural condition raisins: *Provided*, That raisins which are certified as off-grade raisins shall continue to be such until successfully reconditioned as standard raisins or become “other failing raisins.”

* * * * *

■ 4. Revise § 989.26 to read as follows:

§ 989.26 Establishment and membership.

A Raisin Administrative Committee is hereby established consisting of 21

members of whom 12 shall represent producers, 8 shall represent handlers, and 1 shall be a public member.

(a) The producer members shall be selected as follows:

(1) Producer members representing the cooperative marketing association(s) shall be members of such association(s) engaged in the handling of raisins, each of which acquired not less than 10 percent of the total raisin acquisitions during the preceding crop year, and those members shall be equal to the product, rounded to the nearest whole number, obtained by multiplying 12 by the ratio of the cooperative marketing association(s) raisin acquisitions are to the acquisitions of all handlers during the preceding crop year.

(2) Producer members representing cooperative bargaining association(s) shall be members of such association(s), and the number of those members shall be equal to the product, rounded to the nearest whole number, obtained by multiplying 12 by the ratio the raisins acquired by handlers from bargaining association members are to the total acquisitions of all handlers during the preceding crop year.

(3) All other producer members, who shall not be members of a cooperative bargaining association(s), cooperative marketing association(s) engaged in the handling of raisins which acquired 10 percent or more of the total acquisitions during the preceding crop year, nor sold for cash to cooperative marketing association(s), shall represent all producers not defined in paragraphs (a)(1) or (a)(2) of this section and shall be selected as designated in the rules and regulations.

(b) The handler members shall be divided into two groups and include the following:

(1) Handler members shall be selected from and represent cooperative marketing association(s) engaged in the handling of raisins each of which acquired not less than 10 percent of the total raisin acquisitions during the preceding crop year, and the number of those members shall be equal to the product, rounded to the nearest whole number, obtained by multiplying 8 by the ratio of the cooperative marketing association(s) raisin acquisitions to the total acquisitions of all handlers during the preceding crop year.

(2) The remaining handler members shall be selected from and represent all other handlers, which would include all independent handlers and small cooperative marketing association(s) who acquired less than 10 percent of the total raisin acquisitions during the preceding crop year. Handler nominees for this group shall be nominated by all

handlers in the group in a manner determined by the Committee, with the approval of the Secretary, and specified in the rules and regulations.

(c) The public member shall be nominated by the Committee and selected by the Secretary as public member.

(d) For each member of the Committee there shall be an alternate member who shall have the same qualifications as the member for whom they are an alternate.

■ 5. Amend § 989.29 by revising paragraph (a) and revising and republishing paragraphs (b)(1) and (2) to read as follows:

§ 989.29 Initial members and nomination of successor members.

(a) *Initial members.* Members and alternate members of the Committee serving immediately prior to the effective date of this amended subpart shall, if thereafter they are eligible, serve on the Committee until April 30, 2026, and until their respective successors have been selected and qualified.

(b) * * *

(1) The Committee shall notify the cooperative marketing association(s) engaged in handling not less than 10 percent of the total raisin acquisitions during the preceding crop year, and cooperative bargaining association(s), of the date by which nominations to fill member and alternate member positions shall be made. The Committee shall give reasonable publicity of a meeting or meetings of producers who are not members of cooperative bargaining association(s), or cooperative marketing association(s) which handled 10 percent or more of the total raisin acquisitions during the preceding crop year, and of independent handlers and cooperative marketing association(s) who handled less than 10 percent of the total raisin acquisitions during the preceding crop year, for the purpose of making nominations to fill the member and alternate member positions prescribed in § 989.26 (a)(3) and (b): *Provided*, That member and alternate member nominations by independent handlers and cooperative marketing association(s) who acquired less than 10 percent of the total raisin acquisitions during the preceding crop year may be made to the Committee by mail in lieu of meetings.

(2)(i) Any producer representing independent producers and producers who are affiliated with cooperative marketing association(s) handling less than 10 percent of the total raisin acquisitions during the preceding crop year must have produced grapes which were made into raisins.

(ii) Each such producer whose name is offered in nomination to represent on the Committee independent producers or producers who are affiliated with cooperative marketing association(s) handling less than 10 percent of the total raisin acquisitions during the preceding crop year shall be given the opportunity to provide the Committee a short statement outlining qualifications and desire to serve if selected. These brief statements, together with a ballot and voting instructions, shall be mailed to all independent producers and producers who are affiliated with cooperative marketing associations handling less than 10 percent of the total raisin acquisitions during the preceding crop year of record with the Committee. The producer candidate receiving the highest number of votes shall be designated as the first member nominee for a member position in which they qualify, the second highest shall be designated as the second member nominee for a member position which they qualify, until nominees for all producer member positions have been filled. Similarly, after all producer member positions have been filled, the producer candidate receiving the highest number of votes shall be designated as the first alternate member nominee for a member position in which they qualify, the second highest shall be designated as the second alternate member nominee for a member position in which they qualify, until nominees for all alternate member positions have been filled.

(iii) In the event there are no qualified candidates for any designated producer member or alternate member positions, such positions may be filled by other producer candidates not otherwise nominated for a position.

(iv) Each independent producer or producer affiliated with cooperative marketing association(s) handling less than 10 percent of the total raisin acquisitions during the preceding crop year shall cast only one vote with respect to each position for which nominations are to be made. Write-in candidates shall be accepted. The person receiving the most votes with respect to each position to be filled, in accordance with paragraph (b)(2)(ii) and (iii) of this section, shall be the person to be certified to the Secretary as the nominee. The Committee may, subject to the approval of the Secretary, establish rules and regulations to effectuate this section.

* * * * *

■ 6. Revise § 989.30 to read as follows:

§ 989.30 Selection.

The Secretary shall select producer, handler, and public members and alternate members in the number specified in § 989.26, as applicable, and with the qualifications specified in § 989.27. Such selections may be made from nominations certified pursuant to § 989.29, or from other eligible producers or handlers.

§ 989.38 [Amended]

■ 7. Amend § 989.38 by removing the numeral “25” and adding in its place the numeral “14”.

§ 989.54 [Amended]

- 8. Amend § 989.54 by:
 - a. Removing paragraph (a)(4);
 - b. Redesignating paragraphs (a)(5) through (9) as paragraphs (a)(4) through (8), respectively; and
 - c. In newly redesignated paragraph (a)(4), removing the text “, considering the estimated world raisin supply and demand situation”.
- 9. Amend § 989.58 by adding paragraph (g) to read as follows:

§ 989.58 Natural condition raisins.

* * * * *

(g) *Quality reconditioned raisins.* All raisins which have been inspected and certified as meeting the minimum grade, quality, and condition standards established pursuant to this section, whether upon incoming inspection or upon later inspection after reconditioning, shall be determined to be standard raisins, labelled accordingly, and shall be eligible for commercial disposition as natural condition raisins or packed raisins in normal outlets.

■ 10. Add § 989.63 to read as follows:

§ 989.63 Contributions.

The Committee may accept voluntary contributions: *Provided*, That such contributions shall only be used to pay expenses authorized under § 989.79. Furthermore, contributions shall be free from any encumbrances by the donor and the Committee shall retain complete control of their use.

■ 11. Add § 989.64 to read as follows:

§ 989.64 Patents, copyrights, trademarks, inventions, product formulations, and publications.

(a) Any patents, copyrights, trademarks, inventions, product formulations, and publications developed through the use of funds received by the Committee under this subpart shall be the property of the U.S. Government, as represented by the Committee, and shall, along with any rents, royalties, residual payments, or

other income from the rental, sales, leasing, franchising, or other uses of such patents, copyrights, trademarks, inventions, product formulations, or publications, inure to the benefit of the Committee; shall be considered income subject to the same fiscal, budget, and audit controls as other funds of the Committee; and may be licensed subject to approval by the Secretary.

(b) Upon termination of this subpart, § 989.92 shall apply to determine disposition of any property, including patents, copyrights, trademarks, inventions, product formulations, and publications developed through the use of funds received by the Committee under this subpart.

(c) Should patents, copyrights, trademarks, inventions, product formulations, or publications be developed through the use of funds collected by the Committee under this subpart and funds contributed by another organization or person, ownership and related rights to such patents, copyrights, trademarks, inventions, product formulations, or publications shall be determined by agreement between the Committee and the person or organization contributing funds towards the development of such patents, copyrights, inventions, trademarks, product formulations, or publications in a manner consistent with paragraph (a) of this section.

(d) Should any patents, copyrights, trademarks, inventions, product formulations, or publications be licensed to the Committee by another person or organization, the rights and obligations regarding such licensed patents, copyrights, trademarks, inventions, product formulations, or publications shall be determined by agreement between the Committee and the person or organization permitting licensure in a manner consistent with paragraph (a) of this section.

§ 989.122 [Removed and Reserved]

■ 12. Remove and reserve § 989.122.

■ 13. Revise and republish § 989.126 to read as follows:

§ 989.126 Representation of the Committee.

(a) Pursuant to § 989.26(a)(3), and commencing with the term of office beginning May 1, 2026, apportionment of independent and small cooperative producers shall be:

(1) One producer member, selected from and representing all producers, who is unaffiliated with any handler (including, but not limited to, ownership, employment, or agent of any handler, and whose family members are

similarly unaffiliated with any handler); and

(2) The remaining producer member(s) selected from and representing all other independent and small cooperative producers.

(b) Pursuant to section § 989.26(b)(2), and commencing with the term of office beginning May 1, 2026, apportionment of the independent and small cooperative marketing association handlers shall be:

(1) Two members selected from and representing the four handler(s) other than major cooperative marketing association handler(s) who acquired the largest percentage of the total raisin acquisitions during the preceding crop year; and

(2) The remaining member(s) selected from and representing all other handlers, including small cooperative marketing association handler(s) and all processors.

■ 14. Revise and republish § 989.129 to read as follows:

§ 989.129 Voting at nomination meetings.

Any person (defined in § 989.3 as an individual, partnership, corporation, association, or any other business unit) who is engaged, in a proprietary capacity, in the production of grapes which are sun-dried or dehydrated by artificial means to produce raisins and who qualifies under the provisions of § 989.29(b)(2) shall be eligible to cast one vote for a nominee for each producer member position and one vote for a nominee for each producer alternate member position on the Committee which is to be filled. Such person must be the one who or which: Owns and farms land resulting in his or its ownership of such grapes produced thereon; rents and farms land, resulting in his or its ownership of all or a portion of such grapes produced thereon; or owns land which he or it does not farm and, as rental for such land, obtains the ownership of a portion of such grapes or the raisins. In this connection, a partnership shall be deemed to include two or more persons (including a husband and wife) with respect to land the title to which, or leasehold interest in which, is vested in them as tenants in common, joint tenants, or under community property laws, as community property. In a landlord-tenant relationship, wherein each of the parties is a producer, each such producer shall be entitled to one vote for a nominee for each producer member position and one vote for each producer alternate member position. Hence, where two persons operate land as landlord and tenant on a share-crop basis, each person is entitled to one vote

for each such position to be filled. Where land is leased on a cash rental basis, only the person who is the tenant or cash renter (producer) is entitled to vote. A partnership or corporation, when eligible, is entitled to cast only one vote for a nominee for each producer position to be filled.

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2026–20792 Filed 10–8–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–11805; Project Identifier MCAI–2026–00811–R; Amendment 39–23491; AD 2026–21–02]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 C–1 helicopters. This AD was prompted by a report of a louver box assembly detaching in flight due to incorrect installation. This AD requires repetitively accomplishing a play check of the affected louver box assembly and, depending on the results of the check, accomplishing corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 26, 2026.

The FAA must receive comments on this AD by November 23, 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–2026–11805; 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 final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT:

Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222–4058; email: *aryanna.t.sanchez@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under **ADDRESSES**. Include “Docket No. FAA–2026–11805; Project Identifier MCAI–2026–00811–R” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, 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 final rule 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 final rule.

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 AD 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 AD, 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 AD. Submissions containing CBI should be sent to Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2026–0152, dated July 30, 2026 (EASA AD 2026–0152) (also referred to as “the MCAI”), to correct an unsafe condition on all AHD Model MBB–BK 117 C–1 helicopters. The MCAI states an occurrence was reported of an affected louver box assembly of the vapor cycle air cooling system part number (P/N) 117–820014 detaching in-flight due to incorrect installation. This condition, if not addressed, could lead to in-flight loss of parts, which could impact the main or tail rotor, lead to reduced control of the helicopter, necessitate an emergency landing, or cause injury to persons on the ground.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–11805.

FAA’s Determination

These products have been approved by the civil aviation authority 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 AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD requires repetitively accomplishing a play check of the

louver box assembly of vapor cycle air cooling system part number (P/N) 117–820014, and if there is any play accomplishing corrective actions in accordance with a method approved by the Manager, International Validation Branch, FAA; or EASA; or AHD’s EASA Design Organization Approval (DOA).

The owner/operator (pilot) holding at least a private pilot certificate may accomplish a play check of the louver box assembly of vapor cycle air cooling system installed on the helicopter, by pulling it upward by hand on all four corners, and must enter compliance into the helicopter maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439. The pilot may perform this action because it only involves checking to see if the louver box assembly is installed firmly, which could be performed equally well by a pilot or mechanic. This is an exception to the FAA’s standard maintenance regulations.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this

rule because if a louver box assembly is incorrectly installed, it could lead to parts separating from the helicopter in flight and impacting the main rotor blade or the tail rotor blade. This condition could also lead to an emergency landing, or impact of parts to persons on ground. The root cause of this separation has been identified as incorrect installation; however, the specific installation deficiency has not yet been fully determined. To ensure this unsafe condition is immediately detected and does not reoccur, a play check for looseness must be done before the first flight of each day. This compliance time is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Interim Action

The FAA considers that this AD is an interim action. If final actions are later identified, the FAA might consider further rulemaking.

Costs of Compliance

The FAA estimates that this AD affects 9 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Play check of the louver box assembly (per check).	1 work-hour × \$85 per hour = \$85 (per check).	\$0	\$85 (per check)	\$765 (per check).

The actions needed as a result of any play in the assembly could vary significantly from helicopter to helicopter. The FAA was unable to obtain costs of any corrective actions from the design approval holders within

the time necessary to address the unsafe condition.

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

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866, and
- (2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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:

2026–21–02 Airbus Helicopters

Deutschland GmbH (AHD): Amendment 39–23491; Docket No. FAA–2026–11805; Project Identifier MCAI–2026–00811–R.

(a) Effective Date

This airworthiness directive (AD) is effective October 26, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Deutschland GmbH (AHD) Model MBB–BK 117 C–1 helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2100, Air conditioning system.

(e) Unsafe Condition

This AD was prompted by a report of a louver box assembly detaching in flight due to incorrect installation. The FAA is issuing this AD to address and prevent incorrectly installed parts. The unsafe condition, if not addressed, could lead to in-flight loss of parts, which could impact the main or tail rotor, lead to reduced control of the helicopter, necessitate an emergency landing, or cause injury to persons on the ground.

(f) Compliance

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

(g) Required Actions

(1) Before the first flight of each day, accomplish a play check of the louver box assembly of the vapor cycle air cooling system part number (P/N) 117–820014, as depicted in Figure 1 to paragraph (g)(1) of this AD, by pulling it upward by hand on all four corners. The owner/operator (pilot) holding at least a private pilot certificate may accomplish this play check, and must enter compliance into the helicopter maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

Figure 1 to paragraph (g)(1)

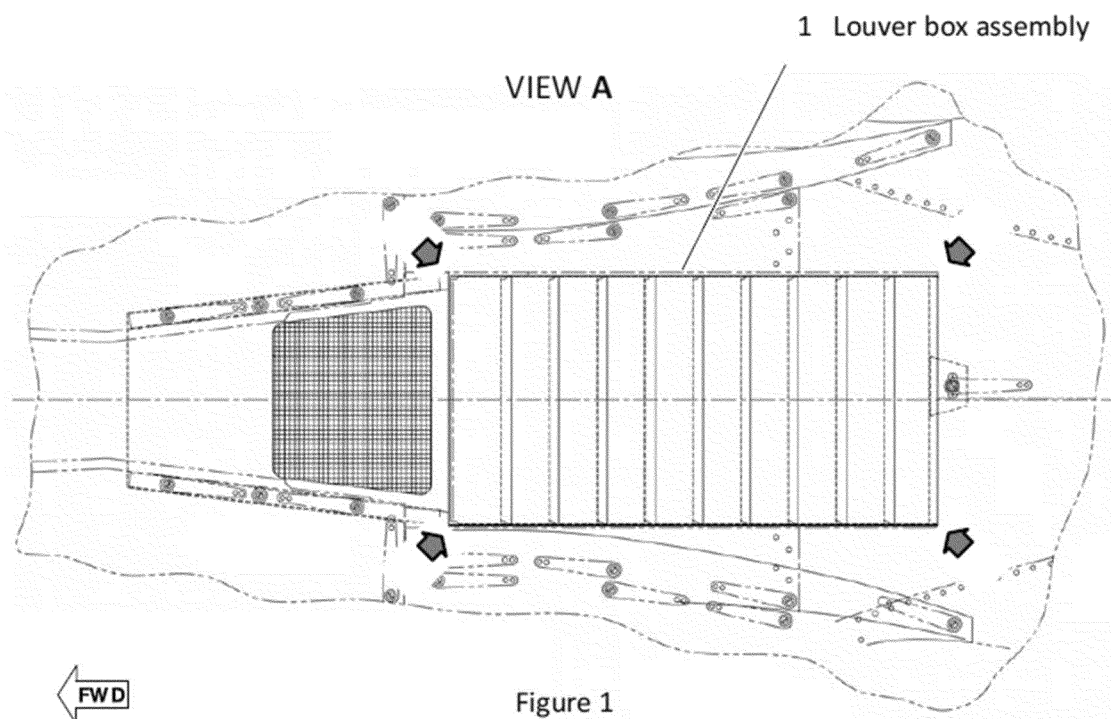


Figure 1

(2) If there is any play found during any check required by paragraph (g)(1) of this AD, before further flight, accomplish corrective actions in accordance with a method approved by the Manager, International Validation Branch, FAA; or EASA; or AHD's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(h) No Reporting Requirement

Although the material referenced in EASA AD 2026-0152 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation 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 International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: AMOC@faa.gov.

(2) 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.

(j) Additional Information

For more information about this AD, contact Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222-4058; email: aryanna.t.sanchez@faa.gov.

(k) Material Incorporated by Reference

None.

Issued on October 6, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026-20722 Filed 10-7-26; 11:15 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2026-N-10994]

Medical Devices; Immunology and Microbiology Devices; Classification of the Hematopoietic Cell Enrichment Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the hematopoietic cell enrichment kit into

class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the hematopoietic cell enrichment kit. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 9, 2026. The classification was applicable on November 6, 2023.

FOR FURTHER INFORMATION CONTACT:

Allen Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3248, Silver Spring, MD 20993-0002, 301-796-4806, Allen.Williams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the hematopoietic cell enrichment kit into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate

device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 12, 2022, FDA received STEMCELL Technologies Canada Inc.’s request for De Novo classification of the EasySep Human Bone Marrow CD138 Positive Selection Kit. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general

controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 6, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21

CFR 866.6120.¹ We have named the generic type of device “hematopoietic cell enrichment kit,” and it is identified as an in vitro diagnostic device intended for the selection and enrichment of specific hematopoietic cells from human whole blood and/or bone marrow collected from patients with hematological malignancies using immunomagnetic bead-based selection. It is intended for use with diagnostic assays as part of the pre-analytical workflow.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR HEMATOPOIETIC CELL ENRICHMENT KITS

Identified risks to health	Mitigation measures
Failure to perform as expected due to errors in enrichment, contributing to false positive or false negative results, or failure to produce results in downstream assays.	Use of certain specimen collection devices. Certain design verification and validation, including certain studies and risk mitigation analysis. Certain labeling information, including limitations, device descriptions, methodology and protocols, and performance information.
Incorrect interpretation of enrichment results by the lab	Certain labeling information, including limitations, device descriptions, methodology and protocols, and performance information. Certain design verification and validation, including certain studies and risk mitigation analysis.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is 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) of the FD&C Act. At this time FDA has not made this determination for hematopoietic cell enrichment kits. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These 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 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved

under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

- 1. The authority citation for part 866 continues to read as follows:
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.
- 2. Add § 866.6120 to subpart G to read as follows:
§ 866.6120 Hematopoietic cell enrichment kit.
(a) *Identification.* A hematopoietic cell enrichment kit is an in vitro diagnostic device intended for the selection and enrichment of specific

¹ 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.

hematopoietic cells from human whole blood and/or bone marrow collected from patients with hematological malignancies using immunomagnetic bead-based selection. It is intended for use with diagnostic assays as part of the pre-analytical workflow.

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

(1) Any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (stand-alone or as part of a test system) for the collection of the sample types with which this device is intended to be used; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

(2) The intended use statement must include:

(i) The intended use specimen type (*i.e.*, human whole blood and/or bone marrow) for each malignancy for which acceptable enrichment has been demonstrated and documented using the minimum volume required to ensure a 95 percent accurate call rate when the cell concentration is at the limit of detection, per the device labeling.

(ii) A detailed description of the cell enrichment target(s).

(iii) A statement that the end-user is responsible for validation of this device for use with the assay.

(3) The labeling required under § 809.10(b) of this chapter must include:

(i) Detailed specifications and procedures, appropriately supported by replicate and stability data, for sample collection, processing, and storage, including acceptable ranges of deviation.

(ii) A detailed device description, including all device parts (*e.g.*, instruments and associated user manuals, antibody(ies), reagents, and consumables) and their use within the enrichment procedure.

(iii) Prominent and conspicuous limiting statements clearly explaining:

(A) Any end-user validation required for use with specific tests and collection devices.

(B) Bone marrow stability is severely compromised after 48 hours (or, alternatively, a different timeframe supported by appropriate specimen stability data required under paragraph (4)(i)(E) of this section).

(C) The device is intended only for enriching hematopoietic cell specimens for use in further processing or analysis using additional independent methods.

(D) Results from the device do not provide information regarding any health conditions.

(E) The device is not intended for cell enumeration.

(F) A detailed summary of the studies required under paragraph (b)(4) of this section.

(4) Design verification and validation must include:

(i) Detailed documentation of the following studies for each intended specimen type and malignancy combination, including the study protocols containing descriptions of the test methods, prescribed methods of data analysis and acceptance criteria, final study reports, and data line listings:

(A) Recovery study data demonstrating the range of the device.

(B) A study demonstrating the device limit of detection by demonstrating the minimum number of cells within a prespecified volume that the device is capable of enriching and the percent enrichment when the concentration of cells is established, using a flow cytometry reference method determined to be acceptable by FDA.

(C) A study demonstrating device reproducibility, including multiple operators at each site using the specified enrichment method(s) and protocol. The evaluation must include multiple runs, different instruments, and three different reagent lots. The study must include specimens with low, medium, and high starting enrichment target levels and result in enrichment and acceptable precision at each level. The study must include specimens containing different genetic alterations representative of the cancer indication or condition.

(D) A study demonstrating device specificity, including interference, to evaluate the impact on cell enrichment.

(E) Studies performed to support the stability of samples using the indicated specimen collection method(s) under various storage times, as applicable.

(ii) Detailed documentation of studies performed to demonstrate on-board and in-use reagent stability, including studies to demonstrate reagent shelf life.

(iii) A shipping-stability study, separate from the on-board and in-use reagent stability study, that demonstrates acceptable stability of the parts that comprise the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-20725 Filed 10-8-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2026-N-10996]

Medical Devices; Immunology and Microbiology Devices; Classification of the System for Detection of Nucleic Acid From Non-Viral Microorganism(s) Causing Sexually Transmitted Infections Using Home-Collected Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 9, 2026. The classification was applicable on November 15, 2023.

FOR FURTHER INFORMATION CONTACT:

Himani Bisht, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3106, Silver Spring, MD 20993-0002, 301-796-6189, Himani.Bisht@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by

reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure.

A device sponsor may utilize either procedure for De Novo classification. Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On November 16, 2020, FDA received LetsGetChecked Inc.’s (formerly PrivaPath Diagnostics Inc.) request for

De Novo classification of the Simple 2 Test. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 15, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.3385.¹ We have named the generic type of device “system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens,” and it is identified as an in vitro diagnostic system intended for self-collecting specimens in home settings or similar environments and testing in a clinical laboratory for detection of nucleic acids from non-viral microorganism(s) causing sexually transmitted infections. The device is intended to aid in the diagnosis of sexually transmitted infections. The device is intended for prescription use or over-the-counter use.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SYSTEMS FOR DETECTION OF NUCLEIC ACID FROM NON-VIRAL MICROORGANISM(S) CAUSING SEXUALLY TRANSMITTED INFECTIONS USING HOME-COLLECTED SPECIMENS

Identified risks to health	Mitigation measures
Risk of false results	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies.

¹ 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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SYSTEMS FOR DETECTION OF NUCLEIC ACID FROM NON-VIRAL MICROORGANISM(S) CAUSING SEXUALLY TRANSMITTED INFECTIONS USING HOME-COLLECTED SPECIMENS—Continued

Identified risks to health	Mitigation measures
Failure to correctly interpret test results	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies.
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, systems for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens include systems that are intended for prescription use only. Prescription devices are subject to the prescription labeling requirements for in vitro diagnostic products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)).

Under the FD&C Act, submission of a premarket notification under section 510(k) is 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) of the FD&C Act. At this time FDA has not made this determination for systems for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These 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 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.3385 to subpart D to read as follows:

§ 866.3385 System for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens.

(a) *Identification.* This device is an in vitro diagnostic system intended for self-collecting specimens in home settings or similar environments and testing in a clinical laboratory for detection of nucleic acids from non-viral microorganism(s) causing sexually transmitted infections. The device is intended to aid in the diagnosis of sexually transmitted infections. The device is intended for prescription use or over-the-counter use.

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

(1) The test must use a sample collection device that is FDA-cleared, -approved, or -classified as 510(k) exempt with an indication for over-the-counter in vitro diagnostic use in molecular testing; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device in which performance data demonstrate that lay users can correctly collect specimens without health care provider (HCP) supervision.

(2) The intended use in the labeling required under § 809.10 of this chapter must include a description of the following: the analytes the device detects and identifies, the clinical indications for which the test is to be used, the specimen types tested, the specific intended population(s), the name of the testing facility or facilities, as applicable, and other conditions of use as appropriate.

(3) The intended use of the device must only include indications for testing of specimens that are appropriate for collection by lay users for which

there are performance data that demonstrate lay users can correctly collect specimens without HCP supervision.

(4) Design verification and validation must include:

(i) A detailed test description of test components, including reagents, instruments, ancillary materials, control elements, and a detailed explanation of the methodology, including pre-analytical methods for processing of specimens, microorganism target(s), identification of target detection reagents (e.g., primers), internal controls, and computational path from collected raw data to reported results (e.g., how collected raw signals are converted into a reported signal and result), as applicable to the detection method and device design.

(ii) A description of the process from acquisition of the collection kit to results reporting.

(iii) Detailed descriptions of the test procedure, the interpretation of test results for clinical specimens, and acceptance criteria for any quality control testing.

(iv) Detailed documentation and test performance results from a clinical study that includes prospective self-collected samples for each claimed specimen type. This study must be performed on a study population consistent with the intended use population and compare the device's performance to results obtained using a comparator that FDA has determined is appropriate. Detailed documentation from the clinical study must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of statistical analyses.

(v) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as failure modes and effects analysis and/or hazard analysis. This must include information that demonstrates the effectiveness of risk control measures and device robustness, including the entire testing procedure from sampling to result interpretation, based on results from the following studies, as applicable per the intended use of the test device: usability studies, user label comprehension studies, and flex studies.

(vi) Detailed documentation of analytical studies, including the limit of detection, inclusivity, cross-reactivity, microbial interference, interfering substances, competitive inhibition, carryover/cross-contamination, specimen stability, within-lab precision, and reproducibility, as applicable.

(vii) Validation data to support specimen integrity during handling and shipping.

(viii) Detailed documentation of reagent stability studies.

(ix) For devices with associated software or instrumentation, a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, hazard analysis, and risk assessment activities.

(5) The labeling required under § 809.10(b) of this chapter must include the following:

(i) Clear information written in appropriate language for the intended user that includes: instructions for sample collection and sample packaging for shipping and transport to the testing site; an explanation of test results and results interpretation, including instructions on what actions to take based on the test results; and information for technical assistance with the collection kit.

(ii) A frequently asked questions section that provides technical and educational information (e.g., information about notifying sexual partners, how to prevent future infections, what to do if symptoms persist after treatment, directions to resources for further information on the disease and epidemiology).

(iii) Warning and limitation statements, including the following:

(A) A negative test result does not preclude the possibility of infection with other pathogens;

(B) The test system is not a substitute for visits to a healthcare provider. The information provided by the product should not be used to start, stop, or change any course of treatment unless advised by the healthcare provider;

(C) Anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines);

(D) Contact a healthcare provider prior to collecting the sample if the user has a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results);

(E) Accurate results are dependent on adequate product storage and adherence to the specimen collection and testing procedures;

(F) Failure to follow test procedures can lead to incorrect results; and

(G) The home collection kit must not be used beyond the expiration date. Use

of expired kits can lead to incorrect results.

(iv) Accessioning criteria for acceptability of samples received by the laboratory (e.g., time from sample collection, transport media leakage, integrity of the sample).

(6) The device's labeling must include a prominent hyperlink to the manufacturer's public website where the manufacturer must make the information identified in this section publicly and prominently available. The information must include, written in language appropriate for the intended user:

(i) A brief summary of the purpose of the test.

(ii) Detailed instructions for proper sample collection and shipping procedures, and interpretation of results.

(iii) Required warnings and limitation statements.

(iv) Contact information for technical assistance with the collection kit (e.g., helpline contact information).

(v) For tests intended for over-the-counter use, information on who should and who should not use this test, and directions for further information for a user who might not be appropriate for testing using this device.

(vi) For tests intended for over-the-counter use, information for users on any follow-up actions (e.g., a link for in-person consultation or telehealth visit with an HCP).

(vii) The performance characteristics established in required studies.

(viii) If appropriate (e.g., recommended by the Centers for Disease Control and Prevention, by current well-accepted clinical guidelines, or by published peer-reviewed research, as determined by FDA), information that the clinical performance is inferior in a specific clinical subpopulation or for a specific claimed specimen type.

(ix) If the device is intended to detect antimicrobial resistance markers, limiting statements, as appropriate, indicating that:

(A) Negative results for claimed resistance markers do not indicate susceptibility of detected microorganisms, as resistance markers not measured by the assay or other potential mechanisms of antibiotic resistance may be present;

(B) Detection of resistance markers cannot be definitively linked to specific microorganisms and the source of a detected resistance marker may be an organism not detected by the assay, including colonizing flora;

(C) Detection of antibiotic resistance markers may not correlate with phenotypic gene expression; and

(D) Therapeutic failure or success cannot be determined based on the assay results, since nucleic acids may persist following appropriate antimicrobial therapy.

(7) The outer box label required under § 809.10(a) of this chapter must include the following:

(i) A description of who may use the home collection kit and age of the intended users.

(ii) A list of the components included.

(iii) A list of the components required, but not provided (e.g., software applications needed to complete the process).

(iv) A statement that this is a home sample collection kit which requires shipping of the sample to a laboratory within the specified timeframe to receive results.

(v) A statement that anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-20727 Filed 10-8-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2026-N-10993]

Medical Devices; Cardiovascular Devices; Classification of the Infant Pulse Rate and Oxygen Saturation Monitor for Over-the-Counter Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the infant pulse rate and oxygen saturation monitor for over-the-counter use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the infant pulse rate and oxygen saturation monitor for over-the-counter use. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance

patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 9, 2026. The classification was applicable on November 8, 2023.

FOR FURTHER INFORMATION CONTACT:

Kimberly Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2272, Silver Spring, MD 20993-0002, 301-796-6017, Kimberly.Crowley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the infant pulse rate and oxygen saturation monitor for over-the-counter use into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section

207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 14, 2022, FDA received Owlet Baby Care, Inc.'s request for De Novo classification of the Dream Sock device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable

assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special

controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device. Therefore, on November 8, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.2705.¹ We have named the generic type of device “infant pulse rate

and oxygen saturation monitor for over-the-counter use,” and it is identified as a device that uses photoplethysmography to measure pulse rate and oxygen saturation in infants. The device may contain alarms that alert the caregiver when vital sign(s) go outside preset threshold(s). FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR INFANT PULSE RATE AND OXYGEN SATURATION MONITORS FOR OVER-THE-COUNTER USE

Identified risks to health	Mitigation measures
Poor quality incoming photoplethysmography signal resulting in failure to detect pulse rate and oxygen saturation.	Clinical performance testing; Human factors testing; Electrical safety testing; Electromagnetic compatibility testing; and Labeling.
Misinterpretation and/or over-reliance on device output, leading to failure to seek treatment despite acute symptoms.	Human factors testing; and Labeling.
Adverse tissue reaction	Clinical performance testing; Biocompatibility evaluation; Human factors testing; and Labeling.
False positive leading to unnecessary medical procedures	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Human factors testing; and Labeling.
False negative resulting in failure to detect high or low pulse rate event and/or low SpO2 level event.	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Human factors testing; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is 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) of the FD&C Act. At this time FDA has not made this determination for infant pulse rate and oxygen saturation monitors for over-the-counter use. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These 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 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have

been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

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

■ 2. Add § 870.2705 to subpart C to read as follows:

§ 870.2705 Infant pulse rate and oxygen saturation monitor for over-the-counter use.

(a) Identification. An infant pulse rate and oxygen saturation monitor for over-the-counter use is a device that uses photoplethysmography to measure pulse rate and oxygen saturation in infants. The device may contain alarms that alert the caregiver when vital sign(s) go outside preset threshold(s).

¹ 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.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include the following:

(i) Evaluation of the effect of confounding variables, like skin pigmentation, on performance;

(ii) Demonstration of the consistency of the output and representativeness of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment; and

(iii) Evaluation of all adverse events, including skin irritation.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include:

(i) Technical specifications of the software, including software algorithm(s) and its inputs and outputs; and

(ii) Specification of acceptable incoming sensor data quality control measures.

(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmography signal quality and validate any alarms.

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

(5) Performance testing must support the electrical safety and electromagnetic compatibility of the electrical components of the device.

(6) Human factors and usability testing must demonstrate the following:

(i) The caregiver can correctly use the device based solely on reading the device labeling; and

(ii) The caregiver can correctly interpret the device outputs and understand next steps to take based on the outputs.

(7) Labeling must include:

(i) Instructions for identifying the intended use population of the device,

including populations where the device should not be used, and conditions of monitoring;

(ii) A description of what the device measures and outputs to the caregiver, including instructions for the interpretation of results and appropriate actions;

(iii) Situations in which the device may not operate at an expected performance level; and

(iv) Instructions for cleaning the device and cleaning frequency.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20726 Filed 10–8–26; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1641]

Schedules of Controlled Substances: Placement of O-Desmethyltramadol in Schedule I; Correction

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Correcting amendment.

SUMMARY: On August 12, 2026, the Drug Enforcement Administration (DEA) published a temporary order placing *O*-desmethyltramadol (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, in schedule I of the Controlled Substances Act. DEA published this temporary order that specifically noted in the summary that the control of *O*-desmethyltramadol included its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, however

inadvertently omitted the correct language that should have been included. This document corrects that error, adding the correct language.

DATES: This correcting amendment is effective October 9, 2026, until August 12, 2028, and applicable beginning August 12, 2026.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The placement of *O*-desmethyltramadol under schedule I was effective on August 12, 2026.¹ After publication of the temporary scheduling order, DEA inadvertently omitted the correct language that should have been included in 21 CFR part 1308. This document corrects the language in 21 CFR part 1308 to include the isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible of *O*-desmethyltramadol.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA corrects 21 CFR part 1308 with the following correcting amendment:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, revise paragraph (h)(88) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(88) *O*-desmethyltramadol, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol)

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¹ Schedules of Controlled Substances: Temporary Placement of *O*-desmethyltramadol in Schedule I, 91 FR 52013 (Aug. 12, 2026).

Signing Authority

This document of the Drug Enforcement Administration was signed on October 6, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–20748 Filed 10–8–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1664]

RIN 1117–ZA08

Schedules of Controlled Substances; Removal of Exemption Status for Inactive Butalbital Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final determination.

SUMMARY: The Drug Enforcement Administration (DEA) is revoking the exempted status for certain nonnarcotic prescription products that are currently on DEA's Table of Exempted Prescription Products, but whose National Drug Codes (NDC) are inactive because they are no longer available and/or the company that applied for the exemption no longer exists. These products will be removed from DEA's Table of Exempted Prescription Products and will no longer be considered exempt prescription products under the Controlled Substances Act. This action does not impact exempted prescription products with active NDC numbers.

DATES: This final determination is effective on November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA any compound, mixture, or preparation containing certain nonnarcotic controlled substances if he finds that it is both (1) approved for prescription use, and (2) contains one or more other active ingredients which are not listed in any schedule and which are included in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.¹ The Attorney General has delegated this authority to the Administrator of DEA (Administrator).² The Administrator may also revoke a previously granted exemption by following the same procedures that are used to evaluate an application for exemption—namely, by publishing in the **Federal Register** a general notice of the proposed rulemaking (NPRM) for revoking the exemption, permitting interested persons to file written comments on or objections to the proposed revocation, considering any comments submitted, and publishing a final order in the **Federal Register** that sets forth the findings of fact and conclusions of law upon which the order is based.³

This final determination revokes the exemption status for certain prescription products previously granted exemption because the National Drug Codes (NDC) of these products are no longer active and/or the companies that originally filed for their exemption no longer exist. This action revokes the exemption status for a number of products and removes them from DEA's Table of Exempted Prescription Products. While this action revokes the exemption status, this action will have no effect on these products because they are no longer marketed.

Background: Exempted Prescription Products

DEA has exempted prescription drug products from certain parts of the CSA when the products meet the requirements for exemption, including the requirement to contain active ingredients believed to vitiate the potential for abuse. The current table of products that have been granted exempted prescription product status, pursuant to 21 CFR 1308.31 and

1308.32, can be found on the DEA Diversion Control Division website.⁴

Butalbital is classified as an intermediate acting barbiturate. Butalbital is a schedule III nonnarcotic controlled substance that falls under DEA Controlled Substances Code Number 2100, as it is a derivative of barbituric acid.⁵ Originally, some butalbital prescription products were exempted by the Bureau of Drug Abuse Control (BDAC) of the Food and Drug Administration (FDA), the predecessor to the Bureau of Narcotics and Dangerous Drugs and later DEA. A panel of public health physicians and FDA medical officers developed the criteria used to exempt butalbital prescription products by BDAC in 1967. These criteria were based upon the expectation that combining the controlled substance with an amount of counteractive drug sufficient to cause early deterrent side effects would vitiate the potential for abuse. For products containing long or intermediate acting barbiturates in combination with analgesics, the criteria provided that an exemption would be granted if, for every 15 mg of barbiturate, the product contained at least (1) 188 mg aspirin; (2) 375 mg salicylamide; or (3) 70 mg phenacetin, acetanilid, or acetaminophen.

Following the establishment of the criteria, DEA approved subsequent applications by new manufacturers based upon the same criteria, whereby the inclusion of these other active ingredients was thought to be in sufficient quantities to vitiate the potential for abuse. The criteria developed in 1967 was originally found to meet the standard for exemption currently described in 21 U.S.C. 811(g)(3)(A), such that if a prescription drug was found to meet the 1967 criteria for exemption, then it also met the test to contain an ingredient that vitiated the potential for abuse under the CSA standard.

Currently, there are 189 butalbital products listed by their NDC on DEA's Table of Exempted Prescription Products. Using the FDA's National Drug Code Directory⁶ and the U.S.

⁴ Available at https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf.

⁵ 21 CFR 1308.13(c)(3).

⁶ FDA's NDC directory contains information about finished, unfinished (e.g., active pharmaceutical ingredients) and compounded drugs. The NDC Directory contains product listing data submitted for all finished drugs including prescription and over-the-counter drugs, approved and unapproved drugs as well as repackaged and relabeled drugs. Drug establishments are required to provide FDA with a current list of all drugs, including active pharmaceutical ingredients manufactured, prepared, propagated, compounded,

¹ 21 U.S.C. 811(g)(3)(A); 21 CFR 1308.31, 1308.32.

² 28 CFR 0.100.

³ See 21 CFR 1308.31(c), (d).

National Institute of Health (NIH)—National Library of Medicines DailyMed database,⁷ DEA determined that 160 of the NDCs correlating to butalbital products on the exempt prescription product list are no longer active and marketed. DEA confirmed with FDA these products are no longer marketed. Thereafter, on May 26, 2026, DEA published an NPRM in the **Federal Register** proposing to remove these inactive products from the exempted prescription product list to accurately portray which products are currently on the market.⁸

Comments Received

DEA received one comment in response to the NPRM for the removal of butalbital products on the exempt prescription product table that are no longer active and marketed.

Comment: One commenter was concerned about the use of FDA's National Drug Code Directory and the NIH DailyMed database to identify products that are no longer marketed to remove them from the DEA Exempted Prescription Product table. The commentor mentioned that a drug product manufactured by a contract manufacturing organization and labeled for a private label distributor may have NDCs that do not appear on the NDC directory or in the DailyMed database.

The commenter proposed that all drug products with currently certified NDC numbers remain on the DEA Exempted Prescription Product Table, and that DEA should utilize FDA's complete drug listing.

DEA Response: DEA appreciates the comment submitted. Items on the DEA Exempted Prescription Product Table are NDC number specific, and the prescription product must be labeled with the exempted NDC number for identification purposes. According to the FDA National Drug Code Directory website, "The NDC Directory contains information on active and certified, finished and unfinished drugs submitted to FDA in structured product labeling electronic listing files by labelers. The NDC Directory contains product listing data submitted for all finished drugs including prescription and over-the-counter drugs, approved and unapproved drugs, as well as repackaged and relabeled drugs."⁹ Because the NDC directory contains the information for the certified finished drugs, in line with the request by the commenter, this directory was used to search for active pharmaceutical products that contain the NDCs of those butalbital products on DEA's exempt prescription product list.

The NIH—National Library of Medicines DailyMed database contains

labeling information and product information that has been submitted to FDA by companies. This database was also searched in conjunction with FDA's NDC directory to confirm products are no longer being marketed.

DEA also reached out directly to FDA prior to the publication of the NPRM as well as in response to the commenter to confirm if these products were active and currently being marketed. DEA confirmed with FDA these products are no longer marketed.

Lastly, there were no comments received from any of the parties that would be directly affected by the removal of these NDCs from the Table of Exempted Prescription Products. Likewise, any product that is no longer exempted under the CSA may still be manufactured and sold, so long as the company and the product conform to all DEA regulations and the CSA.

Therefore, the final determination is being published without any changes.

List of Products To Be Removed From the Table of Exempted Prescription Products

For reasons detailed above, DEA is removing the following prescription products from DEA's Table of Exempted Prescription Products, as set forth below:

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Alpha Scriptics Inc	Butacet Capsules	53121-0133	CA	Butalbital	50
Alphagen Laboratories, Inc	Butalbital and Acetaminophen Capsules 50mg/650mg.	00603-2542	CA	Butalbital	50
Alphagen Laboratories, Inc	Geone Capsules	59743-0004	CA	Butalbital	50
Altana, Inc	Axocet (Butalbital and Acetaminophen)	0281-0389	TB	Butalbital	50
Althon Pharmaceuticals, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP.	66813-074	TB	Butalbital	50
Alvogen, Inc	Butalbital and Acetaminophen Tablets USP 50/325.	47781-0535	TB	Butalbital	50
Alvogen, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP 50/325/40.	47781-0536	TB	Butalbital	50
Alvogen, Inc	Butalbital and Acetaminophen Tablets 50/325 ...	47781-0628	TB	Butalbital	50
Alvogen, Inc	Butalbital, Acetaminophen and Caffeine Tablets (50/325/40).	47781-0625	TB	Butalbital	50
Alvogen, Inc	Butalbital and Acetaminophen Tablets (50/300)	47781-0644	TB	Butalbital	50
American Pharmaceuticals, Inc ..	AMERICET Tablets	58605-0501	TB	Butalbital	50
American Urologicals Inc	Butace	00539-0906	CA	Butalbital	50
Amerisource Health Services Corporation.	Butalbital, Acetaminophen and Caffeine Tablets 50/325/40mg.	68084-0396	TB	Butalbital	50
Aphena Pharma Solutions	Butalbital, Acetaminophen and Caffeine Tablets (50/325/40mg).	71610-0042	TB	Butalbital	50
Atland Pharmaceuticals	Butalbital and Acetaminophen Tablets (25 mg/325 mg).	71993-301	TB	Butalbital	25

or processed for sale in the United States at their facilities. Drugs are identified and reported using a unique NDC, which serves as the FDA's identifier for drugs. FDA publishes the listed NDC numbers in the NDC directory, which is updated daily. Database queried January 27–February 3, 2026.

⁷ The DailyMed database contains labeling, submitted to the FDA by companies, for the following products: FDA-approved products, including prescription drug and biological products

for human use (labeling includes Prescribing Information, patient labeling, and carton and container labeling); drug products and biological products; nonprescription (e.g., over-the-counter) drug and biological products for human use; certain medical devices for human use; medical gases for human and animal use; and prescription and nonprescription drugs for animal use. Also, additional products regulated, but not approved, by the FDA may be found on DailyMed, such as certain

medical devices; cosmetics; dietary supplements; medical foods; and unapproved prescription and nonprescription products. Database queried January 27–February 3, 2026.

⁸ *Schedules of Controlled Substances; Removal of Exemption Status for Inactive Butalbital Products*, 91 FR 30527 (May 26, 2026).

⁹ <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory>.

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Atley Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	59702-661	TB	Butalbital	50
AvKare, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP 50/325/40.	50268-139	TB	Butalbital	50
Baucum Laboratories Inc	Butalbital, Acetaminophen and Caffeine Tablets	54696-0513	TB	Butalbital	50
Blansett Pharm Co	Anolor 300 Capsules	51674-0009	CA	Butalbital	50
Cardinal Health	Butalbital, Acetaminophen and Caffeine Tablets 50mg/325mg/40mg.	55154-7988	TB	Butalbital	50
Cardinal Health	Butalbital, Acetaminophen and Caffeine Tablets 50mg/325mg/40mg.	55154-7147	TB	Butalbital	50
Cardinal Health	Butalbital, Acetaminophen and Caffeine Tablets 50mg/325mg/40mg.	0904-6538	TB	Butalbital	50
Carrick Labs Inc	Phrenilin	00086-0050	TB	Butalbital	50
Carpenter Pharmacal Co	ALAGESIC Tablets	55726-0300	TB	Butalbital	50
Cody Laboratories, Inc	BU-TAB AC	65893-100	TB	Butalbital	50
Columbia Drug Co	Isopap Capsules	11735-0400	CA	Butalbital	50
CTEX Pharmaceuticals, Inc	Butex Forte Capsules	62022-0070	CA	Butalbital	50
CTEX Pharmaceuticals, Inc	Butex Forte Capsules	62022-0074	CA	Butalbital	50
D.M. Graham Laboratories, Inc ..	Butalbital, Acetaminophen and Caffeine Tablets	00756-0111	TB	Butalbital	50
Diversified Health Care Services	Geone Capsules	59743-004	CA	Butalbital	50
Dunhall Pharmacal Inc	Triaprin	00217-2811	CA	Butalbital	50
Duramed Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	51285-0849	TB	Butalbital	50
EconoMed Pharmaceuticals, Inc	ARCET Capsules	38130-0325	CA	Butalbital	50
EconoMed Pharmaceuticals, Inc	ARCET Compound Tablets	38130-0111	TB	Butalbital	50
Equipharm Corp	EQUI-CET Tablets	57779-0111	TB	Butalbital	50
Everett Laboratories, Inc	Repan Capsules	00642-0164	CA	Butalbital	50
Everett Laboratories, Inc	Repan Capsules	00642-0163	CA	Butalbital	50
Everett Laboratories, Inc	Repan Tablets	00642-0162-10	TB	Butalbital	50
Forest Pharmacal Inc	Acetaminophen 325 mg/Butalbital 50 mg	00456-0674	TB	Butalbital	50
Forest Pharmacal Inc	Acetaminophen 500 mg/Butalbital 50 mg	00456-0671	TB	Butalbital	50
Forest Pharmacal Inc	Bancap	00456-0546	CA	Butalbital	50
Forest Pharmacal Inc	Esgic Capsules	00456-0631	CA	Butalbital	50
Forest Pharmacal Inc	ESGIC PLUS Capsules	00456-0679	CA	Butalbital	50
Forest Pharmacal Inc	Esgic Tablets	00456-0630	TB	Butalbital	50
Forest Pharmacal Inc	ESGIC-PLUS	00456-0678	TB	Butalbital	50
Genetco Inc	Butalbital, Apap and Caffeine	00302-0490	TB	Butalbital	50
Geneva Pharmaceuticals, Inc	Butalbital, Acetaminophen and Caffeine Tablets	00781-1901	TB	Butalbital	50
GM Pharmaceuticals (Manufactured by Mikart, Inc.).	Vanatol S (Butalbital, Acetaminophen, & Caffeine Soln 50/325/40.	58809-359	LQ	Butalbital	50
GM Pharmaceuticals (Manufactured by Mikart, Inc.).	Vanatol LQ (Butalbital, Acetaminophen, & Caffeine Soln 50/325/40.	58809-820	LQ	Butalbital	50
Goldline Laboratories	Butalbital, APAP and Caffeine Tablets	00182-1274	TB	Butalbital	50
GSMS Incorporated	Butalbital, Acetaminophen and Caffeine Tablets USP (50/325/40).	60429-589	TB	Butalbital	50
GSMS Incorporated	Butalbital, Acetaminophen and Caffeine Capsules USP (50/300/40).	51407-200	CA	Butalbital	50
Halsey Drug Co Inc	Blue Cross Butalbital, APAP and Caffeine Tablets.	00879-0567	TB	Butalbital	50
Halsey Drug Co Inc	Butalbital and Acetaminophen Tablets	00879-0543	TB	Butalbital	50
Hyrex Pharmaceutical	Two-Dyne Revised	00314-2229	TB	Butalbital	50
International Ethical Laboratories, Inc.	Tencon Tablets	11584-029-01	TB	Butalbital	50
Interstate Drug Exchange	IDE-Cet Tablets	00814-3820	TB	Butalbital	50
Intetlab	CON-TEN	11584-1029	CA	Butalbital	50
Inwood Laboratories, Inc	Butalbital, Acetaminophen and Caffeine Tablets, USP.	0258-3657	TB	Butalbital	50
Keene Pharmacal Inc	Endolar	00588-7777	CA	Butalbital	50
Kenco	Axotal	00013-1301	TB	Butalbital	50
Landry Pharmacal Inc	Febri-dyne Plain Capsules	05383-001	CA	Butalbital	50
Larken Laboratories, Inc	Butalbital and Acetaminophen Tablets (25 mg/325 mg).	68047-722	TB	Butalbital	25
Lasalle Laboratories	Pacaps Modified Formula	48534-0884	CA	Butalbital	50
Lemmon Company	Acetaminophen/Butalbital/Caffeine Tablets	00093-0854	TB	Butalbital	50
LGM Pharma Solutions, LLC	Butalbital, Acetaminophen and Caffeine Capsules (50/300/40 mg).	79739-7029	CA	Butalbital	50
LGM Pharma Solutions, LLC	Butalbital and Acetaminophen Tablets (50/300 mg).	79739-7075	TB	Butalbital	50
Lunsco Inc	Pacaps Capsules	10892-0116	CA	Butalbital	50
Major Pharmaceuticals	Fabophen Tablets	00904-3280	TB	Butalbital	50
Mallard Consumer Products	Anaquan Tablets	59441-0343	TB	Butalbital	50
Mallard Inc	Anoquan Modified Formula	00166-0881	CA	Butalbital	50
Mallinckrodt Inc	Butalbital, Acetaminophen, and Caffeine ("BAC") Tablets USP.	00406-0970	TB	Butalbital	50
Marlop Pharmacal Inc	Dolmar	12939-0812	CA	Butalbital	50

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Marnel Pharmaceuticals	Margesic Capsules	00682-0804	CA	Butalbital	50
Marnel Pharmaceuticals	Marten-Tab Tablets	00682-1400	TB	Butalbital	50
Martec Pharmacal Inc	Butalbital, Acetaminophen and Caffeine Tablets	52555-0079	TB	Butalbital	50
Mayne Pharma	Butalbital, Acetaminophen, & Caffeine Capsules 50/300/40.	51862-542	CA	Butalbital	50
Mayrand Pharmaceuticals, Inc	Sedapap-10 Tablets	00259-1278	TB	Butalbital	50
Midlothian Laboratories (Manufactured by Mikart, Inc.)	Esgic (Butalbital, Acetaminophen, & Caffeine Capsules 50/325/40.	68308-219	CA	Butalbital	50
Midlothian Laboratories (Manufactured by Mikart, Inc.)	Esgic (Butalbital, Acetaminophen, & Caffeine Tablets 50/325/40.	68308-220	TB	Butalbital	50
Midlothian Laboratories (Manufactured by Mikart, Inc.)	Zebutal (Butalbital, Acetaminophen, & Caffeine Capsules 50/325/40.	68308-554	CA	Butalbital	50
Mikart, Inc	Alagesic Capsules	50991-302	CA	Butalbital	50
Mikart, Inc	Bupap	00095-0240	TB	Butalbital	50
Mikart, Inc	Butalbital and Acetaminophen Tablets 50/325	46672-0099	TB	Butalbital	50
Mikart, Inc	Butalbital and Acetaminophen Tablets 50/650	11584-0029	TB	Butalbital	50
Mikart, Inc	Butalbital and Acetaminophen Tablets 50/650	46672-0098	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Capsules.	46672-0228	CA	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Capsules.	00588-7788	CA	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Elixer	46672-0633	EL	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Tablets	52555-0647	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP.	49884-0811	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP.	00258-3665	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Tablets USP (50/325/40).	51862-540	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Tablets, USP.	0591-3416	TB	Butalbital	50
Mikart, Inc	Butalbital and Acetaminophen Capsules 50/300	46672-286	CA	Butalbital	50
Mikart, Inc	Butalbital and Acetaminophen Tablets 50/300	46672-856	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen and Caffeine Tablets, USP.	46672-184	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen, and Caffeine Oral Solution.	66813-073	LQ	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen, and Caffeine Tablets	51432-0034	TB	Butalbital	50
Mikart, Inc	Butalbital, Acetaminophen, and Caffeine Tablets	46672-0059	TB	Butalbital	50
Mikart, Inc	Capacet (Butalbital, Acetaminophen, and Caffeine 50/325/40).	58407-534	CA	Butalbital	50
Mikart, Inc	Cephadyn Tablets	59702-0650	TB	Butalbital	50
Mikart, Inc	Dolgic Plus Tablets	68453-074	TB	Butalbital	50
Mikart, Inc	Dolgic Tablets	62022-0073	TB	Butalbital	50
Mikart, Inc	DOLMAR Tablets	12939-0811	TB	Butalbital	50
Mikart, Inc	Esgic Capsules	00535-0012	CA	Butalbital	50
Mikart, Inc	Esgic Tablets	00535-0011	TB	Butalbital	50
Mikart, Inc	Promacet	58605-524	TB	Butalbital	50
Mikart, Inc	Sedapap Tablets	00259-0392	TB	Butalbital	50
Mikart, Inc. (on behalf of Mayne Pharma).	Butalbital and Acetaminophen Capsules 50/300	51862-544	CA	Butalbital	50
Mikart, Inc. (on behalf of Mayne Pharma).	Butalbital and Acetaminophen Tablets 50/300	51862-538	TB	Butalbital	50
Mikart, Inc. (on behalf of Monarch PCM, LLC).	Vtol LQ (Butalbital, Acetaminophen, Caffeine Oral Solution).	70154-111	LQ	Butalbital	50
Mikart, Inc./Shionogi, Inc	Dolgic Plus Tablets	59630-074	TB	Butalbital	50
Moore Medical Corporation	Butalbital, Acetaminophen and Caffeine Tablets	00839-7831	TB	Butalbital	50
Nexgen Pharma	BUPAP (Butalbital and Acetaminophen 50mg/300mg).	0095-3000	TB	Butalbital	50
Nexgen Pharma	Butalbital with Acetaminophen and Caffeine Tablets.	0722-7029	TB	Butalbital	50
Nexgen Pharma	Butalbital, Acetaminophen and Caffeine Tablets (50mg/325mg/40mg).	0722-7320	TB	Butalbital	50
Northampton Medical, Inc	FEMCET	58436-0703	TB	Butalbital	50
PD-Rx Pharmaceuticals, Inc	Butalbital/APAP/Caffeine Tablets (50mg/325mg/40mg).	55289-0879	TB	Butalbital	50
Pharmaceutical Basics Inc	Butalbital, Acetaminophen and Caffeine Tablets	00832-1102	TB	Butalbital	50
Phlight Pharma, LLC	Allzital (Butalbital and Acetaminophen Tablets (25 mg/325 mg)).	70569-150	TB	Butalbital	25
Poly Pharmaceuticals, Inc	Alagesic	50991-0302	CA	Butalbital	50
Private Formula Inc	Sangesic	00511-1627	TB	Butalbital	30
ProficientRx	Butalb/acet/Caffeine 50mg/300mg/40mg	71205-962	CA	Butalbital	50

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Qualitest Pharmaceuticals, Inc ...	Butalbital, Acetaminophen and Caffeine Tablets 50/325/40mg.	0603–2544	TB	Butalbital	50
Qualitest Pharmaceuticals, Inc ...	Butalbital, Acetaminophen and Caffeine Tablets USP.	0603–2547	TB	Butalbital	50
Qualitest Pharmaceuticals, Inc ...	Butalbital, Acetaminophen and Caffeine Tablets, USP.	0603–2551	TB	Butalbital	50
Qualitest Products Inc	Butalbital, Acetaminophen and Caffeine Tablets	52446–0544	TB	Butalbital	50
Redi-Med	Butalbital Compound Capsules	53506–0103	CA	Butalbital	50
Roberts Pharmaceutical Corporation.	Anoquan	54092–0178	TB	Butalbital	50
Roberts Pharmaceutical Corporation.	Tencet Tablets	59441–0153	TB	Butalbital	50
Rotex Pharmaceuticals, Inc	Rogesic Capsules	31190–0008	CA	Butalbital	50
Rugby Laboratories Inc	Butalbital, Acetaminophen and Caffeine Tablets, USP.	0536–5567	TB	Butalbital	50
Rugby Laboratories Inc	ISOCET Tablets	00536–3951	TB	Butalbital	50
Russ Pharmaceuticals, Inc	FEMCET Capsules	50474–0703	CA	Butalbital	50
Savage Laboratories	AXOTAL	00281–1301	TB	Butalbital	50
Shoals Pharmaceuticals, Inc	Tencet	47649–0370	TB	Butalbital	50
Shoals Pharmaceuticals, Inc	Tencet Capsules	47649–0560	CA	Butalbital	50
Skylar Laboratories, LLC	Allzital (Butalbital and Acetaminophen Tablets) (25 mg/325 mg).	70362–722	TB	Butalbital	25
Skylar Laboratories, LLC	Butalbital and Acetaminophen Tablets (50 mg/325 mg).	70362–721	TB	Butalbital	50
Solubiomix	Butalbital and Acetaminophen Tablets (50 mg/325 mg).	69499–302	TB	Butalbital	50
Solubiomix	Butalbital and Acetaminophen Capsules (50 mg/300 mg).	69499–342	CA	Butalbital	50
Stewart Jackson Pharmacal, Inc	Ezol	45985–0578	CA	Butalbital	50
STI Pharma, LLC	Butalbital and Acetaminophen Tablets (50 mg/325 mg).	54879–026	TB	Butalbital	50
Tedor Pharma, Inc	Butalbital and Acetaminophen Tablets (50 mg/300 mg).	47781–534	TB	Butalbital	50
Tedor Pharma, Inc	Butalbital and Acetaminophen Tablets (50 mg/325 mg).	43199–053	TB	Butalbital	50
Tedor Pharma, Inc. (Manufactured for Xspire Pharma).	Butalbital, Acetaminophen and Caffeine Caps (50mg/300mg/40mg).	42195–955	CA	Butalbital	50
Trimen Labs	Amaphen Capsules (reformulated)	11311–0954	CA	Butalbital	50
U.S. Pharmaceuticals	Medigesic Capsules	52747–0600	CA	Butalbital	50
UAD Laboratories Inc	Bucet Capsules	00785–2307	CA	Butalbital	50
US Pharmaceuticals Inc	Medigesic Tablets	52747–0311	TB	Butalbital	50
Valeant Pharmaceuticals	Phrenilin Forte	0187–0844	CA	Butalbital	50
Victory Pharma Inc. (Manuf. By West-Ward Pharmaceutical).	Zebutal Brand Butalbital, Acetaminophen, and Caffeine Capsules.	68453–170	CA	Butalbital	50
WE Hauck Inc	G–1 Capsules	43797–0244	CA	Butalbital	50
West-Ward Pharmaceutical Corp	Butalbital with Acetaminophen and Caffeine Tablets.	00143–1787	TB	Butalbital	50
West-Ward Pharmaceutical Corp	Butalbital, Acetaminophen and Caffeine Capsules	00143–3001	CA	Butalbital	50
West-Ward Pharmaceutical Corp	Butalbital, Acetaminophen, and Caffeine Tablets, USP.	00143–1115	TB	Butalbital	50
West-Ward Pharmaceutical Corp	Zebutal Brand Butalbital, Acetaminophen, and Caffeine Capsules.	59630–0170	CA	Butalbital	50
Wraser Pharmaceuticals	Phrenilin Forte (Butalbital, Acetaminophen and Caffeine) 50/300/40.	66992–955	CA	Butalbital	50
Zenith Goldline Pharmaceuticals	Butalbital, Acetaminophen and Caffeine Tablets	00182–2659	TB	Butalbital	50

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

DEA has determined that this rulemaking is not a “significant regulatory action” under section 3(f) of E.O. 12866, Regulatory Planning and Review. This rule has been drafted and reviewed in accordance with E.O. 12866, “Regulatory Planning and Review,” section 1(b), Principles of Regulation and E.O. 13563, “Improving

Regulation and Regulatory Review,” section 1(b), General Principles of Regulation. This action is also not subject to E.O. 14192, “Unleashing Prosperity Through Deregulation,” or E.O. 14294, “Fighting Overcriminalization in Federal Regulations.”.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and

3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or

the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act,¹⁰ has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. There would be no economic impact because the products being removed from DEA's prescription product exempt list are no longer marketed.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995,¹¹ DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year" Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This rule would not impose a new collection of information under the Paperwork Reduction Act of 1995.¹² Also, this rule would not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on October 6, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the

undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–20757 Filed 10–8–26; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2026–1354; FRL–13264–02–R5]

Air Plan Approval; Michigan; Clean Data Determination for the Berrien, MI and Muskegon, MI Areas for the 2015 Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is determining under the Clean Air Act (CAA) that the Berrien County and Muskegon County, Michigan nonattainment areas have attained the 2015 ozone National Ambient Air Quality Standards (NAAQS). This determination, informally known as a clean data determination, is based upon complete, quality assured, and certified ambient air monitoring data for the 2023–2025 design value period showing that the areas achieved attainment of the 2015 ozone NAAQS. This clean data determination also relies upon the Michigan Department of Environment, Great Lakes, and Energy's (EGLE's) exceptional events request submitted to the EPA on December 26, 2025, and which the EPA concurred on January 12, 2026. As a result of this determination, the EPA is suspending the requirements for the Berrien and Muskegon areas to submit attainment demonstrations and associated Reasonably Available Control Measures (RACM), Reasonable Further Progress (RFP) plans, contingency measures for failure to attain or make reasonable progress, and other planning State Implementation Plans (SIPs) related to attainment of the 2015 ozone NAAQS for as long as the areas continue to attain the 2015 ozone NAAQS.

DATES: This final rule is effective on October 9, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2026–1354. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through <https://www.regulations.gov> or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT:

Neena Nallaballi, Air and Radiation Division (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, telephone number: (312) 353–1770, email address: nallaballi.neena@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, the use of "we," "us," or "our" is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

µg/m³ Micrograms per cubic meter
 Agency United States Environmental Protection Agency
 APA Administrative Procedure Act
 AQI Air Quality Index
 CAA Clean Air Act
 EGLE Michigan Department of Environment, Great Lakes, and Energy
 EMBER Expedited Modeling of Burn Events Results
 EPA United States Environmental Protection Agency
 GAM Generalized Additive Model
 GLELC Great Lakes Environmental Law Center
 MDA8 Maximum daily eight-hour average ozone concentration
 NAAQS National Ambient Air Quality Standards
 NPRM Notice of Proposed Rulemaking
 PM_{2.5} Particulate Matter <2.5 µm in Diameter
 RACM Reasonably Available Control Measures
 RFP Reasonable Further Progress
 SIP State Implementation Plan
 U.S.C. United States Code

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 - B. Clean Data Policy

¹⁰ 5 U.S.C. 601–602.

¹¹ 2 U.S.C. 1501 *et seq.*

¹² 44 U.S.C. 3501–3521.

III. Final Action

IV. Statutory and Executive Order Reviews

I. Background Information

On March 12, 2026, the EPA proposed to determine under the CAA that the Berrien, Michigan and Muskegon, Michigan areas have attained the 2015 ozone NAAQS. The EPA's proposed determination of attainment under the Clean Data Policy, known informally as a clean data determination, was made after reviewing the ozone monitoring data from EGLE's monitoring sites in the Berrien and Muskegon areas for the 2023–2025 period.¹ An explanation of the CAA requirements, a detailed analysis of the revisions, and the EPA's reasons for this determination were provided in the notice of proposed rulemaking (NPRM) and will not be restated here. This action suspends the requirements for both areas to submit an attainment demonstration, an RFP plan, contingency measures, and other planning requirements related to attainment of the 2015 ozone NAAQS on the condition that both of the areas continue to attain the 2015 ozone NAAQS.

II. Response to Comments

The EPA's March 12, 2026, NPRM opened a 30-day comment period, which closed April 13, 2026. Three comments were received. An adverse comment was submitted by the Great Lakes Environmental Law Center (GLELC). The remaining two comments were generally supportive. Summaries of the adverse comments and the EPA's responses are provided below. All comments received are included in the docket for this action.

A. Exceptional Events Demonstrations

Comment: Commenters are concerned about excluding ozone data under the Exceptional Events Rule because wildfire smoke impacts are no longer rare.

Response: While the EPA agrees that wildfire smoke impacts to the Upper Midwest have been more frequent in the last several years, the EPA remains obligated to follow the exceptional events provisions set forth in the CAA. Pursuant to CAA section 319(b), the EPA promulgated the "Exceptional Events Rule," codified primarily at 40 CFR 50.14, 50.1 and 51.930. These provisions set the criteria and process for excluding air quality monitoring data directly affected by exceptional events from the Administrator's determinations regarding exceedances or violations of the NAAQS. The Code

of Federal Regulations, at 40 CFR 50.14, further clarifies that every wildfire occurring predominantly on wildland presumptively meets the criteria categorizing it as "not reasonably controllable or preventable." As such, wildfires constitute natural events which affect the air quality in a way that establishes a clear causal relationship between the event and the monitored exceedance. Thus, the exclusion of wildfire smoke-impacted ozone data at the Muskegon and Coloma monitors is appropriate because these events satisfy the requirements of an exceptional events demonstration as set forth in the CAA and the Exceptional Events Rule.

Comment: The commenters state that, "EPA's weight of evidence approach for assessing exceptional event demonstrations violates the plain text of the Clean Air Act."

Response: The EPA disagrees that the weight of evidence approach violates the CAA. CAA section 319(b)(3)(B) requires the causal relationship to be "clear," and as explained in the preamble to the 2016 Exceptional Events Rule, it is appropriate for the EPA to consider all relevant evidence and qualitatively "weigh" it based on its relevance to the Exceptional Events Rule criterion being addressed, the degree of certainty, its persuasiveness, and other considerations appropriate to the individual pollutant and the nature and type of event.² Courts have confirmed that it is reasonable for the EPA to use a "weight of evidence" analysis when implementing the CAA.³ The weight of evidence method is an appropriate and reasonable approach which has been used historically and successfully under key CAA programs. The weight of evidence approach is the EPA's process for assessing whether an exceptional events demonstration meets the requirement for a clear causal relationship at CAA section 319(b)(3)(B)(ii).

Furthermore, and more recently, the EPA's concurrence based on a weight of evidence approach for evaluating exceptional events was upheld in *Sierra Club v. EPA*, 161 F.4th 934 (6th Cir. 2025). The Court's opinion states, "the EPA met the requirement to demonstrate that it 'reasonably

considered the relevant issues and reasonably explained the decision.'"

Even if the monitored data and/or technical analyses may not unequivocally support the causal relationship, State agencies should submit available information regarding the event and the monitored exceedances or violations. It may still be possible, with a weight of evidence approach, to clearly establish the existence of a causal connection between the data or analyses and the event causing elevated ozone concentrations. Under that approach, each piece of information or analysis—favorable or unfavorable—is considered, but by itself is not conclusive.

Comment: The commenters state that, "It's unclear what causation standard and burden of proof EPA applied in this proposed rule. Whatever the causation standard and burden of proof, the Commenters believe Michigan has failed to satisfy both the causation standard and to meet its burden of proof."

Response: The EPA evaluates exceptional event demonstrations on a case-by-case basis using a weight of evidence approach to assess whether a clear causal relationship exists between the event and the exceedance. The "EPA Guidance on the Preparation of Exceptional Events Demonstrations for Wildfire Events that May Influence Ozone Concentrations" uses a three-tier approach for addressing the clear causal relationship element with a wildfire ozone demonstration, recognizing that some require more evidence to demonstrate the clear causal relationship.⁴ Tier 3 analyses include additional evidence beyond what is required for Tier 1 and Tier 2 demonstrations because these events are more complex. EGLE submitted a Tier 3 demonstration consistent with this guidance. The record includes multiple lines of evidence showing wildfire smoke transport and ground level impacts at the Muskegon and Coloma monitors, including: photographic evidence, regional ozone and PM_{2.5} Air Quality Index maps, National Oceanic and Atmospheric Administration Hazard Mapping System Fire and Smoke maps, Hybrid Single-Particle Lagrangian Integrated Trajectory analyses, local and regional meteorological evidence, the presence of elevated surface level PM_{2.5} concentrations, the EPA's Expedited Modeling of Burn Events Results (EMBER) screening-level photochemical modeling analysis, the Generalized

² 81 FR 68216, 68230 (Oct. 3, 2016).

³ See, e.g., *Env'tl. Def. v. EPA*, 369 F.3d 193 (2d Cir. 2004) (upholding the EPA's approval of a State's attainment demonstration using photochemical grid modeling and a weight of evidence analysis), *BCCA Appeal Group v. EPA*, 355 F.3d 817 (5th Cir. 2003) (finding that the EPA's conclusion that the weight of evidence approach to approving attainment demonstrations was consistent with the CAA, reasonable and entitled to deference).

⁴ <https://www.epa.gov/air-quality-analysis/final-guidance-preparation-exceptional-events-demonstrations-wildfire-events>.

¹ 91 FR 12123 (Mar. 12, 2026).

Additive Model (GAM) statistical model, the EPA's Met-Adjusted Ozone Trends statistical model, and a matching day analysis for the July 15, 2025, event day at Muskegon. Across these independent methods, results collectively show wildfire smoke caused elevated ozone concentrations on the event days. Using a weight of evidence approach, the EPA concluded that EGLE met the burden of proof by successfully demonstrating a clear causal relationship between the wildfire events and the monitored exceedances at the Muskegon and Coloma monitors.

Comment: Several comments note that EGLE did not adequately demonstrate the wildfire smoke was the "proximate cause" of the ozone exceedances or that the ozone exceedances were "directly due" to wildfire smoke and therefore do not satisfy the clear causal connection. These include assertions that: for several event days, if modeled smoke impacts were removed, the maximum daily eight-hour average ozone concentration (MDA8) would be greater than the NAAQS; wildfire smoke only added minor contributions to total ozone concentrations as modeled by the tools; exceedances were due to local industry or vehicles as modeled impacts were minor; not all days had quantifiable ozone concentrations from wildfire smoke calculated; and there were discrepancies in computed concentrations between models.

Response: For the EPA to concur on an exceptional events demonstration and exclude data from regulatory use, CAA section 319(b) and 40 CFR 50.14 require a clear causal relationship between the event and the monitored exceedance. The EPA evaluates the clear causal connection between the exceptional events and the monitored exceedances using a weight of evidence approach and not the "but for" or "proximate cause" methods. The weight of evidence approach looks at all the information available and evaluates how supportive and relevant each line of evidence is to the overall clear causal relationship. Before the 2016 Exceptional Events Rule revision, the 2007 Exceptional Events Rule required agencies to show that there would have been no exceedance or violation "but for" the event also known as the "but for" criterion. In the most recent revisions to the EPA's Exceptional Event Rule in 2016, the EPA removed the "but for" test so that it no longer requires quantitative analyses intended to subtract estimated wildfire smoke contributions from reported monitoring

concentrations.⁵ Accordingly, there is no requirement in the EPA's current Exceptional Event Rule to (1) quantify exact wildfire contributions, (2) show the event was the "predominant cause," or (3) rule out all other sources.

There are many factors that contribute to regional ozone concentrations in the Midwest, such as natural emissions of precursors, transport of ozone and precursors from distant locations, local precursor emissions, and meteorology. On these event days, wildfire smoke was also a contributor to elevated ozone concentrations, causing the exceedance. The presence of routine local emissions does not preclude a finding that wildfire smoke was the cause of the monitor exceedance where the evidence shows a clear causal connection between the event and the exceedance. An exceptional event may still be the cause of an exceedance even in the presence of other sources.

The "directly due" concept is satisfied by the totality of evidence showing a clear causal connection. Typically, a single analysis may not conclusively link an exceptional event to a monitored exceedance. The EPA therefore applies a weight of evidence approach, evaluating multiple, independent lines of evidence collectively to determine a clear causal relationship. This approach is reflected in the "EPA Guidance on the Preparation of Exceptional Events Demonstrations for Wildfire Events that May Influence Ozone Concentrations" and has been upheld by the Sixth Circuit in *Sierra Club v. EPA*, 161 F.4th 934 (2025).

The meteorological and statistical models and analyses have uncertainty. Differences among model outputs do not invalidate the demonstration because such differences are expected given that the models use different methodologies, inputs, and parameters. As described in the EPA's EMBER Overview document:

There is uncertainty in photochemical model estimates of fire impacts as is true of all available methods for attributing ozone concentrations to fire emissions. As noted in the 2016 Wildfire Guidance, 'predictions of fire impacts on air quality are complex due to uncertainties in emissions, height of emissions, plume temperature, and plume chemistry (including radiative impacts on chemistry). However, with proper set-up, application, and evaluation, air quality models can be used to indicate fire impacts on [ozone] concentrations. Combining multiple types of analysis, including photochemical modeling, air quality monitoring data, and meteorological analyses, offers a comprehensive approach

for understanding wildfire effects on ozone exceedances.⁶

The models are meant to estimate the magnitude of the event's impact on the ozone exceedances, plume timing, and spatial extent. The 2016 Exceptional Events Rule does not require the exact wildfire smoke contribution to be quantified and instead uses a weight of evidence approach.

The results of the GAM, EMBER, and Met-Adjusted Ozone Trends models on the event days for Muskegon County and Berrien County are supportive of wildfire smoke impacts coupled with the additional evidence provided in EGLE's demonstration. Although the models estimate different levels of wildfire smoke impacts at the monitors, they consistently confirm wildfire smoke elevated ozone concentrations and are supportive to the overall weight of evidence.

The exceptional event rule and the EPA's exceptional events guidance states "The EPA does not expect an air agency to prepare all identified analyses but only those that add to their weight of evidence supporting the clear causal relationship." In this instance, EGLE provided the appropriate level of evidence, including both a statistical regression modeling analysis and a photochemical modeling analysis, and the EPA determined that EGLE's demonstration included sufficient evidence to demonstrate a clear causal relationship between the fire and the monitored ozone exceedances.

Comment: The commenters note that EGLE relied on PMO3smoke data for monitors 36 to 40 miles from the Muskegon and Coloma monitors which are not representative of Muskegon County and Berrien County air quality and that no exceptional event was proposed for the Holland monitor.

Response: The GAM tool must have a monitoring site collecting PM_{2.5} and ozone monitoring data to compute smoke-related ozone residuals. The events that impacted Muskegon and Berrien Counties in EGLE's exceptional events demonstrations were regional wildfire smoke events, affecting large portions of the United States including the Holland and Jenison monitors. The Muskegon and Coloma ozone monitoring sites do not have PM_{2.5} monitoring instruments, so EGLE and the EPA analyzed the nearby Holland and Jenison ozone sites that also have PM_{2.5} data as a proxy for the Muskegon and Coloma sites. With the large-scale

⁶ <https://www.epa.gov/system/files/documents/2026-06/expedited-modeling-of-burn-events-results-ember-overview-document-for-data-years-of-2021-2025.pdf>.

⁵ 81 FR 68216 (Oct. 3, 2016).

smoke plumes and shared shoreline meteorology patterns on the event days, a distance of 35–40 miles is not expected to have significant impacts on the results generated by this tool.

EGLE's decision to not request exclusion of ozone data for the Holland ozone monitoring site is not relevant to the EPA's evaluation of the evidence submitted by EGLE for the Berrien and Muskegon County demonstrations.

Comment: Commenters note that Michigan did not utilize EMBER or other tools to show contribution of the exceptional event to ozone concentrations on July 15, 2025, compared to other pollution sources.

Response: The "EPA Guidance on the Preparation of Exceptional Events Demonstrations for Wildfire Events that May Influence Ozone Concentrations" explains that States may include a matching day analysis, statistical regression analyses, or a photochemical analysis, to provide additional evidence supporting a clear causal relationship between wildfire smoke and the ozone exceedances they request to exclude. That guidance also expressly states that the "EPA does not expect an air agency to prepare all identified analyses" and that "the submitting air agency and the EPA Regional office should discuss the appropriate level of evidence during the initial notification process." Therefore, the EPA does not require a photochemical analysis, or an explanation for its absence, to concur on exceptional event demonstrations.

In the EPA's response to EGLE's initial notification, the EPA confirmed that this demonstration needed to address the Tier 3 clear causal criterion. EGLE provided a matching day analysis and the EPA's Met-Adjusted Ozone Trends analysis for July 15, 2025. Both analyses demonstrate wildfire smoke impacts on the event day at the Muskegon monitor. At the time of the EPA's decision to concur on these exceptional events, the EPA's EMBER screening-level photochemical model only included data for 2023, and the University of Washington's GAM statistical model only included data through 2024.

Comment: Commenters note that the PMO3smokeTool demonstrated wildfire smoke impacted ozone concentrations from 13.0 to 15.9 ppb and is only representative of 15% to 20% of the total ozone concentration on the event days, asserting that local industry and vehicles are thus responsible for a majority of the ozone. Commenters also note that Michigan did not demonstrate the wildfire smoke was the "proximate" cause of the ozone exceedances on the Muskegon event days on June 19, 2023,

and June 29, 2023, and that the "proximate cause" of the exceedances were industrial facilities and vehicles. The commenters note that the tools EGLE used in their demonstrations show only a 10% to 20% contribution of wildfire smoke to the ozone levels. They argue that these "relatively minor impacts" cannot be the "proximate cause" of the ozone exceedances.

Response: As described in previous responses, the 2016 Exceptional Events Rule relies on a weight of evidence approach to demonstrate a clear causal relationship between the events and the exceedances. Thus, the State is not required to subtract estimated smoke impacts from observed ozone, provide exact quantification or a "predominant cause," or rule out all other sources in order to establish that exceedances were "directly due" to wildfire smoke.

Comment: The commenters state that Michigan has failed to provide adequate public notification of the events in violation of the Clean Air Act.

Response: The Exceptional Events Rule does not specify how States must provide public notification of an event. EGLE has demonstrated that they have processes in place to notify the public when there is high confidence of adverse air quality impacts. EGLE's air quality forecasts and near real-time continuous data provided the public notice of ozone concentrations meeting an Air Quality Index (AQI) rating of "Unhealthy for Sensitive Groups" or worse on the event days after ambient concentrations of ozone rose quickly due to the distant Canadian fires. Data from the air monitors are provided, in near real-time, to the EPA's AirNow website as well as EGLE's MiAir website.⁷ Additionally, AirNow's EnviroFlash is a system that sends emails to subscribers about their daily air quality forecast and current conditions. Air agencies issue air quality forecasts based on measured near real-time air quality levels and weather information. The forecast is then provided to local media, posted online, and sent out to EnviroFlash subscribers. Furthermore, EnviroFlash allows subscribers to opt in to receive notifications at the Unhealthy for Sensitive Groups and higher AQI categories. EGLE maintains a robust forecasting program and issues alerts when elevated PM_{2.5} or ozone are expected. Even when forecasts don't fully capture an unfolding air quality event, AirNow, MiAir, and EnviroFlash alert the public in near real-time when

air quality does become Unhealthy for Sensitive Groups or greater.

B. Clean Data Policy

Comment: Commenters assert that while the EPA's original clean data policy states that the EPA would annually review the data and revoke the suspension if the area subsequently violated the standards, the EPA's rules do not make this review mandatory or set a deadline for it. Commenter further asserts that the EPA has not explained how a citizens' suit to force the EPA to carry out this review should proceed.

Response: A clean data determination suspends requirements for the area to submit attainment demonstrations and the associated RACM, RFP plans, contingency measures for failure to attain or make reasonable progress and other planning SIPs related to the attainment of the standard, for as long as the area continues to attain the standard, in accordance with the provisions set forth at 40 CFR 51.1318. The suspended planning requirements are suspended either until the area is redesignated to attainment for the ozone NAAQS, at which point the requirements no longer apply, or until the EPA determines that the area has failed to meet the ozone NAAQS, at which point the requirements go back into effect. The area is then required to submit the suspended plans within the time frame established by the EPA; at that time citizens can assess their legal options.

For the Berrien and Muskegon areas specifically, should the areas retain their nonattainment designation, then within six months of the areas' attainment date of August 3, 2027, the EPA would be obligated under CAA section 181(b)(2) to determine whether the areas attained the 2015 ozone NAAQS based on monitoring data from 2024–2026.⁸ Should those data show that an area is violating the 2015 ozone NAAQS, the EPA would issue a CAA section 181(b)(2) finding that the areas failed to attain by the Serious area attainment date and would be reclassified by operation of law to the next higher classification and the areas' clean data determinations would be rescinded.

The Clean Data Policy set forth in the 1995 Seitz Memorandum is codified for the 1997 ozone NAAQS, 2008 ozone NAAQS, and 2015 ozone NAAQS at 40 CFR 51.918, 51.1118, and 51.1318, respectively. This policy has been upheld by the D.C. Circuit and all other

⁸In this action, EPA is finalizing a clean data determination based on monitoring data from 2023–2025.

⁷<http://www.deqmiar.org/>.

courts that have considered it.⁹ In the recent December 5, 2025, Sixth Circuit decision¹⁰ the Court upheld the EPA's authority to approve a State's exceptional events demonstration and apply the Clean Data Policy to an ozone nonattainment area that attained the 2015 ozone NAAQS.

The commenters raised structural and statutory objections to the Clean Data Policy provisions at 40 CFR 51.1318. These comments are not relevant to the EPA's determination of attainment with respect to the Berrien and Muskegon areas and should have been raised at the time the 2015 Ozone NAAQS implementation rule was promulgated.¹¹ The 2015 ozone NAAQS and the implementing regulation were promulgated through notice and comment rulemaking subject to the judicial review provisions of CAA section 307(b). A petition for review must be filed within sixty days from the date of notice of such promulgation appears in the **Federal Register**. No comments were submitted regarding provisions of 40 CFR 51.1318 during the comment period for the 2015 ozone NAAQS implementation rule. Therefore, these comments fall outside the scope of this action.

III. Final Action

The EPA is determining under the CAA that the Berrien and Muskegon areas in Michigan have attained the 2015 ozone NAAQS. This clean data determination is based upon complete, quality assured, and certified ambient air monitoring data for the 2023–2025 design value period showing that those areas achieved attainment of the 2015 ozone NAAQS. This clean data determination relies on EGLE's exceptional events request submitted to the EPA on December 26, 2025, which the EPA concurred on January 12, 2026. As a result of this determination, the requirements for the area to submit attainment demonstrations and associated RACM, RFP plans, contingency measures for failure to attain or make reasonable progress and

other planning SIPs related to attainment of the 2015 ozone NAAQS, are suspended for as long as the areas continue to attain the 2015 ozone NAAQS.

In accordance with 5 U.S.C. 553(d) of the Administrative Procedure Act (APA), the EPA finds there is good cause for this action to become effective immediately upon publication. The immediate effective date for this action is authorized under 5 U.S.C. 553(d)(1). Section 553(d)(1) of the APA provides that final rules shall not become effective until 30 days after publication in the **Federal Register** “except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction.” The purpose of this provision is to “give affected parties a reasonable time to adjust their behavior before the final rule takes effect.”¹² However, when the Agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. The EPA has determined that this rule relieves a restriction because this rule suspends the requirements for the area to submit attainment demonstrations and associated RACM, RFP plans, contingency measures for failure to attain or make reasonable progress and other planning SIPs related to attainment of the 2015 ozone NAAQS, for as long as the area continues to attain the 2015 ozone NAAQS. For this reason, the EPA finds good cause under 5 U.S.C. 553(d)(1) for this action to become effective on the date of publication of this action.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to review State choices, and approve those choices if they meet the minimum criteria of the CAA. Accordingly, this final action constitutes a clean data determination for the Berrien and Muskegon areas for the 2015 ozone NAAQS based on air quality data resulting in suspension of certain Federal requirements State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law.

¹² *Omnipoint Corp. v. Fed. Comm'n Comm'n*, 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States v. Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history).

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is not an Executive Order 14192 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This action will not impose any requirements on small entities beyond those imposed by state law.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate 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. 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 rule does not have Tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments. Thus, Executive Order 13175 does not apply to this rule.

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

This action is not subject to Executive Order 13045 because it is not 3(f)(1) significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action

⁹ The Court of Appeals for the District of Columbia Circuit (D.C. Circuit) upheld EPA's rule embodying the Clean Data Policy for the 1997 8-hour ozone standard. *NRDC v. EPA*, 571 F.3d 1245 (D.C. Cir. 2009). Other courts have reviewed and considered rulemakings applying EPA's Clean Data Policy and have consistently upheld them. *Sierra Club v. EPA*, 99 F.3d 1551 (10th Cir. 1996); *Sierra Club v. EPA*, 375 F.3d 537 (7th Cir. 2004); *Our Children's Earth Foundation v. EPA*, No. 04–73032 (9th Cir. June 28, 2005 (Memorandum Opinion)), *Latino Issues Forum v. EPA*, Nos. 06–75831 and 08–71238 (9th Cir. March 2, 2009 (Memorandum Opinion)).

¹⁰ *Sierra Club v. EPA*, 161 F.4th 934 (6th Cir. 2025).

¹¹ 83 FR 62998 (Dec. 3, 2018).

present a disproportionate risk to children because it approves a State program.

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

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act

This rulemaking does not involve technical standards.

K. Congressional Review Act

This action is subject to the Congressional Review Act, and the 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).

L. Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 8, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 25, 2026.

Anne Vogel,
Regional Administrator, Region 5.

For the reasons stated in the preamble, title 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 52.1170, the table in paragraph (e) is amended by adding a second entry for “2015 Ozone Clean Data Determination” before the entry for “2015 8-hour ozone Moderate RFP plans and motor vehicle emission budgets” to read as follows:

§ 52.1170 Identification of plan.

* * * * *
(e) * * *

EPA-APPROVED MICHIGAN NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Comments
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
2015 Ozone Clean Data Determination.	Berrien nonattainment area (Berrien County) and Muskegon nonattainment area (part of Muskegon County).	N/A	October 9, 2026, 91 FR [Insert Federal Register page where the document begins].	EPA’s final determination suspends the requirements to submit an attainment demonstration and other associated nonattainment planning requirements for the Berrien and Muskegon nonattainment areas for as long as the areas continue to attain the 2015 ozone standard.
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[FR Doc. 2026–20736 Filed 10–8–26; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 679
[Docket No. 260305–0066; RTID 0648–XF997]
Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish Reserves in the Bering Sea and Aleutian Islands Management Area

Correction

In rule document 2026–20019, appearing on pages 61795 through

61796 in the issue of Wednesday, September 30, 2026, make the following correction:
On page 61795, in the third column, on the first line of the **DATES** section, “October 30, 2026” should read “September 30, 2026”.
[FR Doc. C1–2026–20019 Filed 10–8–26; 8:45 am]
BILLING CODE 0099–10–P

Proposed Rules

Federal Register

Vol. 91, No. 195

Friday, October 9, 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.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 337

RIN 3064–AG26

Extensions of Credit to Insiders

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The FDIC is extending the public comment period on the proposed rule “Extensions of Credit to Insiders,” which was published in the **Federal Register** on August 6, 2026. The FDIC is extending the public comment period from October 5, 2026, to November 4, 2026, to provide interested parties with additional time to analyze the proposal and prepare comments.

DATES: Comments must be received on or before November 4, 2026.

ADDRESSES: Comments should be directed to the FDIC as follows:

You may submit comments to the FDIC, identified by RIN 3064–AG26, by any of the following methods:

- **FDIC Website:** <https://www.fdic.gov/federal-register-publications>. Follow instructions for submitting comments on the agency website.
- **Email:** Comments@fdic.gov. Include RIN 3064–AG26 in the subject line of the message.
- **Mail:** Jennifer M. Jones, Deputy Executive Secretary, Attention: Comments—RIN 3064–AG26, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- **Hand Delivery to FDIC:** Comments may be hand-delivered to the guard station at the rear of the 550 17th Street NW building (located on F Street) on business days between 7 a.m. and 5 p.m.
- **Public Inspection:** Comments received, including any personal information provided, may be posted without change to <https://www.fdic.gov/federal-register-publications>. Commenters should submit only

information that the commenter wishes to make available publicly. The FDIC may review, redact, or refrain from posting all or any portion of any comment that it may deem to be inappropriate for publication, such as irrelevant or obscene material. The FDIC may post only a single representative example of identical or substantially identical comments, and in such cases will generally identify the number of identical or substantially identical comments represented by the posted example. All comments that have been redacted, as well as those that have not been posted, that contain comments on the merits of the proposed rule will be retained in the public comment file and will be considered as required under all applicable laws. All comments may be accessible under the Freedom of Information Act.

Follow the search instructions on <https://www.regulations.gov> to view public comments.

This proposal, all comments received, and a summary of not more than 100 words of the proposed rule pursuant to the Providing Accountability Through Transparency Act of 2023 are available at <https://www.fdic.gov/resources/regulations/federal-register-publications/>.

FOR FURTHER INFORMATION CONTACT:

Division of Risk Management Supervision: Peter A. Martino, Senior Examination Specialist, 813–390–8508, PMartino@fdic.gov; Ryan C. Senegal, Chief, Examination Support Section, 980–249–3863, RSenegal@fdic.gov. Legal Division: Gregory S. Feder, Counsel, 202–898–8724, GFeder@fdic.gov; Shane M. Bogusz, Senior Attorney, 571–366–0212, SBogusz@fdic.gov.

SUPPLEMENTARY INFORMATION: On August 6, 2026, the FDIC published in the **Federal Register** (91 FR 50730) a document proposing to increase quantitative thresholds for certain extensions of credit to insiders of FDIC-supervised institutions, as restricted by the Federal Reserve Act and regulations promulgated thereunder. Specifically, the proposal would raise and index certain dollar-based thresholds to align the thresholds with those proposed by the Board of Governors of the Federal Reserve under Regulation O of the Federal Reserve Act.¹ The proposal

would also establish an indexing methodology to automatically adjust such thresholds every five years to reflect economic growth and inflation. The proposed rule stated that the comment period would close on October 5, 2026. An extension of the comment period will provide additional opportunity for the public to prepare comments to address the matters raised by the proposed rule. Therefore, the FDIC is extending the comment period for the proposed rule on extensions of credit to insiders from October 5, 2026, to November 4, 2026.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 6, 2026.

Jennifer M. Jones,
Deputy Executive Secretary.

[FR Doc. 2026–20735 Filed 10–8–26; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2025–D–6952]

Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a draft guidance for industry titled “Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants.” The draft guidance states that, at this time and based on our current understanding of the risks, FDA does not intend to enforce certain regulatory requirements as they apply to certain entities and/or activities. The applicable requirements are established in our regulation titled “Requirements for Additional Traceability Records for Certain Foods.”

¹ See 91 FR 49526 (Aug. 4, 2026).

DATES: Submit either electronic or written comments on the draft guidance by November 23, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any FDA 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, Room 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-D-6952 for "Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants: Draft Guidance for Industry." 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.gpo.gov/fdsys/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, Room 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 Office of Strategy and Risk Prioritization, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Katherine Vierk, Office of Strategy and Risk Prioritization, Human Foods Program Food and Drug Administration,

5001 Campus Dr., College Park, MD 20740, 240-402-2122, Katherine.Vierk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry titled "Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants: Guidance for Industry." We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on implementing the final rule titled "Requirements for Additional Traceability Records for Certain Foods" (see 21 CFR Part 1, Subpart S). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. In the **Federal Register** of November 21, 2022, we published a final rule titled "Requirements for Additional Traceability Records for Certain Foods" (87 FR 70910) (Food Traceability Rule) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). The purpose of this draft guidance for industry is to state that FDA, at this time and based on our current understanding of the risk, does not intend to enforce certain regulatory requirements as they apply to certain entities subject to the Food Traceability Rule.

The Food Traceability Rule has a full exemption for small retail food establishments (RFEs) and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (21 CFR 1.1305(i)) ("small retail and restaurant exemption"). Since the issuance of the final rule, regulated entities from the RFE and restaurant industries have brought to light challenges associated with complying with the rule for small businesses that are not small enough to be eligible for the small retail and restaurant exemption. Therefore, FDA intends to exercise enforcement discretion for all requirements in the Food Traceability Rule for RFEs and restaurants that have an average annual monetary value of food sold or provided during the previous 3-year period of greater than \$250,000 but no more than \$1,000,000

(on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

The draft guidance represents the current thinking of FDA on implementing the Food Traceability Rule. It does not establish any rights for any person and is not binding on FDA or the public.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this draft 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 part 21 have been approved under OMB control number 0910–0560.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence

to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20721 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–119882–25]

RIN 1545–BS06

Application of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 to the Refunded Portion of Certain Federal Refundable Tax Credits; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of a notice of public hearing on a proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations (REG–119882–25) published in the **Federal Register** on August 20, 2026. The proposed regulations would provide that the refunded portion of certain refundable Federal income tax credits available to individuals is a “Federal public benefit” under the Personal Responsibility and Work

Opportunity Reconciliation Act of 1996 (PRWORA).

DATES: The public hearing scheduled for October 14, 2026, at 10 a.m. ET is cancelled.

ADDRESSES: See public comments submitted electronically via the Federal eRulemaking Portal at <https://www.regulations.gov> by searching IRS and (REG–119882–25).

FOR FURTHER INFORMATION CONTACT: Publications and Regulations Section at (202) 317–6901 (not toll-free numbers) or by email to publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on August 20, 2026 (91 FR 53812) announced that a public hearing was scheduled for October 14, 2026, at 10 a.m. ET. The subject of the hearing is under 26 CFR part 1. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying to submit a request to testify and an outline of the topics to be addressed by October 5, 2026. We did not receive any requests to testify or outlines of topics. Therefore, the public hearing scheduled for October 14, 2026, at 10 a.m. ET is cancelled.

Oluwafunmilayo A. Taylor,

Section Chief, Publications and Regulations Section, Associate Chief Counsel, (Procedure & Administration).

[FR Doc. 2026–20790 Filed 10–8–26; 8:45 am]

BILLING CODE 4831–GV–P

Notices

Federal Register

Vol. 91, No. 195

Friday, October 9, 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

Notice of Public Meetings of the Georgia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Georgia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold public meetings via Zoom. The purpose of the first two meetings are to continue to hear expert testimony on the Committee's selected civil rights topic on the school-to-prison pipeline in Georgia and the third meeting is to debrief and continue briefing planning to hear further testimony.

DATES: Thursday, October 29, 2026; 10:30 a.m.–12:30 p.m. (ET): Briefing Panel 2

Registration Link (Audio/Visual):
https://www.zoomgov.com/webinar/register/WN_GNUTAPWSR-OCd4htEtDU7A.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 168 8986 #.

Thursday, November 5, 2026; 11:00 a.m.–1:00 p.m. (ET): Panel 3

Registration Link (Audio/Visual):
https://www.zoomgov.com/webinar/register/WN_eLJUw02HQGWUok_rxtDx7A.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 639 2162 #.

Wednesday, December 2, 2026; 1:00 p.m.–12:00 p.m. (ET): Debrief & Plan

Registration Link (Audio/Visual):
<https://www.zoomgov.com/webinar/>

register/WN_IJhdPESLTO6akRyJO-3VZw.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 431 6461 #

Agendas: https://usccr.box.com/s/wtnxj5u4y21oothm5he9wwfdhhrik3uh (note: final meeting agendas will be available prior each date).

FOR FURTHER INFORMATION CONTACT:
Mallory Trachtenberg, Designated Federal Officer, at mtrachtenberg@usccr.gov or (202) 809–9618.

SUPPLEMENTARY INFORMATION:

Committee meetings are available to the public through the registration links above. Any interested members of the public may attend committee meetings. Open comment periods will be provided at each meeting to allow members of the public to make oral statements as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of meetings will include a list of persons who are present at meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting “CC” in the meeting platform. To request accommodations, please email ebonor@usccr.gov at least 10 business days prior to the meetings.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meetings. Written comments may be submitted via the following form: <https://wkf.ms/4wEILYL>. Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after meetings. Records of meetings will be available via the file sharing website, <https://bit.ly/42t1cCA>. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at mtrachtenberg@usccr.gov.

Dated: October 6, 2026.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2026–20703 Filed 10–8–26; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Virginia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of Virtual Meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Virginia Advisory Committee (Committee) to the Commission will hold public meetings via Zoom. The purpose is for the Committee to continue to hear expert testimony and continue briefing planning on the committee's chosen topic of study on Compliance with *Students for Fair Admissions* at Virginia Public Universities.

DATES: Tuesday, October 27, 2026; 11:30 a.m.–12:30 p.m.: Briefing Planning
Registration Link (Audio/Visual):
https://www.zoomgov.com/webinar/register/WN_A7PzWQPzTX6Lhla9rI9MVg.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 683 6308 #.

Tuesday, November 10, 2026; 10:30 a.m.–12:30 p.m.: Panel 2

Registration Link (Audio/Visual):
https://www.zoomgov.com/webinar/register/WN_HBzKiOlxSyOgZhhWJBrDA.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 479 5033 #.

Tuesday, December 15, 2026; 11:30 a.m.–1:30 p.m.: Debrief & Plan

Registration Link (Audio/Visual):
https://www.zoomgov.com/webinar/register/WN_pCdY9KuQQsu3ng15k7sAyg.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 385 9141 #.

Agendas: https://usccr.box.com/s/6f37l6j5z1wtciqzqi7g3s1la7zdzde9f (note:

final meeting agendas will be available prior to the meeting dates).

FOR FURTHER INFORMATION CONTACT:

Mallory Trachtenberg, Designated Federal Officer, at mtrachtenberg@usccr.gov or (202) 809–9618.

SUPPLEMENTARY INFORMATION: Virtual committee meetings are available to the public through the registration links above. Any interested member of the public may join at the links to listen to meetings. Open comment periods for each date will be provided to allow members of the public to make statements as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of the meetings will include a list of persons who are present at the meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting “CC” in the Zoom meeting platform. To request additional accommodations, please email ebohor@usccr.gov at least 10 business days prior to each meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Mallory Trachtenberg at <https://tinyurl.com/4fjtwv3h>. Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via the file sharing website, <https://bit.ly/3ZzHlj5>. Persons interested in the work of this Committee are directed to the Commission’s website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at mtrachtenberg@usccr.gov.

Dated: October 6, 2026.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2026–20702 Filed 10–8–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–406–2026]

Foreign-Trade Zone 16; Approval of Subzone Status; Yazaki North America, Inc.; Petoskey, Michigan

On August 13, 2026, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Sault Ste. Marie Economic Development Corporation, grantee of FTZ 16, requesting subzone status subject to the existing activation limit of FTZ 16, on behalf of Yazaki North America, Inc., in Petoskey, Michigan.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (91 FR 53402, August 18, 2026). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 16C was approved on October 6, 2026, subject to the FTZ Act and the Board’s regulations, including section 400.13, and further subject to FTZ 16’s 2,000-acre activation limit.

Dated: October 6, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–20780 Filed 10–8–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–129–2026]

Foreign-Trade Zone (FTZ) 40, Notification of Proposed Production Activity; Norman Noble Company Inc.; (Implantable Medical Devices); Highland Heights, Ohio

The Cleveland Cuyahoga County Port Authority, grantee of FTZ 40, submitted a notification of proposed production activity to the FTZ Board (the Board) on behalf of Norman Noble Company Inc. (Norman Noble) for Norman Noble’s facilities in Highland Heights, Ohio, within Subzone 40R. The notification conforming to the requirements of the Board’s regulations (15 CFR 400.22) was received on September 25, 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 products include: stents (abdominal aortic aneurysm; cardio; carotid; neurovascular; peripheral below-the-knee; superficial femoral artery; venous); tips (atherectomy; clot removal); atrial fibrillation frame bars; various plates (extremity; maxillofacial); screws (extremity; maxillofacial); heart pump cannulas; anchors (ligament repair; extremity suture); assemblies (spinal implant; multi-leaf collimator); vessel closure implants; extremity staples; and, vena cava filters (duty rate is duty-free).

The proposed foreign-status materials/components include tungsten plates, nitinol tubes, and stainless steel tubes (duty rate ranges from duty-free to 6.6%).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962, or section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 232, and 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 November 18, 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 Juanita Chen at juanita.chen@trade.gov.

Dated: October 6, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–20775 Filed 10–8–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B-128-2026]****Foreign-Trade Zone (FTZ) 50,
Notification of Proposed Production
Activity; Sanyo Denki America, Inc.;
(Cooling, Servo, and Power Systems
and Assemblies); Torrance, California**

Sanyo Denki America, Inc. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in Torrance, California, within FTZ 50. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 24, 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 products include: various rails (mounting support; magnetic); various fans (axial; centrifugal); various assemblies (fan; printed circuit; electric motor); filter kits for fans; stepper motors with output not exceeding 37.5 watts; alternating current motors with output exceeding 18.65 watts but not exceeding 37.5 watts; motors with output not exceeding 750 watts; amplifiers; static converters; lithium-ion batteries; battery packs; battery cases; distribution boards for voltage not exceeding 1,000 volts; circuit breakers; and, insulated electric conductors (duty rate ranges from duty-free to 5.7%).

The proposed foreign-status materials/components include: plastic components (inverter cabinets; power stands; housings); printed catalogs; stainless steel components (screws; machine frames; cooling manifolds; nozzles; motor shafts; motor bearings); steel components (wire; mounting brackets; clips; finger guards; heat sinks; housings; bases; guide rails; carriages; spindle housings; protective guards; bearings; shafts; motor frames); iron mounting brackets; copper components (anchor brackets; electrical connections; motor coils; connectors); various fans (axial; blower and centrifugal; cooling); aluminum fan blades; liquid cooling fan systems; filters (fan; noise); brass nozzles; cables (connection; electrical); servo motors with power output from

18.65 watts to 37.5 watts; DC stepper motors with power output to 37.5 watts; servo motors with power output to 1k watts and up; single linear motors; generators; magnetic linear rails motor stators; motor rotors; AC/DC drivers; wiring harnesses; USBs; static amplifiers; power converters; static converter battery packs; permanent magnets; lithium-ion batteries; dry contacts; smart card storage devices; resistors for power handling capacity; wire wound variable resistors; sensors (temperature; humidity); receptacle boxes; controllers (programmable logic; electrical); power conditioners; electrical plastic boards; contact interface cards; fan motor integrated circuits; insulated plastic connector fittings; training and demonstration equipment for industrial motor control and automation systems; tachometers; airflow testers; and, carbon brushes for motors (duty rate ranges from duty-free to 8.5%).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962, or section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 232, and 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 November 18, 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 Juanita Chen at juanita.chen@trade.gov.

Dated: October 6, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026-20776 Filed 10-8-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B-21-2026]****Foreign-Trade Zone (FTZ) 183;
Authorization of Production Activity;
Ultra Clean Technology Systems and
Service, Inc.; (Inputs Primarily for
Semiconductor Industry); Manor,
Texas**

On February 17, 2026, Ultra Clean Technology Systems and Service, Inc.

submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 183, in Manor, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (91 FR 8819, February 24, 2026). On October 6, 2026, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: October 6, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026-20773 Filed 10-8-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board****[B-127-2026]****Foreign-Trade Zone (FTZ) 16,
Notification of Proposed Production
Activity; Yazaki North America, Inc.;
(Stamped Copper Terminals);
Petoskey, Michigan**

Yazaki North America, Inc. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Petoskey, Michigan within FTZ 16. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 21, 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 stamped copper terminals (duty free).

The proposed foreign-status materials/components include: copper-zinc alloy coils; copper-nickel alloy coils; refined copper coils; copper-tin alloy coils; and flat-rolled cold-rolled stainless steel (duty rate ranges from duty-free to 3.0%).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade

Expansion Act of 1962 or section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 232 and 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 November 18, 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 John Frye at John.Frye@trade.gov.

Dated: October 6, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026-20774 Filed 10-8-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-580-884]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Final Results of Countervailing Duty Administrative Review; 2023

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines Hyundai Steel Company (Hyundai Steel) and POSCO, producers/exporters of certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea), received countervailable subsidies during the period of review (POR) January 1, 2023, through December 31, 2023.

DATES: Applicable October 9, 2026.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger or Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-2517 or (202) 482-5305, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 10, 2026, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited interested

parties to comment.¹ On August 7, 2026, Commerce extended the deadline for the final results of this review to no later than September 30, 2026,² and on September 29, 2026, we extended the deadline by seven additional days, to October 7, 2026.³ For a complete description of the events that occurred since the *Preliminary Results*, see the Issues and Decision Memorandum.⁴

Scope of the Order⁵

The merchandise covered by this Order is hot-rolled steel from Korea. For a complete description of the scope of the Order, see Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <https://access.trade.gov/frnotices>.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we find that there is a subsidy, *i.e.*, a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁶ For a full description of the

methodology underlying all of Commerce's conclusions, see the Issues and Decision Memorandum.

Changes Since the Preliminary Results

Based on comments received from interested parties, we made certain changes to POSCO's countervailable subsidy rate calculation from the *Preliminary Results*. For a discussion of these changes, see the Issues and Decision Memorandum.

Final Results of Review

We determine the following net countervailable subsidy rates exist for the period January 1, 2023, through December 31, 2023.

Producer/exporter	Subsidy rate (percent <i>ad valorem</i>)
Hyundai Steel Company ⁷	1.28
POSCO ⁸	3.68

Disclosure

Commerce intends to disclose its calculations performed in connection with the final results of review to interested parties within five days of public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For Hyundai Steel and POSCO, Commerce will instruct CBP to assess countervailing duties at the subsidy rates listed in the table above. 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

of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

⁷ As discussed in the *Preliminary Results* PDM, Commerce has found Hyundai Green Power Co. Ltd. to be cross-owned with Hyundai Steel.

⁸ As discussed in the *Preliminary Results* PDM, Commerce has found the following companies to be cross-owned with POSCO: POSCO Future M; POSCO Holdings; POSCO M-Tech, POSCO Nippon Steel RHF Joint Venture Co., Ltd., and POSCO Mobility Solutions. We note that POSCO also exported certain subject merchandise through an affiliated trading company, POSCO International Corporation (POSCO International). We examined POSCO International in the context of POSCO, and POSCO International's subsidies are included in POSCO's total subsidy rate.

¹ See *Certain Hot-Rolled Steel Flat Products from Republic of Korea: Preliminary Results and Rescission, in Part, of Countervailing Duty Administrative Review; 2023*, 91 FR 18398 (April 10, 2026) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Extension of Deadline for Final Results of Countervailing Duty Administrative Review," dated August 7, 2026.

³ See Memorandum, "Extension of Deadline for Final Results of Countervailing Duty Administrative Review," dated September 29, 2026.

⁴ See Memorandum, "Issues and Decision Memorandum for the Final Results of the Administrative Review of the Countervailing Duty Order on Certain Hot-Rolled Steel Flat Products from the Republic of Korea; 2023," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁵ See *Certain Hot-Rolled Steel Flat Products from Brazil and the Republic of Korea: Amended Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders*, 81 FR 67960 (October 3, 2016) (*Order*).

⁶ See sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E)

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).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for the companies listed above on shipments of the subject merchandise entered, or withdrawn from warehouse for consumption on or after the date of publication of the final results of this administrative review.

For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific rate applicable to the company or the all-others rate, as appropriate. These cash deposits, when imposed, shall remain in effect until further notice.

Administrative Protective Order (APO)

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

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: October 6, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the *Order*
- IV. Subsidies Valuation Information
- V. Analysis of Programs
- VI. Discussion of the Issues
 - Comment 1: Whether the Provision of Electricity Is Subsidized by the Government of Korea (GOK)
 - Comment 2: Whether the Provision of Korea Emissions Trading System (K-ETS) Permits is Countervailable
 - Comment 3: Whether Commerce Incorrectly Attributed Electricity for More than Adequate Remuneration (MTAR) Benefits Received by POSCO International Corporation (POSCO International) to POSCO
 - Comment 4: Whether the Benchmark Selected for the Electricity for MTAR Program is Appropriate
 - Comment 5: Whether POSCO International's Korea Export-Import Bank (KEXIM) Overseas Investment Credit Program (OICP) Loan is Tied to the Production of Non-Subject Merchandise
 - Comment 6: Whether to Modify POSCO's KEXIM OICP Loan Benchmark
 - Comment 7: Whether to Modify the Benchmark Interest Rate Used for Calculating a Benefit for the KEXIM Export Growth Loan Program
 - Comment 8: Whether the Constructing and Operation of Workplace Nursery Program is Countervailable

- Comment 3: Whether Commerce Incorrectly Attributed Electricity for More than Adequate Remuneration (MTAR) Benefits Received by POSCO International Corporation (POSCO International) to POSCO
- Comment 4: Whether the Benchmark Selected for the Electricity for MTAR Program is Appropriate
- Comment 5: Whether POSCO International's Korea Export-Import Bank (KEXIM) Overseas Investment Credit Program (OICP) Loan is Tied to the Production of Non-Subject Merchandise
- Comment 6: Whether to Modify POSCO's KEXIM OICP Loan Benchmark
- Comment 7: Whether to Modify the Benchmark Interest Rate Used for Calculating a Benefit for the KEXIM Export Growth Loan Program
- Comment 8: Whether the Constructing and Operation of Workplace Nursery Program is Countervailable

VII. Recommendation

[FR Doc. 2026–20778 Filed 10–8–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–842]

Passenger Vehicle and Light Truck Tires From Thailand: Preliminary Results and Rescission, in Part, 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) preliminarily determines that passenger vehicle and light truck tires (PVLTT) from Thailand were sold in the United States at less than normal value during the period of review (POR) July 1, 2024, through June 30, 2025. Interested parties are invited to comment on these preliminary results.

DATES: Applicable October 9, 2026.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo or Jacob Saude, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2371 or (202) 482–0981, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2024, Commerce published in the **Federal Register** a notice of opportunity¹ to request an

¹ See *Antidumping or Countervailing Duty Order, Finding or Suspended Investigation; Opportunity to*

administrative review of the antidumping duty order on PVLTT from Thailand.² On August 22, 2026, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice of initiation of an administrative review of the *Order*.³

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.⁴ Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ On June 4, 2026, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(h)(2), Commerce extended the due date for the preliminary results until September 30, 2026.⁶

For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.⁷ A list of the topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS, which is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/frnotices>.

Request Administrative Review and Join Annual Inquiry Service List, 90 FR 27841 (June 30, 2025).

² See *Passenger Vehicle and Light Truck Tires from the Republic of Korea, Taiwan, and Thailand: Antidumping Duty Orders and Amended Final Affirmative Antidumping Duty Determination for Thailand*, 86 FR 38011 (July 19, 2021) (*Order*).

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 90 FR 41043 (August 22, 2025).

⁴ See Memorandum, “Deadlines Affected by the Shutdown of the Federal Government,” dated November 14, 2025.

⁵ See Memorandum, “Tolling of all Case Deadlines,” dated November 24, 2025.

⁶ See Memorandum, “Passenger Vehicle and Light Truck Tires from Thailand: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review; 2024–2025,” dated June 4, 2026.

⁷ See Memorandum, “Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Passenger Vehicle and Light Truck Tires from Thailand; 2024–2025,” dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Scope of the Order

The products covered by the *Order* are PVLTV from Thailand. For a complete description of the scope of the *Order*, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and (2) of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, see the Preliminary Decision Memorandum.

Rescission of Administrative Review in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Requests for review were timely withdrawn for the companies identified in Appendix II. Because the requests for review were timely withdrawn and no other parties requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding the review with respect to these companies.⁸

Rate for Companies Not Individually Examined

The Act and Commerce's regulations do not address the establishment of a weighted-average dumping margin to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair-value (LTFV) investigation, for guidance when calculating the weighted-average dumping margin for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally equal to the weighted

average of the estimated weighted-average dumping margins established for exporters and producers individually examined, excluding rates that are zero, *de minimis* (i.e., less than 0.50 percent), or determined entirely on the basis of facts available.

Where the dumping margin for individually examined respondents are all zero, *de minimis*, or based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use "any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated."

Because Commerce preliminarily calculated a weighted-average dumping margin for Sumitomo Rubber (Thailand) Co., Ltd. (SRT) that is not zero or *de minimis*, or based entirely on facts available, we have preliminarily assigned the companies that were not selected for individual examination, the weighted-average dumping margin calculated for SRT, consistent with guidance in section 735(c)(5)(A) of the Act.⁹

Preliminary Results of Review

We preliminarily determine the following weighted-average dumping margins exist for the period July 1, 2024, through June 30, 2025:

Producer/exporter	Weighted-average dumping margin (percent)
Sumitomo Rubber (Thailand) Co., Ltd	1.14
Review-Specific Rate for Non-Examined Companies ¹⁰	1.14

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these 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 this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and

Compliance. Pursuant to 19 CFR 351.309(c)(1)(ii), we have modified the deadline for interested parties to submit case briefs to Commerce to no later than 21 days after the date of the publication of this notice.¹¹ Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹² Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹³ All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.¹⁴ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹⁵

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants, and whether any participant is a foreign national; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made,

¹¹ See 19 CFR 351.309.

¹² See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

¹³ See 19 CFR 351.309(c)(2) and (d)(2).

¹⁴ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹⁵ See *APO and Service Procedures*.

⁸ See Sentury's Letter, "Sentury Withdrawal of Request for Antidumping Administrative Review," dated December 22, 2025; Otani's Letter "Withdrawal of Request for Administrative Review," dated January 5, 2026; Bridgestone's Letter, "Bridgestone Withdrawal of Request for Administrative Review 2024–2025," dated January 5, 2026; Deestone's Letter, "Withdrawal of Request for Administrative Review," dated January 6, 2026; and Maxxis Letter, "Withdraw Request for Administrative Review," dated January 6, 2026.

⁹ See Memorandum, "Calculation of the Rate for Non-Examined Companies for the Preliminary Results," dated concurrently with this notice.

¹⁰ See Appendix III.

Commerce will inform parties of the scheduled date for the hearing.¹⁶

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

If SRT's weighted-average dumping margin is not zero or *de minimis* (i.e., less than 0.50 percent) in the final results of this review, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.¹⁷ To determine whether an importer-specific, per-unit assessment rate is *de minimis*, in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. If SRT's weighted-average dumping margin is zero or *de minimis* or where an importer-specific *ad valorem* assessment rate is zero or *de minimis*, we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.¹⁸

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by SRT for which it did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate in the original LTFV investigation if there is no rate for the intermediate company(ies) involved in the transaction.¹⁹

For companies for which we are rescinding this administrative review (see Appendix II) antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping

duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period of review, in accordance with 19 CFR 351.212(c)(1)(i). For these companies, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these preliminary results in the **Federal Register**.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative 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).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be equal to the weighted-average dumping margin established in the final results of this review (except, if that rate is *de minimis* within the meaning of 19 CFR 351.106(c)(1), then the cash deposit rate will be zero); (2) for producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review or a prior segment of the proceeding but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 17.06 percent, the all-others rate established in the LTFV investigation.²⁰ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate

regarding the reimbursement of antidumping 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 duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h)(2) and 351.221(b)(4).

Dated: October 6, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Discussion of the Methodology
- V. Currency Conversion
- VI. Recommendation

Appendix II

Companies Rescinded From Review

1. Bridgestone Company Ltd.; Bridgestone Tire Manufacturing (Thailand) Co., Ltd.; Thai Bridgestone Co., Ltd.
2. Deestone Corporation Public Company Limited; Deestone Corporation Ltd.; Deestone Limited; Deestone International Company Limited; Svizz-One Corporation Limited; Siamtruck Radial Company Limited
3. General Rubber (Thailand) Co., Ltd.
4. Maxxis International (Thailand) Co. Ltd.
5. Otani Radial Co., Ltd.; Otani Tire Co., Ltd.
6. Sentury Tire (Thailand) Co., Ltd.

Appendix III

Non-Examined Companies Receiving a Review-Specific Rate

1. S.R. Tyres Co., Ltd.
2. Siam Rubber Co., Ltd.
3. Vee Tyre & Rubber Co., Ltd.
4. Yokohama Rubber Co., Ltd.
5. Yokohama Tire Manufacturing (Thailand) Co., Ltd.

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¹⁶ See 19 CFR 351.310(d).

¹⁷ See 19 CFR 351.212(b)(1).

¹⁸ See 19 CFR 351.106(c)(2); see also *Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification*, 77 FR 8101, 8103 (February 14, 2012).

¹⁹ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

²⁰ See *Order*, 86 FR at 38012.

DEPARTMENT OF COMMERCE

International Trade Administration

[A-555-002]

Certain Paper Shopping Bags From Cambodia: Preliminary 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) preliminarily determines that certain paper shopping bags (paper shopping bags) from Cambodia were sold in the United States at less than normal value (NV) during the period of review (POR), January 3, 2024, through June 30, 2025. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable October 9, 2026.

FOR FURTHER INFORMATION CONTACT: Travis Hargett, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-4604.

SUPPLEMENTARY INFORMATION:**Background**

On July 18, 2024, Commerce published in the **Federal Register** the antidumping duty (AD) order on paper shopping bags from Cambodia.¹ On June 30, 2025, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.² On August 22, 2025, based on timely requests for review, in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order* covering four producers/exporters.³

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.⁴ Additionally, due to a backlog of documents that were

electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.⁵ On May 15, 2026, we extended the preliminary results of this review to September 30, 2026.⁶ On September 23, 2026, we extended the preliminary results of this review to October 7, 2026.⁷

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.⁸ A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS, which is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <https://access.trade.gov/frnotices>.

Scope of the Order

The merchandise subject to the *Order* is paper shopping bags from Cambodia. For a complete description of the scope of the *Order*, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. Furthermore, pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available, with adverse inferences for UUPak Company Limited (UUPak). For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rate for Non-Individually Examined Companies

There are two companies for which a review was requested, and which were not selected as mandatory respondents or found to be affiliated with a mandatory respondent. The Act does not address the establishment of a rate to apply to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce's regulation at 19 CFR 351.109(g) states that Commerce will determine the rate for non-selected companies by following the process set forth in 19 CFR 351.109(f)(1)–(2), which generally parallels the process for determining the all-others rate in an investigation under section 735(c)(5) of the Act.

Under section 735(c)(5)(A) of the Act and 19 CFR 351.109(f), the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any rates that are zero, *de minimis* (i.e., less than 0.5 percent), or determined entirely on the basis of facts available. Where the weighted-average dumping margin for each of the individually examined companies is zero, *de minimis*, or based entirely on facts available, section 735(c)(5)(B) of the Act and 19 CFR 351.109(f)(2)(iii) provide that Commerce may use "any reasonable method" to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted-average dumping margins determined for the exporters and producers individually investigated.

In this administrative review, we preliminarily calculated a weighted-average dumping margin for Nice Packaging (Cambodia) Co., Ltd. (Nice Packaging) that is not zero, *de minimis*, or based entirely on facts otherwise available, and preliminarily assigned a dumping margin for UUPak based entirely on facts otherwise available. Therefore, we are preliminarily assigning the weighted-average dumping margin calculated for Nice Packaging to the companies under review that were not selected for individual examination, consistent with the guidance in section 735(c)(5)(A) of the Act.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following estimated weighted-average dumping

¹ See *Certain Paper Shopping Bags from Cambodia, Colombia, India, Malaysia, Portugal, Taiwan, the People's Republic of China, and the Socialist Republic of Vietnam: Antidumping Duty Orders*, 89 FR 58334 (July 18, 2024) (*Order*).

² See *Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List*, 90 FR 27841 (June 30, 2025).

³ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 90 FR 41043 (August 22, 2025).

⁴ See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated November 14, 2025.

⁵ See Memorandum, "Tolling of all Case Deadlines," dated November 24, 2025.

⁶ See Memorandum, "Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated May 15, 2026.

⁷ See Memorandum, "Second Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated September 23, 2026.

⁸ See Memorandum, "Decision Memorandum for the Preliminary Results of the Administrative Review of the Antidumping Duty Order on Certain Paper Shopping Bags from Cambodia; 2024–2025," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

margins exist for the period January 3, 2024, through June 30, 2025:

Producer/exporter	Weighted-average dumping margin (percent)
Nice Packaging (Cambodia) Co., Ltd	20.08
UUPak Company Limited	* 73.30
Brandart S.p.A	20.08
TB Packaging (Cambodia) Co., Ltd	20.08

* This rate is based on total AFA.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these 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 this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Pursuant to 19 CFR 351.309(c)(1)(ii), we have modified the deadline for interested parties to submit case briefs to Commerce to no later than 21 days after the date of the publication of this notice.⁹ Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.¹⁰ Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.¹¹ All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.¹² Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including

citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).¹³

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants, and whether any participant is a foreign national; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.¹⁴

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

If Nice Packaging's weighted-average dumping margin is not zero or *de minimis* (i.e., less than 0.50 percent) in the final results of this review, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.¹⁵ To determine whether an importer-specific, per-unit assessment rate is *de minimis*, in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. If Nice Packaging's

weighted-average dumping margin is zero or *de minimis* or where an importer-specific *ad valorem* assessment rate is zero or *de minimis*, we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.¹⁶

In accordance with Commerce's "automatic assessment" practice, for entries of subject merchandise during the POR produced by Nice Packaging for which it did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate calculated in the LTFV investigation if there is no rate for the intermediate company(ies) involved in the transaction.¹⁷

For the companies listed above which were not selected for individual review, we will assign an assessment rate based on the review-specific rate, calculated as noted in the "Rate for Non-Individually Examined Companies" section, above. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.¹⁸

Commerce intends to issue assessment instructions to CBP regarding Nice Packaging, UUPak Company Limited, and the non-selected companies listed above 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).

Cash Deposit Requirements

The following 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) the cash deposit rate for each company listed above will be the rate established in the final results of this review, except

⁹ See 19 CFR 351.309.
¹⁰ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*, 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).
¹¹ See 19 CFR 351.309(c)(2) and (d)(2).
¹² We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

¹³ See *APO and Service Procedures*.
¹⁴ See 19 CFR 351.310(d).
¹⁵ See 19 CFR 351.212(b)(1).

¹⁶ See 19 CFR 351.106(c)(2); see also *Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification*, 77 FR 8101, 8103 (February 14, 2012).
¹⁷ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).
¹⁸ See section 751(a)(2)(C) of the Act.

if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not covered by this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the LTFV investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 7.07 percent, the all-others rate established in the LTFV investigation.¹⁹ These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping 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 duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: October 6, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Affiliation
- V. Application of Facts Available and Use of Adverse Inference
- VI. Discussion of the Methodology
- VII. Currency Conversion
- VIII. Recommendation

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COMMISSION OF FINE ARTS

Notice of Meeting

Per 45 CFR Chapter XXI § 2102.3, the next meeting of the U.S. Commission of Fine Arts is scheduled for October 15, 2026, at 9:00 a.m. and will be held in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW, Washington, DC 20001-2728. Items of discussion may include buildings, infrastructure, parks, memorials, and public art.

Draft agendas and additional information regarding the Commission are available on our website: www.cfa.gov. Inquiries regarding the agenda, as well as any public testimony, and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing cfastaff@cfa.gov; or by calling 202-504-2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated October 5, 2026, in Washington, DC.

Zakiya N. Walters,

Administrative Officer.

[FR Doc. 2026-20717 Filed 10-8-26; 8:45 am]

BILLING CODE 6330-01-P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, October 14, 2026-10:00 a.m.

PLACE: The meeting will be held remotely.

STATUS: Closed Commission Meeting.

MATTERS TO BE CONSIDERED: Briefing matter.

CONTACT PERSON FOR MORE INFORMATION:

Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548, 301-504-7479 (Office) or 240-863-8938 (Cell).

Dated: October 7, 2026.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2026-20815 Filed 10-7-26; 4:15 pm]

BILLING CODE 6355-01-P

COUNCIL OF THE INSPECTORS GENERAL ON INTEGRITY AND EFFICIENCY

Senior Executive Service Performance Review Board Membership

AGENCY: Council of the Inspectors General on Integrity and Efficiency.

ACTION: Notice.

DATES: Applicable October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Andrew Cannarsa, CIGIE Executive Director, (202) 292-2603. Individual Office of Inspectors General at the telephone numbers listed below.

SUPPLEMENTARY INFORMATION:

I. Background

The Inspector General Act of 1978, as amended, created the Offices of Inspectors General as independent and objective units to conduct and supervise audits and investigations relating to Federal programs and operations. The Inspector General Reform Act of 2008 established the Council of the Inspectors General on Integrity and Efficiency (CIGIE) to address integrity, economy, and effectiveness issues that transcend individual Government agencies; and increase the professionalism and effectiveness of personnel by developing policies, standards, and approaches to aid in the establishment of a well-trained and highly skilled workforce in the Offices of Inspectors General. CIGIE is an interagency council whose executive chair is the Deputy Director for Management, Office of Management and Budget, and is comprised principally of the 70 Inspectors General (IGs).

II. CIGIE Performance Review Board

Under 5 U.S.C. 4314(c)(1)(5), and in accordance with regulations prescribed by the Office of Personnel Management, each agency is required to establish one or more Senior Executive Service (SES) performance review boards. The purpose of these boards is to review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive. The current members of the Council of the Inspectors General on Integrity and Efficiency Performance Review Board, as of October 1, 2026, are as follows:

Agency for International Development,
Phone Number: (202) 330-3720,
CIGIE Liaison—Bianca Girault,
(202) 330-3720, bgirault@oig.usaid.gov

- Gabriele Tonsil—Acting Assistant

¹⁹ See Order, 89 FR at 58335.

- Inspector General for Audits, Inspections, and Evaluations
- Khadija Walker—Deputy Assistant Inspector General for Audit
 - Derek Santos—General Counsel and Chief Operating Officer
- Department of Agriculture, Phone Number: (301) 458-1695, CIGIE Liaison—Jessica Washington, (301) 458-1695, *jessica.washington@oig.usda.gov*
- Janet Sorensen—Assistant Inspector General for Audit
 - Yaris Rivera-Rojas—Deputy Assistant Inspector General for Audit
 - Nicole Gardner—Assistant Inspector General for Investigations
 - Justin Fielder—Deputy Assistant Inspector General for Investigations
 - Mily Le—Assistant Inspector General for Management
 - Christy Slamowitz—Counsel to the Inspector General
 - Anthony Nardoizzi—Deputy Inspector General
- Department of Commerce, Phone Number: (301) 486-3142, CIGIE Liaison—Teresa Hardy, (202) 480-5164, *thardy@oig.doc.gov*
- Eric Maddox—Assistant Inspector General for Investigations
 - Arthur Scott—Assistant Inspector General for Audit and Evaluation
 - Richard Bachman—Assistant Inspector General for Management
 - Robert Johnston—General Counsel/Chief of Staff
- Council of the Inspectors General on Integrity and Efficiency, Phone Number: (202) 292-2600, CIGIE Liaison—Zeina Aboumrad, (202) 253-4728, *zeina.aboumrad@cigie.gov*
- Andrew Cannarsa—Executive Director
- Department of Defense/War, Phone Number: (703) 604-8324, CIGIE Liaison—Thomas Burgess, (703) 601-5800, *thomas.l.burgess@dodig.mil*
- Jaryd M. Bern—Assistant Inspector General for Legislative Affairs & Communications
 - David P. Bennet—General Counsel
 - Bryan T. Clark—Assistant Inspector General for Evaluations (Program, COCOM, and OCO Operations)
 - David A. Core—Principal Deputy General Counsel
 - Ogochukwu A. Ekwuabu—Assistant Inspector General for Strategic Planning and Performance
 - Leo J. FitzHarris—Deputy Inspector General for Mission Support
 - Grant A. Fleming—Assistant Inspector General for Investigations
 - Marguerite C. Garrison—Deputy Inspector General for
- Administrative Investigations
- James R. Ives—Principal Assistant Inspector General for Investigations
 - Carmen J. Malone—Assistant Inspector General for Audit (Readiness and Cyber Operations)
 - Brett A. Mansfield—Deputy Inspector General for Audit
 - Troy M. Meyer—Deputy Inspector General for Overseas Contingency Operations
 - Harris S. Quddos—Chief Information Officer
 - Michael J. Roark—Deputy Inspector General for Evaluations
 - Karla Roark—Assistant Inspector General for Cyber Operations
 - Gregory P. Shilling—Assistant Inspector General for Investigations (Internal Operations)
 - Janet L. Stallings—Principal Assistant Inspector General for Audit
 - Steven A. Stebbins—Principal Deputy Inspector General
 - Randolph R. Stone—Assistant Inspector General for Evaluations (Space, Intelligence, Engineering and Oversight)
 - Richard B. Vasquez—Assistant Inspector General for Audit (Readiness and Global Operations)
 - Lorin T. Venable—Assistant Inspector General for Audit (Financial Management and Reporting)
 - Willie L. Young—Principal Assistant Inspector General for Mission Support
 - Eric W. Zeeman—Principal Assistant Inspector General for Administrative Investigations
- Defense Intelligence Agency, Phone Number: (202) 231-1000, CIGIE Liaison—Roger Bend, (202) 231-1058, *roger.bend@dodig.mil*
- Jeremy Kirkland—Inspector General
 - Aimee Peralta—Deputy Inspector General
- Department of Education, Phone Number: (202) 245-6900, CIGIE Liaison—Theresa Perolini, (202) 987-0174, *theresa.perolini@ed.gov*
- René Rocque—Deputy Inspector General
 - Jason Williams—Assistant Inspector General for Investigations
 - Antigone Potamianos—Counsel to the Inspector General
 - Theresa Perolini—Assistant Inspector General for Enterprise and External Affairs
 - Keith Cummins—Assistant Inspector General for Audit Services
 - Terry Harris—Assistant Inspector General for Technology Services
- Department of Energy, Phone Number: (202) 586-4993, CIGIE Liaison—
- Ryan Cocolin, (202) 586-8672, *ryan.cocolin@hq.doe.gov*
- Sarah Nelson—Inspector General for Management
 - Lew Sessions—Assistant Inspector General for Investigations
 - Matthew Dove—Assistant Inspector General for Audits
 - Deborah Thomas—Deputy Assistant Inspector General Audits
 - Carlos Diaz—Deputy Assistant Inspector General Audits
- Environmental Protection Agency, Phone Number: (202) 250-8800, CIGIE Liaison—Jee Kim, (202) 407-6528, *kim.jee@epa.gov*
- Nicole Murley—Deputy Inspector General Performing the duties of the Inspector General
 - Erica Kavanagh—Associate Deputy Inspector General
 - Mary Katherine Trimble—Assistant Inspector General for Audit
 - Marcus Gullet—Deputy Assistant Inspector General for Audit
 - Paul Bergstrand—Assistant Inspector General for Special Review and Evaluation
- Federal Communications Commission, Phone Number: (202) 418-0470, CIGIE Liaison—Kevin Beynum, (202) 253-6971, *kevin.beynum@fcc.gov*
- Travis J. Farris—Counsel to the Inspector General
 - James Izzard, Jr.—Assistant Inspector General for Investigations
- Federal Labor Relations Authority, Phone Number: (771) 444-5712, CIGIE Liaison—Dana Rooney, (771) 444-5713, *drooney@flra.gov*
- Dana Rooney—Inspector General
- Federal Maritime Commission, Phone Number: (202) 523-5863, CIGIE Liaison—Jon Hatfield, (202) 523-5863, *jhatfield@fmc.gov*
- Jon Hatfield—Inspector General
- Federal Trade Commission, Phone Number: (202) 326-3527, CIGIE Liaison—Jennifer Herrmann, (202) 326-5207, *jherrmann@ftc.gov*
- Marissa Gould—Acting Inspector General
- General Services Administration, Phone Number: (202) 501-0450, CIGIE Liaison—Sarah Breen, (202) 273-7284, *sarah.breen@gsa.gov*
- Robert C. Erickson, Jr.—Acting Inspector General
 - Edward J. Martin—Associate Inspector General
 - R. Nicholas Goco—Assistant Inspector General for Auditing
 - Barbara E. Bouldin—Deputy Assistant Inspector General for Acquisition Program Audits
 - Brian J. Gibson—Deputy Assistant Inspector General for Real Property Audits

- Kristine M. Preece—Assistant Inspector General for Administration
 - Christopher W. Pehrson—Counsel of the Inspector General
 - Jamie M. Willemin—Assistant Inspector General for Investigations
 - Karla M. Myers—Assistant Inspector General for Inspections
- Department of Health and Human Services, Phone Number: (202) 619–3148, CIGIE Liaison—Kalpana Vissa, (202) 680–3721, kalpana.vissa@oig.hhs.gov
- Juliet Hodgkins—Principal Deputy Inspector General
 - Megan Tinker—Deputy Inspector General for Immediate Office/Chief of Staff
 - Robert Owens, Jr.—Deputy Inspector General for Management and Policy
 - Ann Maxwell—Deputy Inspector General for Evaluation and Inspections
 - Erin Bliss—Assistant Inspector General for Evaluation and Inspections
 - Melicia Seay—Assistant Inspector General for Evaluation and Inspections
 - Susan Edwards—Deputy Assistant Inspector General for Legal Affairs
 - Susan Gillin—Assistant Inspector General for Legal Affairs
 - Carla Lewis—Assistant Inspector General for Audit Services
 - John Hagg—Assistant Inspector General for Audit Services
 - Lucia Fort—Assistant Inspector General for Audit Services
 - Brenda Tierney—Assistant Inspector General for Audit Services
 - Tamara Lilly—Assistant Inspector General for Audit Services (Cybersecurity and IT Audits)
 - Maria Thompson—Assistant Inspector General for Information Technology
 - Kaitlin Devine—Assistant Inspector General/Chief Data Officer
 - David Sherman—Assistant Inspector General/Deputy Chief Financial Officer
 - Derrick Franklin—Assistant Inspector General for Investigations
 - Miranda Bennett—Assistant Inspector General for Investigations
 - Scott Lampert—Assistant Inspector General for Investigations
- Department of Homeland Security, Phone Number: (202) 981–6000, CIGIE Liaison—Elizabeth Haefeli, (202) 878–0685, elizabeth.haefeli@oig.gov
- Glenn Sklar—Principal Deputy Inspector General
 - Dustin Razi—Chief of Staff
 - Mark Searight—Assistant Inspector General for Audit
 - Erika Lang—Assistant Inspector General
 - Thomas Kait—Deputy Inspector General for Inspections and Evaluations
 - Sandra Parsons—Deputy Inspector General
 - Nguyen Tinh—Assistant Inspector General for Law Enforcement and Terrorism
- Department of Housing and Urban Development, Phone Number: (202) 869–3399, CIGIE Liaison—Kudakwashe Ushe, (202) 869–3399, kushe@hudoig.gov
- Jeffrey Breen—Deputy Assistant Inspector General for Investigation
 - Toccoaro Green—Chief Information Officer
 - Sarah Sequeira—Deputy Assistant Inspector General for Audit
 - Kilah White—Assistant Inspector General for Audit
 - Kudakwashe Ushe—Assistant Inspector General for Management
- Department of the Interior, Phone Number: (202) 208–5745, CIGIE Liaison—Karen Edwards, (202) 208–5635, karen_edwards@doioig.gov
- Matthew Elliott—Assistant Inspector General for Investigations
 - Jorge Christian—Assistant Inspector General for Management
 - Justin Martell—General Counsel
 - Michael O'Rourke—Assistant Inspector General for Strategy, Data and Innovation
 - Nicole Miller—Assistant Inspector General for Audits, Inspections & Evaluations
 - Jill Baisinger—Chief of Staff
- Department of Justice, Phone Number: (202) 514–3435, CIGIE Liaison—Alyssa Poole, (202) 441–8117, alyssa.poole@usdoj.gov
- Michael Sean O'Neill—Assistant Inspector General for Oversight and Review
 - Jason R. Malmstron—Assistant Inspector General for Audit
 - Carol S. Taraszka—Deputy Assistant Inspector General for Audit
 - Sean Relay—Deputy Assistant Inspector General for Audit
 - Kevin M. Strug—Deputy Assistant Inspector General for Audit, Office of Data Analytics
 - Arianne Tice—General Counsel
 - Dung Phan—Deputy Assistant Inspector General Information Technology
 - Sandra Murphy—Assistant Inspector General Investigations
 - Allison E. Russo—Assistant Inspector General for Evaluation and Inspections
 - Michael E. Pannone—Deputy Assistant Inspector General for Evaluation and Inspections
 - Mark L. Hayes—Assistant Inspector General for Management and Planning
 - Nancy House—Deputy Assistant Inspector General for Management and Planning
- Department of Labor, Phone Number: (202) 693–7100, CIGIE Liaison—Erin Zickafoose, (202) 693–7062, zickafoose.erin@oig.dol.gov
- Jason Abend—Assistant Inspector General for Investigations—Labor Racketeering and Fraud
 - Scott Ewalt—Deputy Assistant Inspector General for Investigations—Labor Racketeering and Fraud
 - Jessica Southwell—Chief Performance and Risk Management Office
- National Aeronautics and Space Administration, Phone Number: (202) 358–1220, CIGIE Liaison—Raleigh McElevy, (202) 913–3780, raleigh.e.mcelevey@nasa.gov
- Robert (Bob) Steinau—Assistant Inspector General for Investigations
 - Kathryn Sheehy—Assistant Inspector General for Management
- National Labor Relations Board, Phone Number: (202) 273–1960, CIGIE Liaison—James Tatum, (202) 273–1961, james.tatum@nrlb.gov
- Ruth Blevins—Inspector General
- National Science Foundation, Phone Number: (703) 292–7100, CIGIE Liaison—Lisa Vonder Haar, (703) 292–2989, lvonderh@nsf.gov
- Theresa Hull—Assistant Inspector General for Inspections and Evaluations
 - Javiar Inclan—Assistant Inspector General for Management
 - Catherine DelPrete—General Counsel to the Inspector General
- Nuclear Regulatory Commission, Phone Number: (301) 415–5930, CIGIE Liaison—Christine Arroyo, (240) 760–5546, christine.arroyo@nrc.gov
- Ziad Buhaissi—Deputy Inspector General
 - Hruta Vikar—Assistant Inspector General for Audits
 - Malion Bartley—Assistant Inspector General for Investigations
- Office of Personnel Management, Phone Number: (202) 606–1200, CIGIE Liaison—Caprice Miller, (202) 606–2063, caprice.miller@opm.gov
- Michael R. Esser—Deputy Inspector General Performing the Duties of the Inspector General
 - Drew M. Grimm—Assistant Inspector General for Investigations
 - Faiza Mathon-Mathieu—Assistant

Inspector General, Office of Legal & Legislative Affairs

- Nicholas E. Hoyle—Assistant Inspector General, Office of Management
- Monyca W. Peyton—Deputy Assistant Inspector General, Office of Management
- Robin A. Thottungal—Deputy Assistant Inspector General Chief Information Officer, Office of Management

United States Postal Service, Phone Number: (703) 248–2100, CIGIE Liaison—Agapi Doulaveris, (703) 248–2286, adoulaveris@uspsoig.gov

- Julius Rothstein—Deputy Inspector General/Attorney
- Robert Kwalwasser—Assistant Inspector General for Investigations
- Michael Mikulka—Deputy Assistant Inspector General for Investigations

Railroad Retirement Board, Phone Number: (312) 751–4690, CIGIE Liaison—Endea Murry, (312) 751–4334, endea.murry@oig.rrb.gov

- Shanon E. Holman—Assistant Inspector General for Audit/Principal Deputy Performing the Duties of the Inspector General
- Patricia Marshall—General Counsel

Small Business Administration, Phone Number: (202) 798–5818, CIGIE Liaison—Renee Russo Johnson, (202) 798–5818, renee.russojohnson@sba.gov

- Sheldon Shoemaker—Deputy Inspector General
- Andrea Deadwyler—Assistant Inspector General for Audits
- Lucine Willis—Deputy Assistant Inspector General for Audits
- Francine Hines—Assistant Inspector General, Management and Operations

Social Security Administration, Phone Number: (410) 965–9991, CIGIE Liaison—Craig Meklir, (240) 603–6566, craig.meklir@ssa.gov

- Michelle L. Anderson—Assistant Inspector General for Audit
- Jeffrey Brown—Deputy Assistant Inspector General for Audit
- Adriana Menchaca-Gendron—Assistant Inspector General for Resource Management
- B. Chad Bungard—Chief of Government Relations
- Joscelyn Funnié—Assistant Inspector General for Information Technology
- Kevin Huse—Deputy Assistant Inspector General for Investigations

Department of State, Phone Number: 571–348–0200, CIGIE Liaison—Tyler Lopez, (571) 348–5491, james.t.lopez@stateoig.gov

- Arne Baker—Acting Inspector General

- Norman P. Brown—Acting Deputy Inspector General
- Beverly J. Charlton—Deputy Assistant Inspector General for Audits Global Emergencies and Emerging Risk Directorate
- Molly Hines—Acting Assistant Inspector General for Management/Executive Director
- Jason T. Loeffler—Deputy Assistant Inspector General for Investigations
- Nicole S. Matthis—Chief of Staff
- Jeffrey D. McDermott—Assistant Inspector General for Whistleblower Integrity and Special Projects
- Ryan McGonagle—Deputy Assistant Inspector General for Inspections
- Robert J. Smolich—Assistant Inspector General for Investigations
- Gayle L. Voshell—Deputy Assistant Inspector General for Audits Core Operations and Global Governance Directorate
- Kevin J. Young—Deputy Assistant Inspector General for Technology

Department of Transportation, Phone Number: (202) 366–1959, CIGIE Liaison—Nathan P. Richmond, (202) 493–0422, nathan.richmond@oig.dot.gov

- Mitchell (Mitch) Behm—Deputy Inspector General
- Andrea Nossaman—Assistant Inspector General for Operations
- Elise Chawaga—Principal Assistant Inspector General for Investigations
- Justin Bidwell—Deputy Assistant Inspector General for Investigations
- Nelda Smith—Assistant Inspector General for Audits and Evaluations
- Marshall Jackson—Assistant Inspector General for Audits
- Dormayne Dillard-Christian—Assistant Inspector General for Financial, Information Technology, and Procurement Audits
- Tiffany Mostert—Assistant Inspector General for Surface Transportation Audits
- Amy Berks—General Counsel

Department of the Treasury, Phone Number: (202) 927–0650, CIGIE Liaison—Nancy Osborn, (202) 486–1149, osbornn@oig.treas.gov

- Loren Sciurba—Deputy Inspector General
- Pauletta Battle—Acting Assistant Inspector General for Audit

Treasury Inspector General for Tax Administration/Department of the Treasury, Phone Number: (800) 366–4484, CIGIE Liaison—Becky D'Ambrosio, (771) 233–5281, rebecca.dambrosio@tigta.treas.gov

- Heather Hill—Principal Deputy Inspector General
- Diana Tengesdal—Deputy Inspector General for Audit
- Linna Hung—Assistant Inspector

General for Audit, Security and Information Technology Services

- Deann Baiza—Assistant Inspector General Audit, Return Processing and Account Services
- Matthew Weir—Assistant Inspector General for Audit, Compliance and Enforcement Operations
- Nancy LaManna—Deputy Inspector General for Inspections and Evaluations
- John Kirk—Deputy Inspector General for Investigations
- Tyler Yetter—Assistant Inspector General for Investigations
- Michael Goduti—Assistant Inspector General for Investigations
- Scott Moffit—Assistant Inspector General for Investigations
- Char Dae' Love-Jones—Deputy Inspector General for Mission Support
- Gladys Hernandez—Chief Counsel
- Lori Creswell—Deputy Chief Counsel

Department of Veterans Affairs, Phone Number: (202) 264–9376, CIGIE Liaison—Kiyana Bonner, (202) 309–3599, kiyana.bonner@va.gov

- Silas Darden—Assistant Inspector General for Investigations
- Leigh Ann Searight—Deputy Assistant Inspector General for Audits and Evaluations

Andrew Cannarsa,
Executive Director.

[FR Doc. 2026–20753 Filed 10–8–26; 8:45 am]

BILLING CODE 6820–C9–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the Sentinel Deployment and Minuteman III Decommissioning and Disposal

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: The Department of the Air Force (DAF) is issuing this notice to prepare a Supplemental Environmental Impact Statement (SEIS) to the Environmental Impact Statement for *Sentinel (Ground Based Strategic Deterrent (GBSD) Program Deployment and Minuteman III Decommissioning and Disposal* (2023 EIS) and the May 2023 Record of Decision (ROD) which documented DAF's decision regarding sequential replacement of all land-based Minuteman III (MMIII) intercontinental ballistic missiles (ICBM) in the United States with a technologically advanced

Sentinel ICBM system on base at Francis Emroy Warren Air Force Base (AFB) (FE Warren) in Wyoming, Malmstrom AFB (Malmstrom) in Montana, and Minot AFB (Minot) in North Dakota and in the missile fields across five states. The SEIS will analyze potential environmental impacts associated with changes to the Proposed Action analyzed in the 2023 EIS. The “Sentinel Weapon System Program” (“Sentinel Program” from this point forward) addressed in the 2023 EIS and the May 2023 ROD was formerly known as the “GBSD.” This SEIS is being prepared in accordance with the National Environmental Policy Act of 1969 (NEPA) (42 United States Code 4321 *et seq.*), as amended by the Fiscal Responsibility Act of 2023, the 2026 Department of War and the 2026 DAF NEPA Implementing Procedures. DAF is the lead agency for the Proposed Action. The Bureau of Indian Affairs, Bureau of Land Management, Bureau of Reclamation, U.S. Army Corps of Engineers, U.S. Forest Service, U.S. Fish and Wildlife Service, and U.S. Department of Agriculture Farm Service Agency will be invited to participate as Cooperating Agencies. DAF will consult with, and obtain the comments of, federally recognized Native American Tribes and federal agencies that have jurisdiction by law or special expertise related to the environmental analysis.

DATES: A public scoping period of 30 days will take place starting from the date of publication of this Notice of Intent in the **Federal Register**. DAF requests comments on alternatives, impacts, relevant information, studies, or analyses with respect to the Proposed Action. Comments should be submitted in writing to the website or address listed in the **ADDRESSES** section and will be accepted at any time during the SEIS process; however, to ensure DAF has sufficient time to consider public input, please submit within the 30-day scoping period. The Draft SEIS is anticipated to be provided for public comment in fall 2027. The Final SEIS is anticipated for publication in Spring 2028.

ADDRESSES: The project website at <http://www.sentinelseis.com> provides information on the SEIS and the scoping process and can be used to submit scoping comments electronically. Scoping comments may also be submitted by email to SentinelSEIS@tetratech.com, including “Sentinel SEIS” in the subject line, or by U.S. mail to Sentinel SEIS, c/o Tetra Tech, 711 Navarro Street, Suite 560, San Antonio, Texas 78215. SEIS inquiries and requests for digital or print copies of scoping materials are available upon

request at the email or mailing address provided. For printed material requests, the standard U.S. Postal Service shipping timeline will apply. Members of the public who are interested in additional information about the project are encouraged to visit the project website.

FOR FURTHER INFORMATION CONTACT: For inquiries regarding accommodations under the Americans with Disabilities Act or questions regarding the Proposed Action, scoping, and SEIS development, please contact: Air Force Global Strike Command Public Affairs, Lt. Col. Rodney E. Ellison Jr., at (318) 456–1305, Monday through Friday from 8:00 a.m. to 5:00 p.m. Central Time, or by email to afgsc.paworkflow@us.af.mil.

SUPPLEMENTARY INFORMATION: The overarching Purpose and Need for the SEIS remain the same as the 2023 EIS. The Purpose of the Proposed Action is to replace all land-based MMIII missiles deployed in the continental United States with the Sentinel Program and to ensure the nation continues to maintain safe, secure, and effective ICBMs and associated infrastructure for the land-based leg of its nuclear weapons program in support of national security objectives. The Need for the Proposed Action is compliance with Public Law 115–232 and to ensure the United States continues to have effective, responsive, and resilient ICBMs and associated infrastructure for the land-based leg of its nuclear weapons program and the capacity and adaptability to manage and respond to shifting global requirements. The specific Need for the Proposed Action in this SEIS is that the original approach to recapitalizing all existing MMIII infrastructure could not be carried forward because key Sentinel Program milestones were no longer achievable due to cost and schedule risks associated with converting existing Launch Facility (LF) sites to Launch Silo (LS) sites. Pursuant to the July 2024 Acquisition Decision Memorandum directing the restructure of the Sentinel Program, DAF evaluated optimized deployment strategies to reduce execution risk, stabilize costs, and address the complexities of legacy infrastructure. DAF restructured its basing approach from legacy facility reutilization to the construction of modernized, new-built LS sites that are adaptable to future technological advancements.

The Proposed Action of this SEIS would include, at each missile field, plausible redesign, function, and relocation of workforce hubs to support construction efficiency; closure in place of a selected number of the current 150

MMIII LF sites; disposal of existing Missile Alert Facility (MAF) and LF sites; conversion of qualifying LF sites to LS sites; reutilization of MAF sites for Launch Center (LC) development, procurement of easements for new utility corridors, including fiber-optic cables not evaluated in the 2023 EIS; in-field MH–139 (Grey Wolf) helicopter refueling and rearming capability at selected LC sites; and construction of additional on-base facilities or infrastructure. Missile field-specific aspects of the Proposed Action include land acquisition through real estate transactions for new LS and LC sites at FE Warren and Minot; possible replacement of an existing LF site with an LC site at FE Warren; expansion northwest of the existing missile field at FE Warren; expansion west and east of the existing missile field at Minot; reutilization of former 564th Missile Squadron geographic sites as swing space and establishment of temporary laydown areas at Malmstrom. The Proposed Action also includes up to 30 new LS sites at FE Warren, and up to 60 new LS sites at Malmstrom and Minot.

The SEIS will also analyze the No Action Alternative. Under the No Action Alternative, the DAF would continue to implement the May 2023 ROD. It would sequentially replace all land-based MMIII ICBMs and reutilize 80 percent of existing utility corridors while constructing only 20 percent of new utility corridors in newly established easements with a technologically advanced Sentinel ICBM system on base and in the missile fields at FE Warren, Malmstrom, and Minot. Although the No Action Alternative presumes the present course of action identified in the May 2023 ROD, the DAF will compare the impacts of the Proposed Action to the baseline conditions identified in the 2023 EIS for purposes of assessing the environmental impacts of the proposed alternatives in the SEIS. The No Action Alternative is not a reasonable alternative because it has been deemed unachievable due to cost, schedule, siting, and engineering constraints.

DAF has determined that the Proposed Action has the potential to be located within a floodplain. Thus, the Proposed Action is subject to the requirements and objectives of Executive Order (E.O.) 11988, “Floodplain Management.” This NOI serves as the public notice directed by E.O. 11988 to encourage early and meaningful public participation.

(Authority: 42 United States Code 4321, *et seq.*, and Department of War and Department

of Air Force National Environmental Policy Act Implementing Procedures.)

Crystle C. Poge,

Air Force Federal Register Liaison Officer.

[FR Doc. 2026–20724 Filed 10–8–26; 8:45 am]

BILLING CODE 3911–44–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–SCC–3037]

Agency Information Collection Activities; Comment Request; Integrated Postsecondary Education Data System (IPEDS) 2026–27 Through 2028–29

AGENCY: National Center for Education Statistics (NCES), Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before December 8, 2026.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2026–SCC–3037. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the National Center for Education Statistics; Institute of Education Sciences; U.S. Department of Education; IES—D Street; Room 10.8.0.D; 400 Maryland Ave. SW; Washington, DC 20202–1200.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Matthew Soldner, NCESCommissioner@ed.gov.

SUPPLEMENTARY INFORMATION: The Department, 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 Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is the estimated burden of the data collection accurate; (2) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (3) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Integrated Postsecondary Education Data System (IPEDS) 2026–27 through 2028–29.

OMB Control Number: 1850–0582.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 61,467.

Total Estimated Number of Annual Burden Hours: 818,023.

Abstract: The National Center for Education Statistics (NCES) is seeking clearance, including revisions, for the 2026–27, 2027–28, and 2028–29 Integrated Postsecondary Education Data System (IPEDS) data collections. The currently active OMB clearance for IPEDS (1850–0582, v. 33) was granted on August 05, 2024, approved with change on December 16, 2025, and extends through August 31, 2027.

IPEDS is a web-based data collection system designed to collect basic data from all postsecondary institutions in the United States and the other jurisdictions. The IPEDS data collection enables NCES to report on key dimensions of postsecondary education such as admission and enrollments, degrees and other awards earned, tuition and fees, average net price, student financial aid, graduation rates, student outcomes, revenues and expenditures, faculty salaries, and staff employed. IPEDS data are available to the public through multiple websites,

including the College Navigator and IPEDS Use the Data websites. The reported data is also used for research and analysis to inform decisionmakers at institutions, state and federal government, and other stake holding parties. All Title IV institutions are required to respond to IPEDS (Section 490 of the Higher Education Amendments of 1992 [Pub. L. 102–325]). IPEDS allows other (non-Title IV) institutions to participate on a voluntary basis.

In Version 34 of this clearance, NCES proposes changes only to the Admissions and Consumer Transparency Supplement (ACTS). Specifically, we propose: (1) a change in the eligibility criteria for the ACTS components; (2) improvements in the ACTS aggregator tool; (3) removal of variables that, despite their potential analytic utility, were determined during the disclosure avoidance process to reduce the utility of the ACTS data collection overall; and (4) clarifications to instructions and item definitions based on feedback from institutions and practitioners provided prior to a recent Technical Review Panel (TRP) held in 2026. All other IPEDS survey components are unchanged from the previously approved collection.

NCES encourages the public to thoroughly review and comment upon the contents of this package.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–20754 Filed 10–8–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, November 18, 2026; 6–8 p.m. EST.

ADDRESSES: Department of Energy (DOE) Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37831. This meeting will be held in-person at the DOE Information Center

and virtually. To receive the virtual access information, please send an email to: orssab@orem.doe.gov at least two days prior to the meeting.

FOR FURTHER INFORMATION CONTACT:

Melyssa P. Noe, Deputy Designated Federal Officer, U.S. Department of Energy, Oak Ridge Office of Environmental Management (OREM), P.O. Box 4067, EM-94, Oak Ridge, TN 37831; Phone (865) 241-3315; or Email: Melyssa.Noe@orem.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: At the request of the Assistant Secretary or Field Managers, the Board may provide community-based advice and recommendations concerning any EM program activities, such as clean-up activities and environmental restoration; waste management and disposition; excess facilities; future land use and long-term stewardship; communications; and budget priorities. The Board also provides an avenue to fulfill public participation requirements outlined in the Comprehensive Environmental Response, Compensation, and Liability Act (CERLA), Federal Facility Agreements, Consent Orders, Consent Decrees and Settlement Agreements.

Tentative Agenda: (agenda topics are subject to change; please email orssab@orem.doe.gov for the most current agenda)

- OREM Presentation to the Board
- Discussion
- Public Comment Period
- Board Business

Public Participation: The meeting is open to the public and public comment can be given orally or in writing. Fifteen minutes are allocated during the meeting for public comment and those wishing to make oral comment will be given a minimum of two minutes to speak. Written comments received at least two working days prior to the meeting will be provided to the members and included in the meeting minutes. Written comments received within two working days after the meeting will be included in the minutes. For additional information on public comment and to submit written comment, please email orssab@orem.doe.gov. The EM SSAB, Oak Ridge, welcomes the attendance of the public at its meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Melyssa P. Noe at least seven days in advance of the meeting.

Meeting Conduct: The Designated Federal Officer is empowered to

conduct the meeting in a fashion that will facilitate the orderly conduct of business. Questioning of board members or presenters by the public is not permitted.

Minutes: Minutes will be available at the following website: <https://www.energy.gov/orem/listings/oak-ridge-site-specific-advisory-board-meetings>.

Signing Authority: This document of the Department of Energy was signed on October 7, 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 7, 2026.

Jennifer Hartzell,

*Alternate Federal Register Liaison Officer,
U.S. Department of Energy.*

[FR Doc. 2026-20782 Filed 10-8-26; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/livestreamed meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, November 17, 2026; 9 a.m.–4 p.m. EST.

ADDRESSES: Advanced Manufacturing Collaborative, 4345 Trolley Line Road, Aiken, South Carolina 29801. This meeting will be held in-person at the Advanced Manufacturing Collaborative and streamed on YouTube, no registration is necessary. The link for the livestream can be found on the following website: <https://www.youtube.com/@SRSCAB/streams>.

FOR FURTHER INFORMATION CONTACT:

James Tanner, Office of External Affairs, U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 646-2167; or Email: james.tanner@srs.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: At the request of the Assistant Secretary or Field Managers, the Board may provide community-based advice and recommendations concerning any EM program activities, such as clean-up activities and environmental restoration; waste management and disposition; excess facilities; future land use and long-term stewardship; communications; and budget priorities. The Board also provides an avenue to fulfill public participation requirements outlined in the Comprehensive Environmental Response, Compensation, and Liability Act (CERLA), Federal Facility Agreements, Consent Orders, Consent Decrees and Settlement Agreements.

Tentative Agenda: (agenda topics are subject to change; please contact Juanita Campbell at juanita.campbell@srs.gov for the most current agenda)

- Chair Update
- Agency Updates
- Program Presentations to the Board
- Board Business
- Public Comments

Public Participation: The meeting is open to the public and public comment can be given orally or in writing. Fifteen minutes are allocated during the meeting for public comment and those wishing to make oral comment will be given a minimum of two minutes to speak. Written comments received at least two working days prior to the meeting will be provided to the members and included in the meeting minutes. Written comments received within two working days after the meeting will be included in the minutes. For additional information on public comment and to submit written comment, please contact srscitizensadvisoryboard@srs.gov. The EM SSAB, Savannah River Site, welcomes the attendance of the public at its meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact srscitizensadvisoryboard@srs.gov at least seven days in advance of the meeting.

Meeting Conduct: The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Questioning of board members

or presenters by the public is not permitted.

Minutes: Minutes will be available at the following website: www.cab.srs.gov.

Signing Authority: This document of the Department of Energy was signed on October 7, 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 7, 2026.

Jennifer Hartzell,

*Alternate Federal Register Liaison Officer,
U.S. Department of Energy.*

[FR Doc. 2026-20781 Filed 10-8-26; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice Of Filings

Take notice that the Commission received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP26-1320-000.
Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate and Non-Conforming Agreements Update (Nov 2026) to be effective 11/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5136.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1321-000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rates Various Filings eff 10-01-2026 to be effective 10/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5155.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1322-000.

Applicants: Portland Natural Gas Transmission System.

Description: § 4(d) Rate Filing: PNGTS Action Alerts and Operational Flow Orders to be effective 11/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5158.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1323-000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (SoCal 2026) to be effective 11/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5161.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1324-000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Semptra November 2026) to be effective 11/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5162.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1325-000.

Applicants: Adelphia Gateway, LLC.

Description: Compliance filing: Adelphia Gateway Order No. 587-AB Compliance Filing to be effective 1/1/2027.

Filed Date: 9/30/26.

Accession Number: 20260930-5165.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1326-000.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rates—Northern to NRG eff 10-1-2026 to be effective 10/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5167.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1327-000.

Applicants: Northern Natural Gas Company.

Description: § 4(d) Rate Filing: 20260930 Negotiated Rate Filing to be effective 10/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5179.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1328-000.

Applicants: Leaf River Energy Center LLC.

Description: Compliance filing: Leaf River Energy Order No. 587-AB Compliance Filing to be effective 1/1/2027.

Filed Date: 9/30/26.

Accession Number: 20260930-5188.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1329-000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Pipeline Safety and Greenhouse Gas Cost Adjustment Mechanism—2026 to be effective 11/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5202.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1330-000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreements—Morgan Stanley and Seneca Resources to be effective 11/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5214.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1331-000.

Applicants: Mississippi Hub, LLC.

Description: Annual Penalty Disbursement Report of Mississippi Hub, LLC.

Filed Date: 9/30/26.

Accession Number: 20260930-5223.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP26-1332-000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Negotiated Rate Agreements Update (Eco-Energy Oct-Dec 2026) to be effective 10/1/2026.

Filed Date: 9/30/26.

Accession Number: 20260930-5232.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP27-1-000.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Filing—Janix Energy Services, LLC to be effective 10/30/2026.

Filed Date: 10/1/26.

Accession Number: 20261001-5000.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP27-2-000.

Applicants: Northwest Pipeline LLC.

Description: § 4(d) Rate Filing: Non Conforming Service Agreements Idaho Power, Questar, and Puget to be effective 11/1/2026.

Filed Date: 10/1/26.

Accession Number: 20261001-5002.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP27-3-000.

Applicants: Venture Global Gator Express, LLC.

Description: § 4(d) Rate Filing: Statement of Negotiated Rate TSAs filing to be effective 10/31/2026.

Filed Date: 10/1/26.

Accession Number: 20261001-5073.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP27-4-000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—10/01/2026 to be effective 10/1/2026.

Filed Date: 10/1/26.

Accession Number: 20261001-5118.

Comment Date: 5 p.m. ET 10/13/26.

Docket Numbers: RP27–5–000.
Applicants: Saltville Gas Storage Company L.L.C.
Description: § 4(d) Rate Filing: SGSC 2026 Fuel Filing to be effective 11/1/2026.
Filed Date: 10/1/26.
Accession Number: 20261001–5119.
Comment Date: 5 p.m. ET 10/13/26.
Docket Numbers: RP27–6–000.
Applicants: Trunkline Gas Company, LLC.
Description: § 4(d) Rate Filing: Tariff Updates—Displacement Points to be effective 11/1/2026.
Filed Date: 10/1/26.
Accession Number: 20261001–5120.
Comment Date: 5 p.m. ET 10/13/26.
Docket Numbers: RP27–7–000.
Applicants: ETC Tiger Pipeline, LLC.
Description: § 4(d) Rate Filing: Tariff Updates—Displacement Points to be effective 11/1/2026.
Filed Date: 10/1/26.
Accession Number: 20261001–5121.
Comment Date: 5 p.m. ET 10/13/26.
Docket Numbers: RP27–8–000.
Applicants: Gulf Run Transmission, LLC.
Description: § 4(d) Rate Filing: Revisions Related to Displacement Points to be effective 11/1/2026.
Filed Date: 10/1/26.
Accession Number: 20261001–5125.
Comment Date: 5 p.m. ET 10/13/26.
Docket Numbers: RP27–9–000.
Applicants: Mountain Valley Pipeline, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—10/01/2026 to be effective 10/1/2026.
Filed Date: 10/1/26.
Accession Number: 20261001–5131.
Comment Date: 5 p.m. ET 10/13/26.
Docket Numbers: RP27–10–000.
Applicants: Spire MoGas Pipeline LLC.
Description: § 4(d) Rate Filing: Spire MoGas Negotiated Rate Tariff Filing to be effective 11/1/2026.
Filed Date: 10/1/26.
Accession Number: 20261001–5161.
Comment Date: 5 p.m. ET 10/13/26.
 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: RP26–1100–001.

Applicants: White River Hub, LLC.
Description: Compliance filing: Order No. 587–AB Amendment Filing to be effective 1/1/2027.
Filed Date: 10/1/26.
Accession Number: 20261001–5003.
Comment Date: 5 p.m. ET 10/13/26.
Docket Numbers: RP26–1231–001.
Applicants: Florida Southeast Connection, LLC.
Description: Compliance filing: Amendment to Order No. 587–AB Compliance Filing (RP26–1231-) to be effective 1/1/2027.
Filed Date: 10/5/26.
Accession Number: 20261005–5111.
Comment Date: 5 p.m. ET 10/19/26.
Docket Numbers: RP26–1319–001.
Applicants: Equitrans, L.P.
Description: Tariff Amendment: Amend Remove Expired Negotiated Rate Agreement—11/1/2026 to be effective 11/1/2026.
Filed Date: 9/30/26.
Accession Number: 20260930–5191.
Comment Date: 5 p.m. ET 10/13/26.
 Any person desiring to protest in any of 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.

Dated: October 06, 2026.
Carlos D. Clay,
Deputy Secretary.
 [FR Doc. 2026–20747 Filed 10–8–26; 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 Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP27–18–000.
Applicants: Iroquois Gas Transmission System, L.P.
Description: § 4(d) Rate Filing: 10.6.26 Negotiated Rates—Citadel Energy Marketing LLC R–7705–38 to be effective 11/1/2026.
Filed Date: 10/6/26.
Accession Number: 20261006–5058.
Comment Date: 5 p.m. ET 10/19/26.
 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.
 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.

Dated: October 6, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026–20744 Filed 10–8–26; 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 Exempt Wholesale Generator filings:

Docket Numbers: EG27–2–000.
Applicants: Notch Peak Project, LLC.
Description: Notch Peak Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 10/6/26.
Accession Number: 20261006–5130.
Comment Date: 5 p.m. ET 10/27/26.

Take notice that the Commission received the following Electric Rate filings:

Docket Numbers: ER18–140–018.

Applicants: Lackawanna Energy Center LLC.

Description: Supplement to 06/30/2026 Triennial Market Power Analysis for Northeast Region of Lackawanna Energy Center LLC.

Filed Date: 9/30/26.

Accession Number: 20260930–5271.

Comment Date: 5 p.m. ET 10/21/26.

Docket Numbers: ER24–116–000; ER14–1140–000.

Applicants: Inspire Energy Holdings, LLC, Rhythm Ops, LLC.

Description: Supplement to 07/01/2025, Triennial Market Power Analysis for Southwest Region and Notice of Non-Material Change in Status of Rhythm Ops, LLC, et al.

Filed Date: 9/24/26.

Accession Number: 20260924–5211.

Comment Date: 5 p.m. ET 10/15/26.

Docket Numbers: ER25–209–003.

Applicants: Pacific Gas and Electric Company.

Description: Compliance filing: WDT: Compliance Filing—WDT4 Settlement to be effective 7/1/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5124.

Comment Date: 5 p.m. ET 10/27/26.

Docket Numbers: ER26–3122–001.

Applicants: Montour, LLC.

Description: Tariff Amendment: Cancellation COC date update filing to be effective 9/14/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5137.

Comment Date: 5 p.m. ET 10/27/26.

Docket Numbers: ER27–44–000.

Applicants: Platinum Energy1, LLC.

Description: Application for Market-Based Rate Authorization to be effective 10/6/2026.

Filed Date: 10/5/26.

Accession Number: 20261005–5203.

Comment Date: 5 p.m. ET 10/26/26.

Docket Numbers: ER27–51–000.

Applicants: New York Independent System Operator, Inc., Power Authority of the State of New York.

Description: § 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): NYISO–NYPA Joint 205: Amended LGIA Harlem River Yard SA2881 (CEII) to be effective 9/21/2026.

Filed Date: 10/5/26.

Accession Number: 20261005–5238.

Comment Date: 5 p.m. ET 10/26/26.

Docket Numbers: ER27–52–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: DG&T Engineering Services Agt OTP325 (R.S. No. 813) to be effective 10/7/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5059.

Comment Date: 5 p.m. ET 10/27/26.

Docket Numbers: ER27–53–000.

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): 2026–10–06 SA 4877 METC–Hecate Energy E&P (J3050) to be effective 10/1/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5089.

Comment Date: 5 p.m. ET 10/27/26.

Docket Numbers: ER27–54–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 6009; Queue No. AF2–168 to be effective 12/6/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5117.

Comment Date: 5 p.m. ET 10/27/26.

Docket Numbers: ER27–55–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: GIA, Chambers Storage, WDT1766, SA 1463 to be effective 10/7/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5121.

Comment Date: 5 p.m. ET 10/27/26.

Docket Numbers: ER27–56–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ISA, SA No. 6816; Queue No. AF1–271A to be effective 10/12/2026.

Filed Date: 10/6/26.

Accession Number: 20261006–5136.

Comment Date: 5 p.m. ET 10/27/26.

Take notice that the Commission received the following Qualifying Facility filings:

Docket Numbers: QF27–22–000.

Applicants: Echeneidae Inc.

Description: Form 556 of Echeneidae Inc.

Filed Date: 10/6/26.

Accession Number: 20261006–5093.

Comment Date: 5 p.m. ET 10/27/26.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.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: October 6, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–20745 Filed 10–8–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so

requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the

decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each filing may be viewed

on the Commission's website at <http://www.ferc.gov> using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659.

Docket Nos.	File date	Presenter or requester
Prohibited		
NONE.		
Exempt		
1. EL15-18-000	9-25-2026	FERC Staff. ¹
2. ER26-3380-000, ER26-3515-000	9-28-2026	U.S. Representative Frank Pallone Jr.
3. P-2302-101	9-28-2026	FERC Staff. ²
4. EC26-99-000	9-30-2026	FERC Staff. ³

¹ Letter communication dated 9/23/26 from U.S. Representatives Sarah Elfreth, Glenn F. Ivey, Jaime Raskin, Johnny Olszewski, Jr., Chris Deluzio, Mike Quigley, André Carson, April McClain Delaney, Sarah McBride, Emilia Strong Sykes, and Jonathan L. Jackson.

² Memorandum communication dated 09/28/26 with Mi'kmaq Nation and the Maine State Historic Preservation Office.

³ Letter communication dated 09/28/26 from U.S. Representatives André Carson, Elizabeth Warren, Rashida Tlaib, Victoria Spartz, and Ayanna Pressley.

Dated: October 6, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026-20746 Filed 10-8-26; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OPRM-FAD-243]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202-993-3272 or <https://www.epa.gov/nepa>.

Weekly receipt of Environmental Impact Statements (EIS)

Filed September 28, 2026 10 a.m. EST

Through October 5, 2026 10 a.m. EST
Pursuant to CEQ Guidance on 42 U.S.C. 4332.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search>.

EIS No. 20260131, Draft, NRC, TX,
Combined License Application for the Project Matador Advanced Energy and Intelligence Campus AP1000 Units 1-4, Comment Period Ends: 11/23/2026,

Contact: Lance J Rakovan 301-415-2589.

Amended Notice

EIS No. 20260102, Draft, APHIS, MT,
Grizzly Bear Damage Management in Montana, Comment Period Ends: 11/04/2026, Contact: Dalin Tidwell 406-657-6464.

Revision to FR Notice Published 08/21/2026; Extending the Comment Period from 10/05/2026 to 11/04/2026.

Dated: October 6, 2026.

Kevin Bowman,

Director, Federal Activities Division.

[FR Doc. 2026-20738 Filed 10-8-26; 8:45 am]

BILLING CODE 6560-50-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 November 9, 2026.

A. Federal Reserve Bank of Atlanta
(Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE,

Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Washington State Bancshares, Inc. Employee Stock Ownership Trust, Karen Rowe trustee*; to become a bank holding company by acquiring additional voting shares of Washington State Bancshares, Inc., and thereby indirectly acquiring additional voting shares of Washington State Bank, all of Washington, Louisiana.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–20741 Filed 10–8–26; 8:45 am]

BILLING CODE 6210–01–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 October 26, 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. *David E. Rainbolt GST Trust, dated September 15, 1997, BancFirst as trustee, and Dana Kim Rainbolt, Adam Duston Rainbolt, Samuel Johnson Rainbolt, and Jacob Patrick Rainbolt as trust supervisors of the aforementioned trust, all of Oklahoma City, Oklahoma; and David and Kim Rainbolt Foundation and David E. Rainbolt, Dana Kim Rainbolt, Adam Duston Rainbolt, Samuel Johnson Rainbolt, and Jacob Patrick Rainbolt as directors of the aforementioned foundation, all of Oklahoma City, Oklahoma*; to join the Rainbolt Family Control Group, a group acting in concert, to retain voting shares of BancFirst Corporation, Oklahoma City, Oklahoma, and thereby indirectly retain voting shares of BancFirst, and Pegasus Bank, both of Dallas, Texas, and Worthington Bank, Arlington, Texas. David E. Rainbolt has previously been permitted by the Federal Reserve System to acquire voting shares of BancFirst Corporation and is a member of the Rainbolt Family Control Group. Dana Kim Rainbolt, Adam Duston Rainbolt, Samuel Johnson Rainbolt, and Jacob Patrick Rainbolt have been previously permitted by the Federal Reserve System to be members of the Rainbolt Family Control Group.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–20740 Filed 10–8–26; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5816]

Elite Laboratories, Inc. et al.; Withdrawal of Approval of 16 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on June 3, 2026. The document announced the withdrawal of approval

of 16 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of July 6, 2026. The document indicated that FDA was withdrawing approval of ANDA 207366 for ribavirin solution, 6 grams/vial, held by Navinta LLC, 1499 Lower Ferry Rd., Ewing, NJ 08618; ANDA 212957 for fosaprepitant dimeglumine powder, Equivalent to (EQ) 150 milligrams (mg) base/vial, held by Navinta LLC; and ANDA 218638 for nicardipine hydrochloride (HCl) capsule, 20 mg and 30 mg, held by Navinta LLC. Before FDA withdrew the approval of these ANDAs, Navinta LLC informed FDA that they did not want the approval of the ANDAs withdrawn. Because Navinta LLC timely requested that approval of the ANDAs not be withdrawn, the approval is still in effect. This notice removes the entries for ANDA 207366, ANDA 212957, and ANDA 218638.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 3, 2026 (91 FR 33185), appearing on page 33185 in FR Doc. 2026–11062, the following correction is made:

On page 33185, in the table, the entries for ANDA 207366, ANDA 212957, and ANDA 218638 are removed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20730 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10835]

Par Health USA LLC, U.S. Agent for PH Health Limited, et al.; Withdrawal of Approval of 37 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 37 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the

drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval

of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 071230	Ibuprofen tablet, 300 milligrams (mg)	Par Health USA LLC, U.S. Agent for PH Health Ltd., 300 Tice Blvd., Suite 230, Woodcliff Lake, NJ 07677.
ANDA 071229	Ibuprofen tablet, 200 mg	Do.
ANDA 071231	Ibuprofen tablet, 400 mg	Do.
ANDA 071232	Ibuprofen tablet, 600 mg	Do.
ANDA 071639	Ibuprofen tablet, 200 mg	Do.
ANDA 071644	Ibuprofen tablet, 400 mg	Do.
ANDA 072004	Ibuprofen tablet, 800 mg	Do.
ANDA 075659	AFEDITAB CR (nifedipine) extended-release tablet, 60 mg.	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.) 400 Interpace Parkway, Parsippany, NJ 07054.
ANDA 076024	Fluoxetine hydrochloride (HCl) tablet, equivalent to (EQ) 10 mg base.	Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540.
ANDA 076191	Fexofenadine HCl tablet, 30 mg, 60 mg, and 180 mg.	Barr Laboratories, LLC. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals, USA, Inc.) 400 Interpace Parkway, Parsippany, NJ 07054.
ANDA 076236	FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE (Fexofenadine HCl; pseudoephedrine HCl) extended-release tablet, 60 mg; 120 mg.	Do.
ANDA 076334	PREVIFEM (ethinyl estradiol; norgestimate) tablet, 0.035 mg; 0.25 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 076335	TRI-PREVIFEM (ethinyl estradiol; norgestimate) tablet, 0.035 mg, 0.035 mg, 0.035 mg; 0.18 mg, 0.215 mg, 0.25 mg.	Do.
ANDA 076337	CYCLAFEM 1/35 (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 1 mg.	Do.
ANDA 076338	CYCLAFEM 7/7/7 (ethinyl estradiol; norethindrone) tablet, 0.035 mg, 0.035 mg, 0.035 mg; 0.5 mg, 0.75 mg, 1 mg.	Do.
ANDA 076675	EMOQUETTE (desogestrel; ethinyl estradiol) tablet, 0.15 mg; 0.03 mg.	Do.
ANDA 076681	KIMIDESS (desogestrel; ethinyl estradiol) tablet, 0.15 mg, N/A; 0.02 mg, 0.01 mg.	Do.
ANDA 077075	GILDESS 1.5/30 and GILDESS FE 1.5/30 (ethinyl estradiol; norethindrone acetate) tablet, 0.03 mg; 1.5 mg.	Do.
ANDA 077077	GILDESS 1/20 and GILDESS FE 1/20 (ethinyl estradiol; norethindrone acetate) tablet, 0.02 mg; 1 mg.	Do.
ANDA 077099	ORSYTHIA (ethinyl estradiol; levonorgestrel) tablet, 0.02 mg; 0.1 mg.	Do.
ANDA 077324	Levetiracetam tablet, 250 mg, 500 mg, 750 mg, and 1 gm.	Fosun Pharma USA Inc.
ANDA 077502	MYZILRA (ethinyl estradiol; levonorgestrel) tablet, 0.03 mg, 0.04 mg, 0.03 mg; 0.05 mg, 0.075 mg, 0.125 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 078376	GILDAGIA (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 0.4 mg.	Do.
ANDA 078712	CIPROFLOXACIN EXTENDED RELEASE (ciprofloxacin; ciprofloxacin HCl) extended-release tablet, 212.6 mg; EQ 287.5 mg base.	Fosun Pharma USA Inc.
ANDA 080326	Prednisolone tablet, 5 mg	Lachman Consultant Services, Inc., U.S. Agent for Heather Drug Company, 1600 Stewart Ave., Westbury, NY 11590
ANDA 080339	Prednisolone tablet, 5 mg	Fosun Pharma USA Inc.
ANDA 080832	Diphenhydramine HCl capsule, 25 mg and 50 mg.	Do.
ANDA 081249	ACETAMINOPHEN AND CODEINE PHOSPHATE (acetaminophen; codeine phosphate) tablet, 300 mg; 60 mg.	Do.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 081250	ACETAMINOPHEN AND CODEINE PHOSPHATE (acetaminophen; codeine phosphate) tablet, 300 mg; 30 mg.	Do.
ANDA 086398	BUTALBITAL, ASPIRIN AND CAFFEINE (aspirin; butalbital; caffeine) tablet, 325 mg; 50 mg; 40 mg.	Do.
ANDA 090293	GILDESS 24 FE (ethinyl estradiol; norethindrone acetate) tablet, 0.02 mg; 1 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 091520	Bupropion HCl extended-release tablet, 150 mg	Do.
ANDA 203413	CYCLAFEM 0.5/35 (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 0.5 mg.	Do.
ANDA 203911	FLUDEOXYGLUCOSE F18 (Fludeoxyglucose F-18) injectable, 4–500 millicurie/milliliter (mCi/mL).	Nukemed, Inc. dba SpectronRx, 17490 Dugdale Dr., South Bend, IN 46635.
ANDA 203912	Sodium fluoride F-18 injectable, 10–200 mCi/mL.	Do.
ANDA 204455	AMMONIA N 13 (ammonia N-13) injectable, 30 mCi-300 mCi/8 mL (3.75–37.5 mCi/mL).	Do.
ANDA 205699	Bosentan tablet, 62.5 mg and 125 mg	Par Health USA LLC, U.S. Agent for PH Health Limited, 9 Great Valley Parkway, Malvern, PA 19355.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved abbreviated new drug application violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on November 9, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20762 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6667]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biologics License Applications, Procedures and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 November 9, 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 0910–0338. 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, 240–402–5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biologics License Applications (BLAs), Procedures and Requirements

OMB Control Number 0910–0338—Extension

This information collection helps support implementation of statutory and regulatory requirements under the Public Health Service Act (PHS) and the Federal Food, Drug, and Cosmetic Act (FD&C Act) that govern biologics product licensing. The Food and Drug Administration (FDA) has promulgated regulations in 21 CFR parts 600–680 setting forth applicable standards and procedures that include associated reporting, recordkeeping, and -disclosure requirements. Respondents to the information collection are persons or entities who engage in manufacture of biologics. Respondents to this collection of information are licensed manufacturers of biological products. Based on existing data, we estimate there are 371 such respondents. We provide relevant information and resources on our website at <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber> regarding biologics license applications (BLAs).

Regulations in 21 CFR part 600, subparts A through C (21 CFR 600–600.21), and regulations in 21 CFR 601, subpart A (21 CFR 601.2–21 CFR 601.9) cover general provisions and prescribe requisite content and format elements for applications. Regulations in 21 CFR part 601, subpart C (21 CFR 601.12–21 CFR 601.29) pertain to BLA changes; the electronic submission of information; the suspension, revocation, and reissuance of BLAs; and also provide for

the availability of guidance documents by FDA to assist respondents in complying with applicable requirements (21 CFR 601.29). Regulations in 21 CFR 601, subparts D and E, respectively, establish requirements applicable to diagnostic radiopharmaceuticals and for the accelerated approval of biological products for serious or life-threatening illnesses. Confidentiality of information submitted to FDA is covered in 21 CFR 601, subpart F (601.50–601.51). The regulations also provide for the approval of biological products when human efficacy studies are not ethical or feasible, as established in 21 CFR 601, subpart H. Finally, regulations in 21 CFR parts 610–680 establish both general and specific standards applicable to all biological products, including FDA requests for and protocols as required under 21 CFR 610.2, 660.6, 660.36, and 660.46 (previously approved under OMB control no. 0910–0206), as well as labeling provisions pertaining to exceptions or alternatives to the labeling of products in the Strategic National Stockpile (SNS) established in 21 CFR 610.28 (previously approved under OMB control no. 0910–0616).

To assist respondents with individual information collection elements, we have developed the following instruments, noting that FDA forms may be approved for use in other information collections:

Forms

Form FDA 356h, *Application to Market a New or Abbreviated New Drug or Biologic for Human Use*, provides a uniform format for submitting BLAs. Form FDA 356h is a fillable PDF form that may be submitted through our Electronic Submission Gateway (ESG), for which respondents must create and maintain a user account. Utilizing Form FDA 356h helps to ensure that an application is complete and contains all the necessary information, so that delays due to lack of information may be avoided. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review.

Form FDA 2252, *Transmittal of Annual Report for Drugs and Biologics for Human Use*, is used by an applicant

of a licensed biological product to submit annual reports required by § 601.70(b) (21 CFR 601.70(b)). Form FDA 2252 is also a fillable PDF form.

Form FDA 2253, *Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use*, was developed for use by respondents to transmit specimens of advertisements and promotional labeling (e.g., circulars, package labels, container labels, etc.), as well as labeling changes. The submission of this information is required by § 601.12 (21 CFR 601.12) for biological products and by 21 CFR 314.81 for drug products. Form FDA 2253 is a fillable PDF form.

Form FDA 3674, *Certificate of Compliance Under 42 U.S.C. 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank*, was developed for use by respondents to certify submissions as required by section 402(j)(5)(B) of the Public Health Service (PHS) Act and is submitted through our ESG.

Cover Sheets

As provided for under 21 CFR part 601.2(a), FDA utilizes cover sheets, so denoted for purposes of identifying specific content information within a given application. For more information regarding BLA cover sheets, please refer to <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/regulatory-submissions-electronic-format-cber-regulated-products>.

Guidance Documents

Agency regulations in 21 CFR 601.29 complement our Good Guidance Practice regulations in 21 CFR 10.115 by providing for the issuance of guidance documents to assist respondents with applicable requirements in 21 CFR part 601. We have issued the following guidance documents to assist respondents with activities covered by the information collection:

- The guidance document “*Cooperative Manufacturing Arrangements for Licensed Biologics*,” (November 2008), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cooperative-manufacturing-arrangements-licensed-biologics>, discusses strategies for meeting an

increased need for flexible manufacturing arrangements. Since cooperative manufacturing arrangements can take a considerable amount of time to develop, the guidance is intended to be useful for planning purposes in the early phases of product development. Many companies that perform only limited aspects of manufacturing processes are interested in sharing or contracting parts of manufacturing in order to facilitate product development and manufacturing flexibility. The guidance document discusses recommended communication between licensed manufacturers and contract manufacturers regarding changes to production and facilities, results of tests and investigations regarding the product, types of products manufactured in the contract facility, and standard operating procedures. We believe that the information collection provisions in the guidance do not create a new burden for respondents but incorporate reporting and recordkeeping provisions that are part of usual and customary business practices.

- The guidance document entitled, “*Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies*” (October 2023), describes a standards recognition program for regenerative medicine therapies (SRP–RMT) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products when such standards are appropriate. The guidance document also explains that any interested party may request recognition of a VCS. The guidance document is available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-consensus-standards-recognition-program-regenerative-medicine-therapies>.

In the **Federal Register** of July 6, 2026 (91 FR 41046), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14 Reporting of product deviations by licensed manufacturers	3486	70	7.186	503	2.0	1,006

ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments and transfusion services	3486	2,455	6.630	16,277	2.0	32,554
1271.350(b) Reporting requirements (human cells tissues and cellular and tissue-based products)	3486	86	2.465	212	2.0	424
1271.350(b) CBER addendum report	² 3486A	127	6.50	826	0.25	207
Total				17,818		34,191

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Five percent of the number of respondents ((2,455 + 86) × 0.05 = 127).

Following publication of the 60-day notice, the Agency identified a multiplication and rounding error in the burden calculations. The corrected estimates are reflected in this 30-day notice. This revision does not reflect a substantive or programmatic change to the information collection. Our estimated burden for the information collection reflects an overall increase of approximately 4,612 hours and a corresponding increase of 2,642 responses. We attribute this adjustment to an increase in the number of product deviations we received in FY 2024 from licensed manufacturers, unlicensed registered blood establishments and transfusion services under § 606.171. This is likely due to the issuance of the revised guidance document titled, “Biological Product Deviation Reporting for Blood and Plasma Establishments” (85 FR 14682; March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20768 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0053]

Challenges and Solutions in Lot-Level Food Traceability; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting titled “Challenges and Solutions in Lot-Level Food Traceability.” The purpose of the meeting is to provide a forum for

the public to share information on continued implementation of the “Requirements for Additional Traceability Records for Certain Foods” final rule and areas of concern, especially as they relate to lot-level tracking, and identify potential flexibilities to support compliance.

DATES: The public meeting will be held on November 6, 2026, from 12:00 p.m. to 3:30 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by December 6, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually, and login instructions will be provided at registration.

You may submit comments as follows. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 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–2014–N–0053 for “Challenges and Solutions in Lot-Level Food Traceability: Public Meeting.” 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: Katherine Vierk, Office of Surveillance Strategy and Risk Prioritization, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2122, Katherine.Vierk@fda.hhs.gov; or Alissa Van Wie, Office of Regulations and International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378, Alissa.vanwie@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA final rule, “Requirements for Additional Traceability Records for Certain Foods” (87 FR 70910, November 21, 2022) (Food Traceability Rule), establishes enhanced recordkeeping requirements for those who manufacture, process, pack, or hold foods on FDA’s Food Traceability List (FTL). The Food Traceability Rule requires lot-level tracking for foods on the FTL. Businesses that perform specific activities are required to assign unique codes, known as Traceability Lot Codes (TLCs), that must be passed along unchanged (unless the food is transformed) as the food moves through the supply chain. Entities that handle foods on the FTL are required to record Key Data Elements (KDEs), such as the TLC, when they perform specific

Critical Tracking Events (CTEs), such as initial packing, transformation, and shipping. Lot-level tracking enables rapid tracing of contaminated foods during recall events, allowing FDA to identify the source of the food faster, narrowing the scope of recalls and removing affected product from the supply chain more quickly, resulting in fewer foodborne illnesses and deaths.

The original compliance date for all persons subject to the recordkeeping requirements of the Food Traceability Rule was January 20, 2026. FDA proposed to extend the compliance date for the rule by 30 months to July 20, 2028 (90 FR 38084, August 7, 2025). Subsequently, the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act of 2026 (Pub. L. 119-37) (Continuing Appropriations Act) directed FDA not to enforce the Food Traceability Rule prior to that same date of July 20, 2028. FDA intends to comply with this Congressional directive.

Section 780 of the Continuing Appropriations Act also directed FDA to engage quarterly with regulated entities to identify and implement, as appropriate, additional flexibilities for satisfying the Food Traceability Rule’s lot-level tracking requirement. The public meeting announced in this notice is part of a series of engagements being held to fulfill that directive. As part of the same series of engagements, we previously held a public meeting on June 15, 2026. Prior to that public meeting, we published a discussion paper titled “Identifying Additional Flexibilities for Satisfying the Food Traceability Rule’s Lot-Level Tracking Requirement” (<https://www.regulations.gov/document/FDA-2014-N-0053-1371>). We provided an opportunity for stakeholders to submit feedback on the ideas presented in the discussion paper. We received 26 comments on the discussion paper from industry, trade associations, and technology partners. We have provided a high-level summary of those comments below. All comments can be accessed by searching Docket No. FDA-2014-N-0053 on <https://www.regulations.gov>.

TLC Flexibilities: Many commenters supported flexibility for identification of TLCs by allowing for a reasonable range of TLCs or inferred TLCs to be used when shipping FTL foods from distribution to retail. With both options, several stakeholders noted the need for these flexibilities to be accompanied by guardrails, including documented operational practices, validation exercises, and an understanding that the

reasonable range of TLCs or inferred TLCs be limited to the fewest TLCs possible. However, some commenters expressed concern that a flexibility for TLCs could reduce product-specific traceability and unnecessarily broaden the scope of a recall.

Flexibility for Eatches, Returns, Reclamations, and Food Waste Recovery: There was broad support from stakeholders to provide flexibilities for eatches, returns, and reclamations as these account for a relatively small amount of product that has often been separated from the original case. There was also support for additional clarity on the exemption for donated food to ensure that food waste recovery is not discouraged due to the requirements of the rule.

Intracompany Shipments: Some stakeholders noted continued confusion around the required records for intracompany shipments and requested clarification on these requirements. Some stakeholders also requested flexibility to track incoming and outgoing TLCs with records of internal movements of FTL foods that would be available upon request.

Retail Transformer Shipments: There was broad support from commenters for a simplified, modified recordkeeping framework for retail-kitchen-to-affiliated-store shipments.

Data Standardization: There was strong support among stakeholders for FDA to recognize GS1 as an acceptable data standard for use in identifying shipments of FTL foods. FDA recently posted a FAQ on data standards, which is available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule#TPTS3>.

II. Topics for Discussion at the Public Meeting

The goal of this public meeting is for FDA to hear stakeholder perspectives on lot-level food traceability efforts and implementation challenges facing industry. FDA is interested in learning more about the challenges and potential solutions for satisfying the Food Traceability Rule’s lot-level tracking requirements.

Specifically, we are interested in feedback on the potential flexibilities in achieving compliance with the rule that have been identified to date and on the feedback received on the discussion paper in the docket. We encourage those participating in this public meeting to consider the questions posed in the discussion paper, stakeholder responses to these questions submitted to the docket, and any new ideas regarding flexibilities as you develop your

remarks for this meeting. We also welcome additional comments or presentation materials to be submitted to the docket for consideration.

III. Participating in the Public Meeting

Registration: Please visit the following website for additional information and to register for the public meeting: <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops>.

The virtual public meeting is free and open to the public, but registration is necessary to attend. General registration will remain open until November 5, 2026. Individuals who want to speak during the public comment period must register by October 26, 2026. Same-day registration is not allowed. Instructions for joining the virtual meeting will be provided upon registration.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate all requests to make public comments. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants in advance by November 4, 2026. All requests to make oral presentations must be received by the close of speaker registration on October 26, 2026. All presentations must be given orally; we cannot accommodate slides or visuals on the virtual platform. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-20720 Filed 10-8-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-10396]

Amneal Pharmaceuticals of New York, LLC; Withdrawal of Approval of Abbreviated New Drug Application for Celecoxib Capsules, 50 Milligrams, 100 Milligrams, 200 Milligrams, and 400 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 208833 for Celecoxib capsules, 50 milligrams (mg), 100 mg, 200 mg, and 400 mg, held by Amneal Pharmaceuticals of New York, LLC, 50 Horseblock Rd., Brookhaven, NY 11719 (Amneal). Amneal requested withdrawal of approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of October 9, 2026.

FOR FURTHER INFORMATION CONTACT:

Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On May 31, 2018, FDA approved ANDA 208833 for Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg. The reference listed drug (RLD) is Celebrex (celecoxib) capsules, 50 mg, 100 mg, 200 mg, and 400 mg, approved under new drug application (NDA) 020998. According to annual reports filed with the Agency, the drug products approved under ANDA 208833 have not been commercially manufactured since the ANDA's approval in May 2018.

In a letter dated September 16, 2021, FDA notified Amneal that it had significant concerns about the validity and reliability of bioequivalence and bioavailability data generated by a contract research organization that had conducted studies relied on by ANDA 208833 and instructed Amneal to re-conduct bioequivalence studies for ANDA 208833 at an alternate site. The September 16, 2021, letter also informed Amneal that FDA was changing the therapeutic equivalence evaluation code for Amneal's Celecoxib capsules to "BX."¹ In response to multiple inquiries from the Agency, Amneal committed (on October 14, 2021, October 6, 2022, and September 18, 2023) to submitting new bioequivalence studies to enable FDA to make a full evaluation of therapeutic equivalence between Amneal's Celecoxib capsules and the RLD.

¹ The code BX is assigned to specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence under the policies stated in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") preface, available at <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>. Accessed September 16, 2026.

On February 22, 2024, FDA requested that Amneal describe its efforts to conduct new bioequivalence studies and provide a timeline for completing and submitting these studies and requested that Amneal agree not to distribute the drug products covered by ANDA 208833 until they were shown to be bioequivalent to the RLD based on bioequivalence studies conducted at an alternate site. On March 18, 2024, Amneal submitted a general correspondence communicating its intent to submit new bioequivalence studies by March 2025 and agreeing not to distribute the drug products covered by ANDA 208833 until these studies were completed and were found to demonstrate bioequivalence to the RLD. In November 2024, Amneal's Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg, approved under ANDA 208833, were moved to the discontinued section of the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (known generally as the "Orange Book").

In light of the concerns about the validity and reliability of the bioequivalence data on which ANDA 208833 relied for approval, the absence of new bioequivalence studies demonstrating the bioequivalence of Amneal's Celecoxib capsules to the RLD is a potential problem that is sufficiently serious that the drug should be removed from the market.

As of May 28, 2025, Amneal had not submitted new bioequivalence studies demonstrating the bioequivalence of its Celecoxib capsules to the RLD. Accordingly, FDA suggested that Amneal voluntarily seek withdrawal of approval of ANDA 208833 for Celecoxib capsules under § 314.150(d) (21 CFR 314.150(d)) and note that it was waiving its opportunity for a hearing under § 314.150(a).

In a request for withdrawal of approval submitted June 6, 2025, as amended on June 27, 2025, and July 9, 2025, Amneal requested that FDA withdraw approval of ANDA 208833 for Celecoxib capsules under § 314.150(d) and waived its opportunity for a hearing. Amneal stated that its request for withdrawal of approval was based on Amneal's business decision.

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 208833 for Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg, into interstate commerce without an approved application is illegal and subject to

regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20758 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7426]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 November 9, 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 0910–0814. 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, 240–402–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910–0814—Revision

This information collection helps support implementation of Food and Drug Administration (FDA, agency, us or we) regulations, as well as agency forms and associated guidance. Provisions in section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) set forth general requirements relating to expanded access to unapproved therapies and diagnostics. Sometimes called “*compassionate use*,” expanded access (EA) is a potential pathway for a patient with an immediately life-threatening condition, or serious disease or condition, to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. To facilitate expanded access to investigational drugs by patients, regulations in 21 CFR part 312, subpart I; *Expanded Access to Investigational Drugs for Treatment Use* (21 CFR 312.300–21 CFR 312.320), establish submission requirements that include demonstrating certain criteria have been met, and that content and format requirements have been satisfied. Information collection associated with all other provisions in 21 CFR 312 are included in OMB control no. 0910–0014 unless specifically noted.

The information collection utilizes Form FDA 3926 entitled, “Individual Patient Expanded Access—Investigational New Drug Application (IND).” Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians or industry who want to request expanded access as prescribed in the applicable regulations. We are revising Form FDA 3926 as follows:

- In Field 6, “Treatment Information,” delete the data element “Investigational Drug Name” and replace it with “Planned Date of Treatment Initiation” and revise the data element “FDA Review Division (if known)” to read “FDA Office/Review Division (if known).”
- In Field 9, replace the heading “Contents of Submission” with “Contents of Submission (follow-up/additional submissions only).”

Upon OMB approval of these modifications, we will revise accompanying instructions. Respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application

(IND) (approved under OMB control number 0910–0014), for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a). FDA considers a completed Form FDA 3926 signed by the physician and checked in the box in Field 10.a (*Request for Authorization to use Form FDA 3926*) to be a waiver request in accordance with 21 CFR 312.10.

We continue to maintain an expanded access website (www.fda.gov/news-events/public-health-focus/expanded-access), including associated guidance documents. Regulations in 21 CFR 312.145 (approved in control. 0910–0014) provide for the issuance of guidance documents by FDA to assist respondents in complying with applicable regulations in 21 CFR 312. The guidance document “Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers,” (April 2026), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expanded-access-investigational-drugs-treatment-use-questions-and-answers>, supplements reporting instructions applicable to Form FDA 3926.

Description of Respondents:

Respondents to the collection of information are licensed physicians who request patient access to investigational drugs.

In the **Federal Register** of July 28, 2026 (91 FR 47248), we published a 60-day notice requesting public comment on the proposed collection of information. One comment letter was received, containing multiple comments.

One comment was supportive of the proposed revisions to Form FDA 3926, stating that the changes to the form were appropriate and should make it easier to access investigational therapies efficiently. Other comments stated that the information collected through expanded access should not merely satisfy administrative requirements and suggested that the information collection should be used to facilitate the collection of meaningful and standardized information, including safety data, patient-reported outcomes, biomarker information, and other real-world clinical observations. We appreciate the comment and will take the concerns raised into consideration in future evaluations. No changes were made to the information collection or burden estimates as a result of the comment.

We estimate the burden of the collections of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—CENTER FOR DRUG EVALUATION AND RESEARCH^{1 2 3}

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 3926.	752	1.3484	1,014	0.75 (45 minutes)	761
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 1571.	10	10.8	108	3	324
§ 312.310(d); submissions related to expanded access and treatment of an individual patient for emergency use: Form FDA 3926.	394	1.1371	448	0.75 (45 minutes)	336
§ 312.310(d); submissions related to expanded access and treatment of an individual patient for emergency use: Form FDA 1571.	7	3.2857	23	3	69
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population (Form FDA 1571).	37	1.0541	39	120	4,680
§ 312.320(b) and 312.305(b); submissions related to a treatment IND or treatment protocol (Form FDA 1571).	18	1.0555	19	300	5,700
Total			1,651		11,870

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers may be rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN—CENTER FOR BIOLOGICS EVALUATION AND RESEARCH^{1 2 3}

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926	256	1.4804	379	8	3,032
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926	80	1.2	96	16	1,536
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population: Form FDA 1571	14	1	14	120	1,680
§ 312.320(b) and 312.305(b); number of submissions related to a treatment IND or treatment protocol: Form FDA 1571	3	1	3	300	900
Total			492		7,148

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

³ Numbers may be rounded.

Burden estimates we attribute to the recordkeeping requirements established by the applicable regulations have been updated to include the reporting of data elements using Form FDA 1571. We have characterized the collection activity as recordkeeping, consistent with 5 CFR 1320.3(m) which defines a recordkeeping requirement to include the task of reporting the records to the Federal government. Upon our most recent review, the information collections reflect a cumulative decrease of 11,767 responses and 236,308 burden hours annually.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20765 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1882 and FDA–2020–E–1892]

Determination of Regulatory Review Period for Purposes of Patent Extension; MONOFERRIC

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 MONOFERRIC 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 drug 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 December 8, 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 April 7, 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 December 8, 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-2020-E-1882 and FDA-2020-E-1892 for "Determination of Regulatory Review Period for Purposes of Patent Extension; MONOFERRIC." 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, MONOFERRIC (ferric derisomaltose). MONOFERRIC is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron.
- who have non-hemodialysis dependent chronic kidney disease.

Subsequent to this approval, the USPTO received a patent term restoration application for MONOFERRIC (U.S. Patent Nos. 8,815,301 and 10,414,831) from Pharmacosmos Holding A/S. USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated October 7, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of MONOFERRIC 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 MONOFERRIC is 3,292 days. Of this time, 2,990 days occurred during the testing phase of the regulatory review period, while 302 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:* 1/13/2011. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on 1/13/2011.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* 3/21/2019. FDA has verified the applicant's claim that the

new drug application (NDA) for MONOFERRIC (NDA 208171) was initially submitted on 3/21/2019.

3. *The date the application was approved:* 1/16/2020. FDA has verified the applicant's claim that NDA 208171 was approved on 1/16/2020.

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 1,136 days 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. 2026–20766 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4567]

Determination That LASIX (Furosemide) Oral Solution, 10 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that LASIX (furosemide) oral solution, 10 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, Awo.Archampong-Gray@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved; and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or

suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LASIX (furosemide) oral solution, 10 mg/mL, is the subject of NDA 017688, held by Sanofi-Aventis U.S. LLC., and initially approved on March 8, 1977. LASIX is indicated in adults, infants, and children for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome. Oral LASIX may be used in adults for the treatment of hypertension alone or in combination with other antihypertensive agents.

LASIX (furosemide) oral solution, 10 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated April 23, 2026 (Docket No. FDA–2026–P–4567), under 21 CFR 10.30, requesting that the Agency determine whether LASIX (furosemide) oral solution, 10 mg/mL, has been voluntarily withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LASIX (furosemide) oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LASIX (furosemide) oral solution, 10 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LASIX (furosemide) oral solution, 10 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LASIX (furosemide) oral solution, 10 mg/mL, in the “Discontinued Drug Product List”

section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20764 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10786]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ZANVASTRO (zilganersen)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ZANVASTRO (zilganersen), approved September 3, 2026, manufactured by Ionis Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2771.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will

award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined ZANVASTRO (zilganersen), manufactured by Ionis Pharmaceuticals, Inc., meets the criteria for a priority review voucher. ZANVASTRO (zilganersen) injection is indicated for the treatment of Alexander disease in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ZANVASTRO (zilganersen), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20769 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Submission to OMB for Review and Approval; Public Comment Request; Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 9, 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 Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title:

Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form, OMB No. 0906–XXXX—New.

Abstract: HRSA is proposing a new form to collect organizational National Provider Identifiers (Type 2 NPIs) and Centers for Medicare & Medicaid Services (CMS) Certification Numbers (CCNs) from organizations that apply for HRSA award funding through *Grants.gov*. The form will be completed as part of the *Grants.gov* funding application. This collection is limited to organizational identifiers and will only collect an NPI and/or CCN only from organizations that already have one. An organization is not required to have, or to obtain, an NPI or CCN in order to apply for or receive HRSA funding, and individual applicants (persons) are not asked to provide an individual (Type 1) NPI. Organizational NPIs are issued by the CMS through the National Plan and Provider Enumeration System. CCNs are issued by CMS to providers and suppliers that obtain Medicare or Medicaid certification.

The purpose of this proposed collection is to strengthen the evidence HRSA uses to understand how it meets its mission of improving health outcomes through access to quality services, a skilled health workforce, and innovative, high-value programs. This collection is authorized under section 301 of the Public Health Service Act (42 U.S.C. 241), which authorizes the Secretary of HHS to conduct and support research, investigations, experiments, demonstrations, and studies relating to the causes; diagnosis; treatment; control; and prevention of disease, and to collect and make available information on those activities, including the provision of technical assistance on statistical methods.

HRSA collects this information to support research, program evaluation, and evidence-building consistent with its broader obligations to measure whether award recipients meet program objectives (e.g., 2 CFR 200.301(a)) and to ensure the data underlying HRSA's performance reporting are reliable and accurate (e.g., 31 U.S.C. 1115(b)(7)–(8)), and consistent with the agency evidence-building plan obligations of the Foundations for Evidence-Based Policymaking Act of 2018 (see 5 U.S.C. 312). These provisions inform why reliable provider identity data are useful to HRSA; the authority for this collection is 42 U.S.C. 241. Further, collecting information will enhance accountability in HRSA funding and enable the agency to minimize fraud, waste, and abuse by ensuring that its funding of entities is non-duplicative with funding provided by CMS.

Linking HRSA program data to other datasets, and particularly to datasets at CMS, is currently difficult because HRSA lacks an identifier that reliably and consistently identifies funded organizations across its many programs and across externally available health-care delivery-system data. The Unique Entity Identifier (UEI) obtained from *SAM.gov* identifies the legal entity that receives an award, but it is not used in health-care transactions and does not appear in CMS claims, encounter, certification, or quality datasets. Organizational NPIs and CCNs address this gap because they are already embedded as standard provider-identity keys in widely used, publicly available CMS datasets. The organizational NPI is the standard unique identifier for organization health care providers used in HIPAA-standard transactions and is therefore a stable, externally recognized organizational key; this descriptive fact about how NPIs are used is the reason HRSA considers the NPI a reliable identifier, and is not the legal authority for this collection. CCNs identify Medicare- and Medicaid-certified institutional providers and are the standard key for linking certified facilities to CMS institutional claims, certification files, cost reports, and facility-level quality data.

A 60-day notice was published in the **Federal Register** on July 28, 2026, vol. 91, No. 143; pp. 47253–47255. There were no public comments.

Need and Proposed Use of the Information: All applicants for HRSA funding through *Grants.gov* must obtain a UEI from *SAM.gov* before beginning a funding application. Because UEI does not appear in CMS provider and claims data, collecting organizational NPIs and CCNs from organizations that already

have them allows HRSA to link its program and award data to publicly available external datasets that use those identifiers. Such linkage supports more accurate, efficient, and credible agency analyses of program reach, utilization, cost, quality, and outcomes.

For organizational applicants, the organizational NPI and CCN function as enterprise-level provider-identity keys that connect HRSA's internal funding, program, and service-site data to the external health-care delivery system. The organizational NPI connects funded organizations—including non-institutional providers such as health center organizations, clinics, group practices, laboratories, pharmacies, behavioral health organizations, and telehealth providers—to Medicare professional and supplier claims, Medicare Advantage encounter data, Transformed Medicaid Statistical Information System data, and National Plan and Provider Enumeration System organizational reference files. The CCN connects funded or supported certified facilities—such as hospitals, Critical Access Hospitals, Rural Health Clinics, Federally Qualified Health Centers, hospices, home health agencies, and end-stage renal disease facilities—to CMS institutional claims, the Provider of Services files, Healthcare Cost Report Information System cost reports, and CMS facility-level quality and outcomes data.

Using these identifiers, HRSA can, for example: identify the full set of HRSA programs that support the same provider organization or facility, in order to understand portfolio-level funding concentration, overlap, and potential duplication; distinguish among the legal awardee, the service delivery site, the billing organization, and the certified facility, which are frequently different entities; validate that an organization or facility is represented in CMS certification and enumeration data; detect duplicate or fragmented records across programs using durable, externally verifiable anchors rather than name-and-address matching alone; and build more credible evaluation datasets that compare funded organizations to appropriate comparison groups over time.

This proposed collection differs from HRSA's current practice of collecting these data in two ways. First, it standardizes the collection of organizational (Type 2) NPIs and CCNs across HRSA-supported programs rather than collecting them inconsistently program by program. Second, it does not collect individual (Type 1) NPIs. The collection is limited to organizations that already hold these identifiers;

organizations without an NPI or CCN are not required to obtain one, and their eligibility for HRSA funding is unaffected by whether they provide an identifier.

Data collected through this information collection will be used solely for research, evaluation, and analysis of program reach and effectiveness and for purposes of accountability and oversight—for example, identifying entities funded across HRSA and HHS, assessing program performance through internal and external data linkage, and supporting de-duplication, aggregation, and disaggregation of program data. Because this collection is limited to organizational identifiers, it does not collect individual NPIs or other personally identifiable information, and it is not designed to retrieve records about individuals. Data from this ICR will not be used to verify eligibility or compliance for cash or in-kind assistance under HRSA programs.

HRSA recognizes that these identifiers have inherent limitations and intends to account for them analytically: an organizational NPI may represent a parent organization, subpart, or billing unit rather than a specific site; a CCN identifies a certified facility rather than its corporate owner or the HRSA awardee; NPI issuance does not validate licensure or credentialing; and claims and certification data do not capture all HRSA-funded activity (for example, enabling services, outreach, case management, workforce training, technical assistance, uninsured care, and public-health infrastructure). Accordingly, HRSA will treat external claims and certification data as complementary evidence and will maintain time-aware linkages that account for changes in NPI status, CCN status, ownership, and organizational structure.

Likely Respondents: Organizations applying for HRSA funding through *Grants.gov* that already have an organizational NPI and/or a CCN.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to

transmit or otherwise disclose the information. The total annual burden

hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Applicant type	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Applicant NPIs and CCNs Form ..	No NPI or CCN	3,400	1	3,400	0.02	68.00
	One NPI and/or CCN	1,700	1	1,700	0.05	85.00
	Two or more NPIs and/or two or more CCNs.	1,275	1	1,275	0.10	127.50
Total		6,375		6,375		280.50

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026-20731 Filed 10-8-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Data System for Organ Procurement and Transplantation Network, OMB No. 0906-0110—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 9, 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 a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0906-0110—Revision.

Abstract: Section 372(a) of the Public Health Service Act requires the Secretary of HHS to provide for the continued operation of the Organ Procurement and Transplantation Network (OPTN). Section 372(b)(1)(A) provides that the OPTN shall be operated through awards to public or private entities made by the Secretary. The OPTN is a unique public-private partnership that links professionals involved in the U.S. donation and transplantation system. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits OPTN Board of Directors (BOD)-approved data elements for collection to OMB for official federal approval.

A 60-day Notice was published in the **Federal Register**, Vol. 91, No. 94, FR pp. 27964 (May 15, 2026). There was one comment from a Transplant Center. The commenter requested that HRSA identify the Board-approved revisions and the specific data collection forms affected. The commenter also requested clarification regarding whether the Patient Safety Contact Management and Patient Transfer forms are revisions to existing forms or new data collection requirements, the rationale for the new forms, and how duplicative data collection and additional administrative burden would be avoided. HRSA responded that draft data collection instruments may be requested at any time during the public comment period and will be made available in both clean and redline formats during the 30-day **Federal Register** Notice public comment

period. HRSA clarified that the Patient Safety Contact Management and Patient Transfer forms are new data collection forms and that their inclusion is described in the notice and reflected in the Estimated Annualized Burden Hours table. HRSA also identified where stakeholders can find the rationale for the proposed revisions to existing forms and the addition of new forms. HRSA encourages interested stakeholders to review these materials for additional background on the OPTN policy development process (<https://www.hrsa.gov/optn/policies-bylaws/public-comment>).

Need and Proposed Use of the Information: HRSA and the OPTN BOD use data to develop organ procurement, allocation, and transplantation policies; evaluate member compliance with OPTN policies and HHS regulations; assess member performance; promote patient safety; and fulfill the requirements of the OPTN regulations at 42 CFR part 121. In particular, the regulatory authority in 42 CFR 121.11 (<https://www.ecfr.gov/current/title-42/section-121.11>) requires the OPTN to maintain specified records and make OPTN data available, consistent with applicable laws, to OPTN members, the Scientific Registry of Transplant Recipients, HHS, and the public for evaluation, research, and other purposes.

This is a request to revise the currently approved OPTN information collection, which includes time-sensitive, life-critical information related to transplant candidates; potential organ donors, organ matching and allocation; histocompatibility testing; organ labeling and packaging; and pre- and post-transplant clinical information for transplant recipients and donors. These data are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories.

HRSA and the OPTN use these data to (1) facilitate matching and placement

of donor organs with transplant candidates; (2) monitor member compliance with federal laws, regulations, and OPTN requirements; (3) evaluate and periodically report on the status of organ donation, procurement, and transplantation in the United States; (4) provide data to researchers and government agencies to support scientific, clinical, and policy analyses related to organ transplantation; and (5) perform transplantation-related public health surveillance, including the monitoring of donor-derived infections.

HRSA is requesting approval for the following changes to improve organ matching and allocation, enhance patient safety, and support member compliance with OPTN requirements:

(1) Add two new data collection forms to the OPTN Computer System and the OMB-approved information collection:

a. *The Patient Safety Contact Management Form.* This form will be used by OPTN members to identify the organization's primary and secondary patient safety contacts consistent with the responsibilities outlined in OPTN policy 15.1.

b. *The Patient Transfer Form:* This form will be used by transplant centers to facilitate the transfer of post-transplant patients to another transplant center during ongoing follow-up.

(2) Remove the Vascularized Composite Allograft (VCA) Transplant Candidate Registration. Following implementation of new VCA waitlist registration forms in the OPTN Waiting List system, OPTN members will no longer need to validate the data on the VCA Transplant Candidate Registration form. The form is now read-only, and all updates and validations will be completed directly within the waitlist registration forms.

(3) Remove the Death Notification Registration and Deceased Donor Death Referral forms. Following OMB approval of the OPTN Ventilated Patient Form (OMB Control No: 0906-0112), these collections are no longer needed within the OPTN Data System since the Ventilated Patient Form contains the information previously collected under these forms.

(4) Incorporate minor edits to previously OMB-approved forms for clarity.

Likely Respondents: Transplant Centers, Organ Procurement Organizations (OPOs), and Histocompatibility Laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time

needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The total estimated annual burden for this information collection increased by 52,029.48 hours compared with the information collection package currently approved by OMB, which was approved June 25, 2025. This increase reflects updates to the number of respondents and responses based on actual OPTN data from calendar year 2025, the addition of two new data collection forms, and revisions to existing data collection forms approved by the OPTN BOD. These increases are partially offset by the reduction of 6,960.18 burden hours resulting from the removal of three forms from the OPTN Computer System.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form No.****	Form name	Number of respondents *	Number of responses per respondent	Total responses *	Average burden per response (in hours)	Total burden hours
1	Deceased Donor Registration +	55	452.4	24,882.00	0.48	11,943.36
2	Living Donor Registration	209	31.45	6,573.05	2.2	14,460.71
3	Living Donor Follow-up	209	100.33	20,968.97	1.52	31,872.83
4	Donor Histocompatibility	137	178.56	24,462.72	0.15	3,669.41
5	Recipient Histocompatibility +	137	323.81	44,361.97	0.32	14,195.83
6	Heart Transplant Candidate Registration	149	40.87	6,089.63	0.9	5,480.67
7	Heart Transplant Recipient Registration	149	30.78	4,586.22	1.96	8,988.99
8	Heart Transplant Recipient Follow Up (6 Month)	149	28.51	4,247.99	0.4	1,699.20
9	Heart Transplant Recipient Follow Up (1–5 Year)	149	122.62	18,270.38	0.9	16,443.34
10	Heart Transplant Recipient Follow Up (Post 5 Year)	149	202.66	30,196.34	0.5	15,098.17
11	Heart Post-Transplant Malignancy Form	149	14.58	2,172.42	0.9	1,955.18
12	Lung Transplant Candidate Registration	77	51.26	3,947.02	0.95	3,749.67
13	Lung Transplant Recipient Registration	77	45.34	3,491.18	1.14	3,979.95
14	Lung Transplant Recipient Follow Up (6 Month)	77	41.34	3,183.18	0.5	1,591.59
15	Lung Transplant Recipient Follow Up (1–5 Year)	77	147.7	11,372.90	1.1	12,510.19
16	Lung Transplant Recipient Follow Up (Post 5 Year)	77	162.26	12,494.02	0.6	7,496.41
17	Lung Post-Transplant Malignancy Form	77	22.73	1,750.21	0.4	700.08
18	Heart/Lung Transplant Candidate Registration	75	1.03	77.25	1.16	89.61
19	Heart/Lung Transplant Recipient Registration	75	0.8	60.00	2.09	125.40
20	Heart/Lung Transplant Recipient Follow Up (6 Month)	75	0.75	56.25	0.8	45.00
21	Heart/Lung Transplant Recipient Follow Up (1–5 Year)	75	2.69	201.75	1.1	221.93
22	Heart/Lung Transplant Recipient Follow Up (Post 5 Year)	75	3.64	273.00	0.6	163.80
23	Heart/Lung Post-Transplant Malignancy Form	75	0.2	15.00	0.4	6.00
24	Liver Transplant Candidate Registration	144	112.48	16,197.12	0.8	12,957.70
25	Liver Transplant Recipient Registration	144	85.72	12,343.68	1.2	14,812.42
26	Liver Transplant Recipient Follow Up (6 Month–5 Year)	144	384.5	55,368.00	1	55,368.00
27	Liver Transplant Recipient Follow Up (Post 5 Year)	144	466.79	67,217.76	0.5	33,608.88
28	Liver Recipient Explant Pathology Form	144	7.81	1,124.64	0.6	674.78
29	Liver Post-Transplant Malignancy Form	144	27.19	3,915.36	0.8	3,132.29
30	Intestine Transplant Candidate Registration	17	6.76	114.92	1.3	149.40
31	Intestine Transplant Recipient Registration	17	5.18	88.06	1.8	158.51
32	Intestine Transplant Recipient Follow Up (6 Month–5 Year)	17	23.29	395.93	1.5	593.90
33	Intestine Transplant Recipient Follow Up (Post 5 Year)	17	52.35	889.95	0.4	355.98
34	Intestine Post-Transplant Malignancy Form	17	0.35	5.95	1	5.95
35	Kidney Transplant Candidate Registration	232	225.83	52,392.56	0.8	41,914.05
36	Kidney Transplant Recipient Registration	232	118.94	27,594.08	1.2	33,112.90

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form No.****	Form name	Number of respondents *	Number of responses per respondent	Total responses *	Average burden per response (in hours)	Total burden hours
37	Kidney Transplant Recipient Follow Up (6 Month–5 Year)	232	610.62	141,663.84	0.9	127,497.46
38	Kidney Transplant Recipient Follow Up (Post 5 Year)	232	617.82	143,334.24	0.5	71,667.12
39	Kidney Post-Transplant Malignancy Form	232	31.57	7,324.24	0.8	5,859.39
40	Pancreas Transplant Candidate Registration	127	2.2	279.40	0.6	167.64
41	Pancreas Transplant Recipient Registration	127	0.84	106.68	1.2	128.02
42	Pancreas Transplant Recipient Follow Up (6 Month–5 Year)	127	4.2	533.40	0.5	266.70
43	Pancreas Transplant Recipient Follow Up (Post 5 Year)	127	15.71	1,995.17	0.5	997.59
44	Pancreas Post-Transplant Malignancy Form	127	0.72	91.44	0.6	54.86
45	Kidney/Pancreas Transplant Candidate Registration	127	13.35	1,695.45	0.6	1,017.27
46	Kidney/Pancreas Transplant Recipient Registration	127	6.34	805.18	1.2	966.22
47	Kidney/Pancreas Transplant Recipient Follow Up (6 Month–5 Year)	127	35.55	4,514.85	0.5	2,257.43
48	Kidney/Pancreas Transplant Recipient Follow Up (Post 5 Year)	127	68.19	8,660.13	0.6	5,196.08
49	Kidney/Pancreas Post-Transplant Malignancy Form	127	2.32	294.64	0.4	117.86
50	VCA Transplant Recipient Registration *	23	0.39	8.97	1.36	12.20
51	VCA Transplant Recipient Follow Up *	23	2.91	66.93	1.31	87.68
52	Organ Labeling and Packaging	55	308.47	16,965.85	0.18	3,053.85
53	Organ Tracking and Validating	306	18.68	5,716.08	0.08	457.29
54	Kidney Paired Donation Candidate Registration	155	0.4	62.00	0.26	16.12
55	Kidney Paired Donation Donor Registration	155	0.74	114.70	1.08	123.88
56	Kidney Paired Donation Match Offer Management	155	0.86	133.30	0.67	89.31
57	Disease Transmission Event	306	2.96	905.76	0.6	543.46
58	Living Donor Event	209	0.24	50.16	0.56	28.09
59	Safety Situation	443	1.33	589.19	0.24	141.41
60	Potential Disease Transmission Report	55	14.78	812.90	1.27	1,032.38
61	Request to Unlock Form	443	156.16	69,178.88	0.02	1,383.58
62	Initial Donor Registration *	55	453.87	24,962.85	4.75	118,573.54
63	OPO Notification Limit Administration	55	0.16	8.80	0.17	1.50
64	Potential Transplant Recipient	306	5332.24	1,631,665.44	0.05	81,583.27
65	Donor Hospital Registration	55	0.07	3.85	0.08	0.31
66	Donor Organ Disposition	55	453.87	24,962.85	0.17	4,243.68
67	Transplant Center Contact Management	251	863.46	216,728.46	0.06	13,003.71
68	Adult Kidney Candidate Listing Registration	232	227.93	52,879.76	0.52	27,497.48
69	Pediatric Kidney Candidate Listing Registration	103	11.66	1,200.98	0.47	564.46
70	Adult Kidney Pancreas Candidate Listing Registration	127	13.32	1,691.64	0.37	625.91
71	Pediatric Kidney Pancreas Candidate Listing Registration	29	0.1	2.90	0.3	0.87
72	Adult Pancreas Candidate Listing Registration	127	15.27	1,939.29	0.38	736.93
73	Pediatric Pancreas Candidate Listing Registration	30	1.17	35.10	0.38	13.34
74	Adult Pancreas Islet Listing Registration	18	4.44	79.92	0.38	30.37
75	Pediatric Pancreas Islet Listing Registration ***	18	0	0.00	0.33	0.00
76	Adult Liver Candidate Listing Registration	144	107.35	15,458.40	0.32	4,946.69
77	Pediatric Liver Candidate Listing Registration	59	12.51	738.09	0.4	295.24
78	Adult Intestine Candidate Listing Registration	17	4.53	77.01	0.38	29.26
79	Pediatric Intestine Candidate Listing Registration	17	2.24	38.08	0.43	16.37
80	Adult Heart Candidate Listing Registration	149	36.52	5,441.48	0.83	4,516.43
81	Pediatric Heart Candidate Listing Registration	63	10.3	648.90	0.58	376.36
82	Adult HeartLung Candidate Listing Registration *	75	0.96	72.00	0.85	61.20
83	Pediatric HeartLung Candidate Listing Registration	25	0.2	5.00	0.93	4.65
84	Adult Lung Candidate Listing Registration *	77	50.77	3,909.29	1.01	3,948.38
85	Pediatric Lung Candidate Listing Registration *	45	0.84	37.80	0.84	31.75
86	Candidate Registration Listing Removal	251	305.65	76,718.15	0.18	13,809.27
87	VCA Abdominal Wall Candidate Listing Registration ***	8	0	0.00	0.33	0.00
88	VCA External Male Genitalia Candidate Listing Registration ***	2	0	0.00	0.33	0.00
89	VCA Head and Neck Candidate Listing Registration	9	0.11	0.99	0.33	0.33
90	VCA Lower Limb Candidate Listing Registration ***	4	0	0.00	0.33	0.00
91	VCA Musculoskeletal Composite Graft Segment Candidate Listing Registration ***	2	0	0.00	0.33	0.00
92	VCA Other Genitourinary Organ Candidate Listing Registration	5	0.2	1.00	0.33	0.33
93	VCA Spleen Candidate Listing Registration ***	0	0	0.00	0.33	0.00
94	VCA Upper Limb Candidate Listing Registration ***	11	0	0.00	0.33	0.00
95	VCA Uterus Candidate Listing Registration	6	1.83	10.98	0.33	3.62
96	VCA Vascularized Gland Candidate Listing Registration ***	1	0	0.00	0.33	0.00
97	Organ Export Verification Form	55	0.29	15.95	0.03	0.48
98	OPTN Waiting Time Transfer Form	251	5.32	1,335.32	0.23	307.12
99	OPTN Waiting Time Modification Form	251	23.73	5,956.23	0.22	1,310.37
100	OPTN Renal Waiting Time Reinstatement Form	232	1.33	308.56	0.27	83.31
101	OPTN Pancreas Waiting Time Reinstatement Form	127	0.04	5.08	0.2	1.02
102	Intestinal Waiting Time Reinstatement Form	17	0.06	1.02	0.25	0.26
103	Prior Living Donor Priority	232	0.41	95.12	0.27	25.68
104	Kidney Minimum Acceptance Criteria	232	0.96	222.72	0.3	66.82
105	Adult Liver Status 1A Initial Justification and Extension Form	144	2.13	306.72	0.57	174.83
106	Pediatric Liver Status 1A Initial Justification and Extension Form	59	3	177.00	0.57	100.89
107	Pediatric Liver Status 1B Initial Justification and Extension Form	59	7.1	418.90	0.47	196.88
108	Liver Cholangiocarcinoma (CCA) Initial MELD/PELD Score Exception Form	144	0.83	119.52	0.43	51.39
109	Liver Cholangiocarcinoma (CCA) MELD/PELD Score Exception Extension Form	144	0.67	96.48	0.32	30.87
110	Liver Cystic Fibrosis (CF) Initial MELD/PELD Score Exception and Extension Form	144	0.08	11.52	0.33	3.80
111	Liver Familial Amyloid Polyneuropathy (FAP) Initial MELD/PELD Score Exception Form ***	144	0	0.00	0.4	0.00

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form No.****	Form name	Number of respondents *	Number of responses per respondent	Total responses *	Average burden per response (in hours)	Total burden hours
112	Liver Familial Amyloid Polyneuropathy (FAP) MELD/PELD Score Exception Extension Form.	144	0.01	1.44	0.3	0.43
113	Liver Hepatic Artery Thrombosis (HAT) Initial MELD/PELD Score Exception and Extension Form.	144	0.55	79.20	0.35	27.72
114	Liver Hepatocellular Carcinoma (HCC) Initial MELD/PELD Score Exception Form.	144	22.18	3,193.92	0.47	1,501.14
115	Liver Hepatocellular Carcinoma (HCC) MELD/PELD Score Exception Extension Form.	144	28.84	4,152.96	0.35	1,453.54
116	Liver Hepatopulmonary Syndrome (HPS) Initial MELD/PELD Score Exception Form.	144	1.42	204.48	0.32	65.43
117	Liver Hepatopulmonary Syndrome (HPS) MELD/PELD Score Exception Extension Form.	144	0.81	116.64	0.25	29.16
118	Liver Metabolic Disease Initial MELD/PELD Score Exception and Extension Form.	144	0.84	120.96	0.28	33.87
119	Liver Portopulmonary Hypertension Initial MELD/PELD Score Exception Form.	144	0.52	74.88	0.42	31.45
120	Liver Portopulmonary Hypertension MELD/PELD Score Exception Extension Form.	144	0.38	54.72	0.33	18.06
121	Liver Primary Hyperoxaluria Initial MELD/PELD Score Exception and Extension Form.	144	0.1	14.40	0.35	5.04
122	Liver Other Diagnosis Initial MELD/PELD Score Exception and Extension Form.	144	14.33	2,063.52	0.35	722.23
123	Pediatric Heart and HeartLung Status 1A Initial Justification Form ...	63	15.56	980.28	0.52	509.75
124	Pediatric Heart and HeartLung Status 1A Extension and Appeal Justification Forms.	63	73.57	4,634.91	0.47	2,178.41
125	Pediatric Heart and HeartLung Status 1B Initial Justification Form ...	63	7.05	444.15	0.42	186.54
126	Adult Heart and HeartLung Status 1–6 Justification Form Demographic Data.	149	161.57	24,073.93	0.32	7,703.66
127	Adult Heart and HeartLung Status 1–6 Justification Form Risk Stratification Data.	149	161.57	24,073.93	0.72	17,333.23
128	Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data.	149	8.32	1,239.68	0.58	719.01
129	Adult Heart and HeartLung Status 1 Exception Extension Justification Form Medical Urgency Data.	149	1.1	163.90	0.33	54.09
130	Adult Heart and HeartLung Status 1 Criteria 1 Extension Justification Form Medical Urgency Data.	149	0.87	129.63	0.53	68.70
131	Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data *.	149	28.64	4,267.36	0.8	3,413.89
132	Adult Heart and HeartLung Status 2 Exception Extension Justification Form Medical Urgency Data.	149	19.99	2,978.51	0.33	982.91
133	Adult Heart and HeartLung Status 2 Criteria 1 Extension Justification Form Medical Urgency Data.	149	0.01	1.49	0.42	0.63
134	Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data.	149	5.54	825.46	0.63	520.04
135	Adult Heart and HeartLung Status 2 Criteria 5 Extension Justification Form Medical Urgency Data.	149	1.87	278.63	0.6	167.18
136	Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data *.	149	11.25	1,676.25	0.63	1,056.04
137	Adult Heart and HeartLung Status 3 Exception Extension Justification Form Medical Urgency Data.	149	7.5	1,117.50	0.33	368.78
138	Adult Heart and HeartLung Status 3 Criteria 2 Extension Justification Form Medical Urgency Data.	149	0.54	80.46	0.32	25.75
139	Adult Heart and HeartLung Status 3 Criteria 5 Extension Justification Form Medical Urgency Data.	149	0.04	5.96	0.48	2.86
140	Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data.	149	23.41	3,488.09	0.5	1,744.05
141	Adult Heart and HeartLung Status 4 Exception Extension Justification Form Medical Urgency Data.	149	2.17	323.33	0.25	80.83
142	Adult Heart and HeartLung Status 4 Criteria 2 Extension Justification Form Medical Urgency Data.	149	0.78	116.22	0.4	46.49
143	Adult and Pediatric Lung and HeartLung Goal Exception Form	149	2.79	415.71	0.75	311.78
144	Pediatric Lung Priority 1 Status Justification Form	45	0.53	23.85	0.33	7.87
145	Review Board Voter Form	251	24.75	6,212.25	0.23	1,428.82
146	Living Donor Feedback Form	209	38.86	8,121.74	0.13	1,055.83
147	Extra Vessels Reporting Form	251	59.28	14,879.28	0.03	446.38
148	Non-US Transplants Reporting Form ***	232	0	0.00	0.03	0.00
149	Discrepant HLA Typings Reporting Form *	137	1.27	173.99	5.17	899.53
150	Interim Event Reporting Form	251	88.45	22,200.95	0.06	1,332.06
151	Patient Safety Contact Management Form **	306	42.2	12,913.20	0.14	1,807.85
152	Patient Transfer Form **	251	15.35	3,852.85	0.39	1,502.61
Total		19,314		3,085,444.60		903,607.48

Note: Totals for responses and burden hours may reflect minor discrepancies due to rounding; however, these rounding adjustments do not affect the overall burden estimates presented.

* The numbers of respondents and the numbers of total responses in the burden table were updated with 2025 OPTN data.

** These are new forms.

*** If a form has 0.00 under average number of responses, this is an indicator that there were no submissions in calendar year 2025.

**** As a result of the removal of the Death Notification Registration and the Deceased Donor Death Referral, forms after 65 were renumbered.

+ Forms with minor edits to previously OMB-approved forms.

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026–20732 Filed 10–8–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: December 7–9, 2026.

Time: 7:45 a.m. to 4:45 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: National Institute for Allergy and Infectious Diseases, National Institutes of Health, 50 Center Drive, Room 1227/1233, Bethesda, MD 20892.

Meeting Format: In Person.

Contact Person: Amy Collins, NIAID Committee Manager, National Institutes of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4G39, Bethesda, MD 20892, (301) 761–6311, amy.collins@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on

this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: October 5, 2026.

Margaret N. Vardanian,
Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–20719 Filed 10–8–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA/REAP and SuRE/SuRE-First: Cardiovascular and Respiratory Sciences.

Date: November 4, 2026.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting

Contact Person: Kirk E. Dineley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 806E, Bethesda, MD 20892, 301–435–2591, dineleyke@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Limited Competition: National Primate Research Centers (P51).

Date: November 4–6, 2026.

Time: 12:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Zhuqing Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–5992, zhuqing.li@nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Neuromodulation and Imaging of Neuronal Circuits Study Section.

Date: November 5–6, 2026

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Pablo Miguel Blazquez Gamez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–6923 pablo.blazquezgamez@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative International Research Projects in Reproduction.

Date: November 5, 2026

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Leslie Mccue Turner, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–480–4962, leslie.turner@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Career Development: Musculoskeletal and Oral Sciences.

Date: November 5, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kan Ma, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–8931, mak2@mail.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Science of Implementation in Health and Healthcare Study Section.

Date: November 5–6, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lauren Penney, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–496–1968, penneyls@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIH Health Services and Systems: Career Development Award Grant Review.

Date: November 5–6, 2026.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Claudio Dario Ortiz, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-2073, claudio.ortiz@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Oral, Dental, Craniofacial, and Musculoskeletal Sciences.

Date: November 5, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-1781, liuyh@nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Neurovascular, Blood-Brain Barrier, and Clearance Pathways Study Section.

Date: November 5-6, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nilkantha Sen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-7256, nilkantha.sen@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative International Research Projects.

Date: November 5, 2026.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Tara Roshell Earl, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007C, Bethesda, MD 20892, 301-402-6857, earltr@mail.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Maximizing Investigators' Research Award B Study Section.

Date: November 5-6, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 903-L, MSC 7846, Bethesda, MD 20892, 301-827-5263, sudha.veeraraghavan@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cellular, Developmental, and Bioengineering Sciences.

Date: November 5, 2026.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Archana Jha, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-5945, archana.jha@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Pharmacotherapies For Substance Use Disorders.

Date: November 5, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Izabella Zandberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-0359, izabella.zandberg@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training: Career Development Awards in Basic Neuroscience.

Date: November 5-6, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Gagan Deep Bajaj, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-7377, gagan.bajaj@nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Aging, Injury, Musculoskeletal, and Rheumatologic Disorders Study Section.

Date: November 5-6, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Varsha Shukla, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD

20892, 301-594-2407, Varsha.shukla@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 7, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-20770 Filed 10-8-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuromodulation and Imaging.

Date: November 5, 2026.

Time: 9:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Steven G. Britt, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-451-1486, steve.britt@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training and Career Development: Neurosciences, Development, and Aging.

Date: November 5-6, 2026.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 1009B, MSC 7850, Bethesda, MD 20892, 301-435-1203, laurent.taupenot@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Tissue Formation and Organogenesis Panel.

Date: November 5, 2026.

Time: 10:00 a.m. to 6:15 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Aiwu Cheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-443-3491, chengai@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship Trainings: Chemistry, Biochemistry & Biophysics.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dennis Pantazatos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-2381, dennis.pantazatos@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neural Basis of Motivated Behavior.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-9788, jennifer.schiltz@nih.gov.

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Transmission of Vector-Borne and Zoonotic Diseases Study Section.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Haruhiko Murata, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, National Institutes of Health, Bethesda, MD 20892, 301-594-3245, muratah@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Human Complex Mental Function Study Section.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Joanna Szczepanik, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000D, Bethesda, MD 20892, 301-827-2242, szczepaj@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Cancer and Hematologic Disorders Study Section.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rebecca I. Tinker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-1213, tinkerri@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Health Promotion for Mental Health and Substance Use Study Section.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301-496-0726, prenticekj@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Basic Cancer Mechanism and Therapeutics.

Date: November 5–6, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Shuli Xia, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-496-3396, shuli.xia@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Topics in Basic Cancer Biology.

Date: November 5, 2026.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: E. Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-5622, tiane@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Training: Musculoskeletal and Oral Sciences.

Date: November 6, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Sushmita Purkayastha, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-451-1138, sushmita.purkayastha@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Program Projects: Cardiac Biology and Disorders.

Date: November 6, 2026.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Devaiah N. Ballachanda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801F, Bethesda, MD 20892, 301-480-0816, ballachandad@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PA-26-002 NIH Collaborative International Research Project (Parent PF5 Clinical Trial Optional).

Date: November 6, 2026.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301-827-3069, zhengli@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Review for Clinical Vision Research UG1 Applications.

Date: November 6, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lai Yee Leung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011D, Bethesda, MD 20892, 301-827-8106, leungl2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member
Conflict: Topics in Transplantation and Alloimmunity.

Date: November 6, 2026.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Shannon J. Sherman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-0715, shannon.sherman@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA Panel: Kidney Precision Medicine Project 3.0 Applications.

Date: November 6, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-451-1322, ryan.morris@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member
Conflict: Topics in Pathogenic Eukaryotes.

Date: November 6, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, 301-827-3067, roebuckk@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 7, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-20771 Filed 10-8-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License, Inter-Institutional Agreement-Institution Lead: Antibody Specifically Binding to Severe Fever With Thrombocytopenia Syndrome Virus Antigen and Use Thereof

AGENCY: National Institutes of Health, National Institute of Allergy and Infectious Diseases.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Korea National Institute of Health, located in Cheongju-si, Chungcheongbuk-do, South Korea to practice the invention embodied in the patent application listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before October 26, 2026 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Brian Bailey, Ph.D., Senior Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 2G, MSC9804, Rockville, MD 20852-9804, phone number 240-669-5128, or brian.bailey@nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement: Korean Patent Application No. 10-2025-0196127, filed December 11, 2025, titled "An Antibody Specifically Binding to Severe Fever with Thrombocytopenia Syndrome Virus Antigen and Use thereof" (NIH Tracking Number E-102-2025-0). All rights in this invention have been assigned to Korea National Institute of Health and the Government of the United States of America.

The prospective patent license will be for the purpose of consolidating the patent rights with Korea National Institute of Health, the co-owner of said rights, for commercial development and

marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212.

The prospective interinstitutional agreement will include an exclusive license for NIAID's rights in these jointly owned patent rights. It will be sublicensable, and any sublicenses granted by Korea National Institute of Health will be subject to the provisions of 37 CFR part 404.

The subject patent rights are related to novel antibodies and antigen-binding fragments that specifically bind the Severe Fever with Thrombocytopenia Syndrome (SFTS) virus envelope glycoprotein antigen, including Gn- and Gc-targeting antibodies, together with related pharmaceutical and diagnostic compositions for prevention, diagnosis, mitigation, or treatment of SFTS virus infection. The invention arose from a research collaboration between NIAID and Korea National Institute of Health.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 6, 2026.

Surekha Vathyam,

Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2026-20705 Filed 10-8-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration****Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Comments are invited on: (a) Whether the proposed collections of information are 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 proposed collection of information; (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 collection techniques or other forms of information technology.

Proposed Project: SAMHSA Generic Clearance for the Collection of Qualitative Research and Assessment (OMB No. 0930-0397)—Extension

Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4) establishes the Center for Behavioral Health Statistics and Quality (CBHSQ) within the Substance Abuse and Mental Health Services Administration (SAMHSA). Among other responsibilities, the statute directs CBHSQ to coordinate SAMHSA's integrated data strategy; provide statistical and analytical support for SAMHSA activities; recommend performance metrics to evaluate activities supported by SAMHSA; and coordinate efforts to improve the quality of SAMHSA services and the evaluation of activities carried out by the agency.

Consistent with these authorities, the Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an extension to the generic clearance for purposes of conducting qualitative research to gain a better understanding of emerging substance use and mental health policy issues, improve the development and quality of instruments, and to ensure SAMHSA leadership, centers and offices have recent data and information for program and policy decision-making. This request is an extension of a previously approved collection. There are no changes to the information collection requirements or burden. Editorial and clarifying revisions have been made to the Supporting Statement to improve accuracy, clarity, and consistency; these revisions do not change the scope or burden of the approved collection. By qualitative feedback we mean information that provides useful

insights into perceptions and opinions but are not statistical surveys that yield results that can be generalized beyond the population of study.

This collection of information is necessary to enable SAMHSA to receive feedback in an efficient, timely manner, in accordance with our mission to lead public health and service delivery efforts, that treat mental illness, especially serious mental illness, prevent substance abuse and addiction, and provide treatments and supports to foster recovery while ensuring access and better outcomes for all. SAMHSA is the agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and to improve the lives of individuals living with mental and substance use disorders, and their families. SAMHSA pursues this mission by providing grant funding opportunities and guidance to states and territories, as well as tribal and local communities; technical assistance to grantees and practitioners; publishing and sharing resources for individuals and family members seeking information on prevention, treatment and recovery; collecting, analyzing, and sharing behavioral health data; collaborating with other Federal agencies to evaluate programs and improve policies; and raising awareness of available resources through educational messaging campaigns and events. Activities conducted under this generic clearance may support program improvement, research and assessment, instrument development, identification of emerging behavioral health issues, and other appropriate internal information needs.

ESTIMATED TOTAL BURDEN

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SAMHSA internal and external stakeholders	15,000	1	1	15,000

Send comments to SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57A, Rockville, MD 20852 *OR* email a copy to samhsapra@samhsa.hhs.gov. Written comments should be received by December 8, 2026.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2026-20723 Filed 10-8-26; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF THE INTERIOR**Office of the Secretary**

[A2407-014-004-065516, #O2509-014-004-125222.0; LLMT: PO#4820002691]

National Environmental Policy Act Implementing Procedures: Wintertime Oil and Gas Exploration in the National Petroleum Reserve in Alaska Categorical Exclusion

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: This notice announces a revision to the Department of the Interior (Department)'s National Environmental Policy Act (NEPA) procedures adding a new categorical exclusion (CE) for National Petroleum Reserve in Alaska (NPR-A) wintertime oil and gas exploration activities to the *DOI Handbook of NEPA Implementing Procedures, Appendix 2: Bureau Categorical Exclusions*.

DATES: The CE is effective October 9, 2026.

ADDRESSES: The web address for the Department's Handbook of NEPA Implementing Procedures where the new CE is being added is: <https://www.doi.gov/document-library/handbook/516-dm-1-handbook-national-environmental-policy-act-implementing>. The "Substantiation of Proposed National Environmental Policy Act Categorical Exclusion for NPR-A Wintertime Oil and Gas Exploration Activities" (Substantiation Report) for the CE is available at the BLM National NEPA Register: <http://eplanning.blm.gov> (NEPA number: DOI-BLM-AK-0000-2026-0021-OTHER_NEPA).

FOR FURTHER INFORMATION CONTACT: Wayne Svejnoha, Acting Deputy State Director, Resources, at (907) 271-4407, or wsvejnoh@blm.gov. 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.

SUPPLEMENTARY INFORMATION:

I. Background

The NPR-A consists of approximately 23 million acres on the North Slope of Alaska, administered by the Bureau of Land Management (BLM). Congress established the primary statutory framework for the NPR-A through the Naval Petroleum Reserves Production Act of 1976, Public Law 94-258, 42 U.S.C. 6501 *et seq.* (NPRPA), which transferred administrative jurisdiction over the Petroleum Reserve from the Secretary of the Navy to the Secretary of the Interior and redesignated it as the National Petroleum Reserve in Alaska. In 1980, Congress amended the NPRPA through the Department of the Interior Appropriations Act for Fiscal Year 1981 to direct the Secretary to conduct an expeditious program of competitive leasing of oil and gas in the NPR-A, while providing for such conditions, restrictions, and prohibitions as the Secretary deems appropriate to mitigate reasonably foreseeable and significantly adverse effects on the surface resources of the Petroleum Reserve. That legislation also exempted management of the NPR-A from the Federal Land Policy and Management Act's land use planning and wilderness review requirements, reflecting Congress's intent to dedicate management of the

area to the primary purpose of oil and gas leasing and development, with access as a necessary component of that purpose. The NPRPA is thus a dominant-use statute, and BLM is required to manage the NPR-A primarily for oil and gas leasing, exploration, development, and production, while protecting environmental, fish and wildlife, and historical or scenic values within the NPR-A to the extent consistent with that overriding purpose.

This notice notifies the public of the Department's establishment of the Wintertime Oil and Gas Exploration (WOG) CE for use by the BLM for the approval of seismic surveys, Applications for Permit to Drill (APDs), and grants of Rights of Way (ROWs) in the NPR-A. Each of these types of actions is a narrowly specified type of action, whose environmental consequences are well understood and, as such, is particularly suited for inclusion in a CE. Across Federal oil and gas provinces in the United States, the NPR-A is unique in terms of statutory framework, stakeholders and inhabitants, geography, geology, remoteness, climate, and types of feasible development. This has generally contributed to a relatively expansive project-by-project approach to NEPA compliance, with numerous environmental assessments (EAs) having been completed for individual permitting actions within the NPR-A, each supporting a finding of no significant impact (FONSI) or finding of no new significant impact (FONNSI) for that individual action. This approach to permitting is inefficient—especially for well-understood individual permitting actions in the NPR-A. Improving the efficiency of environmental review is especially important in the NPR-A, where seasonal restrictions and severe weather can constrain when oil and gas companies can pursue construction and operations as authorized by the BLM.

This CE advances U.S. energy policy and U.S. policy for resource development in Alaska by providing a tool for NEPA compliance that reflects the BLM's experience with these individual permitting actions. As set forth in E.O. 14154, *Unleashing American Energy* (Jan. 20, 2025), the Department and other agencies must "undertake all available efforts to eliminate delays within their respective permitting processes, including through, but not limited to, the use of general permitting and permit by rule." As explained in E.O. 14153, *Unleashing Alaska's Extraordinary Resource Potential* (Jan. 20, 2025), it is the policy of the United States to "efficiently and

effectively maximize the development and production of the natural resources located on both Federal and State lands within Alaska" and "expedite the permitting and leasing of energy and natural resources projects in Alaska." While this CE is neither a general permit nor a permit by rule, it is a procedure for NEPA compliance that recognizes the limited environmental consequences of each of these types of permitting actions. The defined criteria for individual proposed permitting actions that may qualify for use of this CE is intended to limit the application of this CE to proposed actions that share common, well-studied characteristics.

NEPA, 42 U.S.C. 4321 *et seq.*, requires Federal agencies to consider the environmental effects of their proposed actions in their decision-making processes and inform and engage the public in that process. To comply with NEPA, agencies determine the appropriate level of review of any major Federal action—an environmental impact statement (EIS), EA, or a categorical exclusion (CE). See generally, 42 U.S.C. 4336 (b); 43 CFR part 46; DOI NEPA Handbook section 1.2 (2026). Where it is reasonably foreseeable that significant environmental effects are likely, the agency must prepare an EIS and document its decision. See generally, 42 U.S.C. 4336 (b)(1); DOI NEPA Handbook section 1.2(a)(5)(ii). Where appropriate, an agency may prepare an EA, and if it reaches a finding of no significant impact (FONSI), it need not prepare an EIS. See generally, 42 U.S.C. 4336(b)(2); DOI NEPA Handbook section 1.6; section 1.2(a)(4).

Consistent with the Department's NEPA procedures, the Department may establish CEs—categories of actions that the agency has determined normally do not significantly affect the quality of the human environment. See 42 U.S.C. 4336(a)(2); 43 CFR 46.205. If the BLM determines that a CE covers a proposed action, it then evaluates the proposed action for extraordinary circumstances, which are factors or circumstances that indicate a normally categorically excluded action may have a significant effect. 43 CFR 46.205, 46.215. If the BLM cannot categorically exclude the proposed action following review for extraordinary circumstances, it will prepare an EA or EIS, as appropriate, before issuing any decision to authorize the action. 43 CFR 46.205(c); 42 U.S.C. 4336(b). For the Department's establishment of this CE, the BLM developed a written record containing information sufficient to substantiate its determination that the category of actions normally does not significantly

affect the quality of the human environment.

In developing the WOGCE, the Department consulted with the Council on Environmental Quality (CEQ) consistent with section 102(2)(B) of NEPA, 42 U.S.C. 4332(2)(B).

II. Categorical Exclusions Justification

The Department and the BLM find that the categories of actions described in the CE being added to DOI's NEPA implementing procedures normally do not significantly affect the quality of the human environment. This finding is based on the BLM's long history of authorizing, regulating, and monitoring winter oil and gas exploration activities in the NPR-A, which demonstrates that winter operations—conducted on ice infrastructure, under Required Operating Procedures (ROPs), and within required environmental safeguards—do not produce significant or lasting environmental impacts. Ongoing improvements in technology, operational practices, and community engagement further reinforce the limited nature of these impacts.

To demonstrate the finding that actions under the proposed CE would normally not significantly affect the quality of the human environment, the BLM reviewed all WOGCE projects that have been approved and implemented over the last 28 years for which the BLM prepared 47 EAs and reached FONSI and findings of no new significant impact (FONSI) that have been verified through post-implementation review and summarized them in the CE substantiation report included in this notice's supporting documentation. These 47 EAs that supported FONSI and FONSI analyzed actions that are similar to and would fall within this CE. That is, because of its extensive experience with these types of actions, the BLM can confirm that the environmental impacts of these actions do not normally rise to the level of significance that would require preparation of an EIS and need not prepare additional EAs for each new action of these types.

Notwithstanding the BLM's findings regarding the normal environmental impacts of these types of individual permitting actions, DOI recognizes that certain proposed actions, when reviewed on a case-by-case basis, may implicate one or more extraordinary circumstances, and for those proposed actions where a normally excluded action may have a significant effect, bureaus will prepare an EA or EIS. Thus, prior to applying any CE, bureaus will review the proposed action to ensure it is covered by the CE and

evaluate the proposed action for the presence of any extraordinary circumstances.

DOI requires that any action for which the new CE is applied must be documented. BLM documents CE use with a checklist to demonstrate: (a) the applicability of the CE, and (b) that no extraordinary circumstances are present such that a normally excluded action may have a significant effect. In such cases where a normally excluded action may have a significant effect, BLM will conduct additional NEPA analysis and prepare an EA or EIS, as appropriate, before authorizing the action.

III. Text Added to the U.S. Department of the Interior Handbook of NEPA Implementing Procedures, Appendix 2: Bureau Categorical Exclusions

The *DOI Handbook of NEPA Implementing Procedures, Appendix 2: Bureau Categorical Exclusions* includes the following language:

* * * * *

Bureau of Land Management

11.9 Actions Eligible for Categorical Exclusion (CE)

* * * * *

B. Oil, Gas, and Geothermal Energy

* * * * *

(9) Approval of seismic surveys, applications for permit to drill, and grants of rights of way for wintertime oil and gas exploration activities within the National Petroleum Reserve-Alaska (NPR-A).

- (a) Covered activities:
 - (i) Vibroseis seismic methods;
 - (ii) Construction of temporary ice road and snow routes for access;
 - (iii) Construction of ice pads, use of camps and associated support equipment;
 - (iv) Water withdrawals and associated access;
 - (v) Appraisal or delineation activities (drilling of wells and sidetracks from existing wells), well stimulation equipment, well testing (e.g., flow tests), well suspension, and plugging, and/or abandonment; and
 - (vi) Helicopter-assisted summer cleanup activities associated with the prior winter drilling season.

* * * * *

Authorities: NEPA, as amended (42 U.S.C. 4321 *et seq.*)

Troy Finnegan,

Deputy Assistant Secretary, Exercising the Delegated Authority of the Assistant Secretary—Policy, Management and Budget.

[FR Doc. 2026–20763 Filed 10–8–26; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2026–0892]

Notice of Availability of the Proposed Notice of Sale for Gulf of America Outer Continental Shelf Oil and Gas One Big Beautiful Bill Act Lease Sale 4

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability for the proposed notice of sale.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) announces the availability of the Proposed Notice of Sale (NOS) for the Gulf of America (GOA) Outer Continental Shelf (OCS) Oil and Gas One Big Beautiful Bill Act (OBBBA) Lease Sale 4 (Lease Sale BBG4). BOEM is publishing this Notice pursuant to its regulatory authority under 30 CFR part 556. Pursuant to Section 19 of the OCS Lands Act, the Secretary of the Interior provides the Governors of affected States and the executive of any affected local government with the opportunity to review and comment on the Proposed NOS. The Proposed NOS describes the proposed size, timing, and location of the sale, including lease stipulations, terms and conditions, minimum bids, royalty rates, and rental rates which are required by Section 50102 of the OBBBA for this sale.

DATES: Comments received from the Governors and the executive of any affected local government on the size, timing, and location of this sale must be submitted to BOEM no later than December 8, 2026. BOEM will publish the Final NOS in the **Federal Register** at least 30 days prior to the date of bid opening. Bid opening is currently scheduled for March 10, 2027.

ADDRESSES: The Proposed NOS for Lease Sale BBG4 and Proposed NOS Package containing information essential to potential bidders may be obtained from the Gulf of America Region Public Affairs Office, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394; telephone: (504) 736–2519. The Proposed NOS and Proposed NOS Package also are available for downloading or viewing on BOEM's website at <http://www.boem.gov/Sale-BBG4/>.

FOR FURTHER INFORMATION CONTACT: Bridgette Duplantis, Section Supervisor, Leasing and Financial Responsibility, Office of Leasing and Plans, 504–736–7502, bridgette.duplantis@boem.gov or

Ben Burnett, Division Manager, Leasing Policy and Management Division, Office of Strategic Resources, 703–787–1782, Benjamin.Burnett@boem.gov.

Authority: This sale will be held pursuant to the requirements of the OBBBA. This Notice of Availability of the Proposed NOS is published pursuant to 43 U.S.C. 1331 *et seq.* (Outer Continental Shelf Lands Act, as amended) and 30 CFR 556.304. Secretary's Order 3451 established the Marine Minerals Administration (MMA) and incorporated the authorities and function of the former BOEM and Bureau of Safety and Environmental Enforcement (BSEE) into the MMA. Accordingly, this notice is issued under the continuing authority of the former BOEM as now delegated to the MMA.

Michael D. Olsen,

Acting Director, Marine Minerals Administration.

[FR Doc. 2026–20767 Filed 10–8–26; 8:45 am]

BILLING CODE 4340–98–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1408]

Certain Hydrodermabrasion Systems and Components Thereof; Notice of Vacatur of the Commission's Final Determination and Mootness of the Investigation by the Federal Circuit Due to Patent Expiration

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission's ("Commission") final determination in the above-captioned investigation has been vacated by the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") and the investigation is terminated as moot as ordered by the Federal Circuit. The investigation was previously terminated on March 23, 2026.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Link, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3103. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 <https://www.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: On July 17, 2024, the Commission instituted this investigation based on a complaint filed on behalf of HydraFacial LLC, f/k/a Edge Systems LLC, of Long Beach, California ("HydraFacial"). 89 FR 58188–89 (July 17, 2024). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), based on the importation into the United States, the sale for importation, or sale within the United States after importation of certain hydrodermabrasion systems and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,865,287 patent ("the '287 patent"). *Id.* The complaint further alleges that an industry in the United States exists as required by section 337. *Id.* The Commission's notice of investigation named as respondents Cartessa Aesthetics, LLC ("Cartessa") of Melville, New York; and Eunsung Global Corp. of Republic of Korea. *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On January 21, 2025, the Commission terminated the investigation as to Eunsung based on a consent order. Order No. 19 (Dec. 19, 2024), *unreviewed by Comm'n* Notice (Jan. 21, 2025).

On March 23, 2026, the Commission terminated the investigation with a final determination finding a violation of the asserted claims of the '287 patent under section 337 by Cartessa. 91 FR 14713–714 (Mar. 26, 2026). However, the Commission suspended enforcement of any remedial orders because the '287 patent would expire on March 29, 2026, during the 60-day period of Presidential review. *Id.* Respondent appealed the Commission's final determination to the Federal Circuit.

While the appeal was pending, the '287 patent expired, and pursuant to their terms, the remedial orders are no longer in effect. Cartessa moved to dismiss the appeal as moot and vacate the Commission opinion. The Commission did not oppose. HydraFacial did not oppose dismissal but opposed vacating the Commission opinion.

On July 23, 2026, the Federal Circuit issued an order vacating the Commission's final determination and remanding the investigation to the Commission with instructions to "dismiss the investigation as moot."

Cartessa Aesthetics, LLC v. United States Int'l Trade Commission, Appeal Nos. 26–1582, 26–1881 (Fed. Cir. July 23, 2026). The Federal Circuit issued the mandate on September 15, 2026.

Because the present investigation was previously terminated, the Commission confirms via this notice that Investigation No. 337–TA–1408 is terminated as moot. The Commission's final determination was vacated per the Federal Circuit's order. *Id.*

The Commission vote for this determination took place on October 3, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Issued: October 2, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–20752 Filed 10–8–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–650–651 (Review)]

Phosphate Fertilizers From Morocco and Russia; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 to determine whether revocation of the countervailing duty orders on phosphate fertilizers from Morocco and Russia would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: October 6, 2026.

FOR FURTHER INFORMATION CONTACT: Stamen Borisson ((202) 205–3125), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office

of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On June 5, 2026, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (91 FR 36612, June 17, 2026); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI

gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the reviews will be placed in the nonpublic record on March 15, 2027, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold an in-person hearing in connection with the reviews beginning at 9:30 a.m. on April 1, 2027. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before 5:15 p.m. on Thursday, March 25, 2027. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the reviews, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3 p.m. the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at <https://www.usitc.gov/calendarpad/calendar.html>.

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on Friday, March 26, 2027. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on March 31, 2027. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is 5:15 p.m. on March 24, 2027. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is 5:15 p.m. on April 8, 2027. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before 5:15 p.m. on April 8, 2027. On April 27, 2027, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before 5:15 p.m. on April 29, 2027, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 6, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-20715 Filed 10-8-26; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1472]

Certain Dynamic Random Access Memory (DRAM) Devices, Products Containing the Same, and Components Thereof; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on Settlement; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("the Commission") has determined not to review an initial determination ("ID") (Order No. 31) issued by the presiding administrative law judge ("ALJ") granting an unopposed motion to terminate the investigation based on settlement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT:

Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (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 <https://www.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 instituted this investigation on January 2, 2026, based on a complaint filed by Netlist, Inc. ("Netlist" or "Complainant") of Irvine, California. 91 FR 155-56 (Jan. 2, 2026). The complaint, as supplemented, alleges violations of section 337 of the

Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dynamic random access memory (DRAM) devices, products containing the same, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 12,373,366 ("the '366 patent"); 10,025,731 ("the '731 patent"); 10,268,608 ("the '608 patent"); 10,217,523 ("the '523 patent"); the '035 patent; and 12,308,087 ("the '087 patent"). *Id.* The complaint further alleges that a domestic industry exists or is in the process of being established. *Id.* The Commission's notice of investigation named as respondents: (1) Samsung Electronics Co., Ltd. of Suwon, Republic of Korea; Samsung Electronics America, Inc. of Plano, Texas; and Samsung Semiconductor, Inc. of Plano, Texas (collectively, "Samsung"); (2) Google LLC ("Google") of Mountain View, California; and (3) Super Micro Computer, Inc. ("SMC") of San Jose, California (collectively, "Respondents"). *Id.* The Office of Unfair Import Investigations ("OUII") is also participating in the investigation. *Id.*

On August 24, 2026, the Commission partially terminated the investigation as to all asserted claims of the '035 patent, claims 2 and 3 of the '608 patent, claims 11 and 15 of the '366 patent, claims 7-9 and 12-16 of the '731 patent, claims 17 and 18 of the '523 patent, and claims 5, 7, 17, 20, 22, and 23 of the '087 patent based on withdrawal of the complaint allegations as to those claims. *See* Order No. 29 (July 23, 2026), *unreviewed by Comm'n Notice* (Aug. 24, 2026).

On August 18, 2026, Netlist and Samsung (collectively, "the Settling Parties") filed a joint motion ("Mot.") to terminate the investigation as to all Respondents based on settlement. The motion notes that agreements between the Settling parties ("Agreements") "completely resolve the dispute between the Settling Parties in this Investigation, as well as between Netlist and any remaining Respondents who receive their accused products from the Samsung Respondents." Mot. at 2. The motion also indicates that Google and SMC do not oppose the motion. *Id.* at 5. On August 27, 2026, OUII filed a response in support of the motion.

On September 4, 2026, the ALJ issued the subject ID (Order No. 31) granting the motion to terminate pursuant to Commission Rule 210.21(b)(1) (19 CFR 210.21(b)(1)). The ID notes that the motion includes confidential and public versions of the Agreements as well as a statement that "there are no other agreements, written or oral, express or

implied, between the Settling Parties concerning the subject matter of this Investigation." ID at 2-3. The ID also notes that "the public interest favors settlement to avoid unnecessary litigation and to conserve public and private resources." *Id.* at 3. The ID concludes that the motion complies with Commission Rule 210.21(b)(1). *Id.* at 4. The ALJ also granted the Settling Parties' request to limit service of the Agreements. *Id.*

No party filed a petition for review of the subject ID.

The Commission has determined not to review the subject ID (Order No. 31). The investigation is terminated.

The Commission's vote for this determination took place on October 6, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 6, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-20716 Filed 10-8-26; 8:45 am]

BILLING CODE 7020-02-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Committee on Rules of Practice and Procedure; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States, Committee on Rules of Practice and Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold an in-person meeting on January 5, 2027 in Washington, DC. The meeting will be conducted in hybrid format with virtual attendance options available. The meeting is open to the public for observation but not participation. A meeting agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <https://www.uscourts.gov/forms-rules/records-rules-committees/agenda-books>.

DATES: January 5, 2027 (meeting date) and December 29, 2026 (registration deadline for in-person observation).

ADDRESSES: Requests to observe must be made in writing by emailing the request to: RulesCommittee_Secretary@ao.uscourts.gov. Please see the **SUPPLEMENTARY INFORMATION** section in

this notice for further instructions on observing the meeting.

FOR FURTHER INFORMATION CONTACT: Carolyn A. Dubay, Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, RulesCommittee_Secretary@ao.uscourts.gov.

SUPPLEMENTARY INFORMATION: To observe the meeting in person, individuals must contact the office listed above by 5 p.m. (eastern time) on December 29, 2026. After this deadline, only virtual observation is permitted. Virtual registration is available until the meeting date, provided it is completed before the projected end time.

(Authority: 28 U.S.C. 2073.)

Dated: October 7, 2026.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2026–20728 Filed 10–8–26; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Vladimir Romaniv, P.A.; Decision and Order

On November 10, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Vladimir Romaniv, P.A., of Yonkers, N.Y. (Registrant). Request for Final Agency Action dated February 13, 2026¹ (Public Interest (PI) RFAA), Exhibit (PI RFAAX) 1, at 1, 6. The OSC/ISO informed Registrant of the immediate suspension of his DEA Certificates of Registration Nos. MR2205602 and MR6587919, pursuant to 21 U.S.C. 824(d), alleging that Registrant's continued registration constitutes “‘an imminent danger to the public health or safety.’” *Id.*, at 1 (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Registrant's DEA registrations, alleging that Registrant's continued registration is inconsistent with the public interest. *Id.* (citing to 21 U.S.C. 823(g)(1), 824(a)(4)).²

¹ This RFAA document is dated February 13, 2025, but this date appears to be a typographical error, because the RFAA was transmitted to the Administrator in 2026.

² Based on the Government's submissions in its PI RFAA, the Agency finds that service of the OSC/ISO on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on November 17, 2025, Registrant

More specifically, the OSC/ISO alleged that from at least January 7, 2025, through at least May 7, 2025, Registrant repeatedly violated federal and state law by issuing multiple prescriptions to a patient for whom Registrant failed to conduct the necessary examination and evaluations to justify prescribing controlled substances because the patient was incarcerated at the time. *Id.*, at 2–4. The OSC/ISO further alleged that Registrant repeatedly violated federal and state law by issuing overlapping prescriptions to this patient for the same controlled substance, as well as by issuing all of the prescriptions at issue without the contact information for Registrant's supervising physician. *Id.* The OSC/ISO alleged that Registrant's prescribing was in violation of 21 CFR 1306.04(a); N.Y. Pub. Health Law §§ 3331(2), 3390; N.Y. Comp. Codes R. & Regs. tit. 10, §§ 80.62(a), 80.65, 80.67(c), 94.2(e)(1)–(2). *Id.*³

The Government's PI RFAA requests that the Agency issue a default final order revoking Registrant's registrations Nos. MR2205602 and MR6587919. PI RFAA, at 5–6.

On November 12, 2025, DEA issued an additional Order to Show Cause (OSC) to Registrant, proposing the revocation of Registrant's DEA Certificate of Registration No. MR7746184,⁴ alleging that Registrant has no state authority to handle controlled substances. Request for Final Agency Action dated February 12, 2026⁵ (Loss of State Authority (LSA) RFAA), Exhibit (LSA RFAAX) 2, at 1, 3 (citing 21 U.S.C. 824(a)(3)).⁶

Specifically, the OSC alleged that Registrant is “currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of

was personally served with the OSC/ISO. PI RFAAX 2, at 1–2; *see also id.*, Appendix A.

³ The Agency need not adjudicate the criminal violations alleged in the OSC/ISO. *Ruan v. United States*, 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

⁴ According to Agency records, Registrant's registration No. MR7746184 expired on April 30, 2026. The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, MD*, 84 FR 68474, 68476–79 (2019).

⁵ The LSA RFAA is dated February 12, 2025, but this date appears to be a typographical error, because the LSA RFAA was transmitted to the Administrator in 2026.

⁶ Based on the Government's submissions in its LSA RFAA, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on November 17, 2025, Registrant was personally served with the OSC. LSA RFAAX 1, at 2; *see also id.*, Appendix A.

Jersey, the state in which [he is] registered with DEA [under registration No. MR7746184].” *Id.*, at 1–2 (citing 21 U.S.C. 824(a)(3)).

On February 12, 2026, the Government submitted a second RFAA requesting that the Agency issue a default final order revoking Registrant's registration, No. MR7746184, based in New Jersey. LSA RFAA, at 3–4.

After carefully reviewing the entire record and conducting analysis as set forth in more detail below, the Agency grants the Government's requests for final agency action and revokes Registrant's registrations Nos. MR2205602, MR6587919, and MR7746184.

I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request “within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default” unless “good cause” is established for the failure. 21 CFR 1301.43(a), (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is “deemed to have waived their right to a hearing and to be in default.” 21 CFR 1301.43(c)(2). Unless excused, a default is deemed to constitute “an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

Both the OSC/ISO and the additional OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. PI RFAAX 1, at 5–6 (citing to 21 CFR 1301.43); LSA RFAAX 2, at 2 (same). According to the Government's RFAs, Registrant failed to request a hearing in response to either the OSC/ISO or the OSC. PI RFAA, at 1–2; LSA RFAA, at 1. Thus, the Agency finds that Registrant is in default and therefore has admitted to the factual allegations in both the OSC/ISO and OSC. 21 CFR 1301.43(e).

II. Loss of State Authority

A. Findings of Fact

According to the OSC, on November 30, 2023, Registrant's New Jersey controlled dangerous substances (CDS) license expired by its own terms. LSA RFAAX 2, at 2. According to New Jersey online records, of which the Agency takes official notice,⁷ Registrant's New

⁷ Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.”

Continued

Jersey CDS license is expired. New Jersey Division of Consumer Affairs License Verification, <https://newjersey.mylicense.com/verification> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to handle controlled substances in New Jersey, the state in which he is registered with DEA under registration No. MR7746184.⁸

B. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 “upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (“The Attorney General can register a physician to dispense controlled substances ‘if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.’ . . . The very definition of a ‘practitioner’ eligible to prescribe includes physicians ‘licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices’ to dispense controlled substances. § 802(21).”). The Agency has applied these principles consistently. *See, e.g., Thomas Earley, D.D.S.*, 91 FR 55624 (2026); *Henry-Norbert O. Ndekwe, MD*, 90 FR 15990 (2025); *Lawrence Rudolph, DMD*, 89 FR 79310 (2024).⁹

United States Department of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

⁸Pursuant to 5 U.S.C. 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” The material fact here is that Registrant, as of the date of this Order, is not licensed to handle controlled substances in New Jersey. Accordingly, Registrant may dispute the Agency’s finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to the DEA Office of the Administrator, Drug Enforcement Administration, at dea.addo.attorneys@dea.gov.

⁹This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a physician . . . or other person licensed, registered, or otherwise permitted,

According to New Jersey statute, “[e]very person who manufactures, distributes, or dispenses any controlled dangerous substance within this State or who proposes to engage in the manufacture, distribution, or dispensing of any controlled dangerous substance within this State, shall obtain a registration issued by the [Division of Consumer Affairs] in accordance with rules and regulations promulgated by it.” N.J. Rev. Stat. § 24:21–10(a) (2025). Further, “dispense” means “to deliver a controlled dangerous substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.” *Id.* § 24:21–2.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to dispense controlled substances in New Jersey because Registrant’s New Jersey CDS license is expired. As discussed, an individual must hold a New Jersey CDS license to dispense a controlled substance in New Jersey. Thus, because Registrant lacks authority to handle controlled substances in New Jersey, Registrant is not eligible to maintain DEA registration No. MR7746184 based in New Jersey. Accordingly, the Agency finds that Registrant’s lack of state authority to handle controlled substances in New Jersey provides a basis for revocation of Registrant’s DEA registration No. MR7746184. 21 U.S.C. 824(a)(3).

III. Public Interest Determination

A. Overview of Law

The Attorney General “may deny, suspend, or revoke [a] registration if . . . the [registrant’s] registration would be ‘inconsistent with the public interest.’” *Gonzales*, 546 U.S. at 251 (quoting 21 U.S.C. 824(a)(4)). The Attorney General’s “discretion in

by . . . the jurisdiction in which he practices . . . to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner’s registration, Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he or she is no longer authorized to dispense controlled substances under the laws of the state in which he or she practices. *See, e.g., Benson Sergiles, P.A.*, 90 FR 32016, 32017 (2025); *Jason Weakley, R.N., A.P.R.N.*, 90 FR 10085 (2025); *Traesa A. Brown, MD*, 89 FR 24035, 24036 (2024).

exercising [the authority to register and deregister practitioners] is spelled out in very broad terms.” *Id.* at 292 (Scalia, J., dissenting); *see also Neumann’s Pharmacy, L.L.C. v. Drug Enf’t Admin.*, 167 F.4th 320, 323 (5th Cir. 2026) (“DEA unquestionably has broad authority to deregister pharmacies and substantial discretion to shape policy within statutory bounds.”). In executing this broad mandate, DEA must continuously balance the CSA’s public interest goals of curbing the “illegal . . . distribution[,] and possession[,] and improper use of controlled substances[, which has] a substantial and detrimental effect on the health and general welfare of the American people,” while ensuring that the public has access to medications that “have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.” 21 U.S.C. 801(1), (2); *see Joanna R. Lampe, Cong. Rsch. Serv.*, R45948, *The Controlled Substances Act (CSA): A Legal Overview for the 119th Congress* (2025), <https://www.congress.gov/crs-product/R45948>.

In the case of a practitioner, Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A)–(E).¹⁰ Just as the phrase “inconsistent with the public interest” is broad, the five factors that Congress directed DEA to consider in determining the public interest are similarly broad, suggesting that Congress intended for DEA to have discretion and flexibility to interpret this language as necessary to implement its critical mission to protect the public from drug abuse and diversion. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394–95 (2024) (noting that “[i]n a case involving an agency . . . the statute’s meaning may well be that the agency is authorized to exercise a degree of discretion,” such as where the statute uses terms or phrases like “‘appropriate or reasonable’” (internal citations omitted)). Indeed, courts have recognized the Agency’s broad discretion to deny applications and deregister practitioners for a wide

¹⁰The five factors are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1)(A)–(E).

variety of conduct that the Agency has determined is inconsistent with the public interest. *See, e.g., Orusa v. Drug Enf't Admin.*, No. 22–3132, 2023 WL 3886403 (6th Cir. June 8, 2023) (physician issuing prescriptions outside the usual course of professional practice and beneath the standard of care); *St. Croix v. Drug Enf't Admin.*, No. 21–1116, 2022 WL 2092177 (D.C. Cir. June 10, 2022) (physician failing to maintain adequate records, prescribing controlled substances without a legitimate medical purpose, storing controlled substances at an unregistered location, failing to provide effective controls to guard against theft or diversion of these substances); *Suntree Pharmacy v. Drug Enf't Admin.*, No. 20–14626, 2022 WL 444357 (11th Cir. Feb. 14, 2022), *cert. denied*, 143 S. Ct. 305 (2022) (pharmacy filling prescriptions outside the usual course of practice).

The CSA's five public interest factors are considered in the disjunctive. *Gonzales*, 546 U.S. at 292–93 (Scalia, J., dissenting) (“It is well established that these factors are to be considered in the disjunctive,” quoting *In re Arora*, 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); *see Morall v. Drug Enf't Admin.*, 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as “applying a multi-factor test through case-by-case adjudication,” quoting *LeMoyné-Owen Coll. v. N.L.R.B.*, 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR at 37508, and the Agency “may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.” *Morall*, 412 F.3d at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.*, 70 FR 33207, 33208 (2007)); *see also Penick Corp. v. Drug Enf't Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it “need not make explicit findings as to each one.” *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. U.S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). “In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the

registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

The Government has the burden of proof in this proceeding, 21 CFR 1301.44(e), and the Agency must make its findings based on “substantial [record] evidence.” 5 U.S.C. 556(d); *see* 5 U.S.C. 706(2); 21 U.S.C. 877. If the Government meets its burden of establishing a *prima facie* case that Registrant's registration is not in the public interest, then the burden shifts to Registrant to rebut the Government's case. *Pharmacy Doctor Enters., Inc. v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 729 (11th Cir. 2019) (citing *Jones Total Health Care Pharmacy*, 881 F.3d at 830).

Registrant is registered in New York, among other states, and the OSC/ISO has alleged violations of state laws in New York. PI RFAAX 1, at 2–4. Accordingly, the Agency must evaluate the Government's evidence under New York law. *See Henry Emery, M.D.*, 90 FR 46927, 46929 (2025) (explaining the Agency analyzes public interest allegations according to the laws in the state where registrant is registered with DEA); *see also* 21 U.S.C. 903 (“No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.”).

B. Applicable Law

According to the CSA's implementing regulations, a lawful controlled substance prescription is one that is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a); *see Gonzales*, 546 U.S. at 274; *United States v. Hayes*, 595 F.2d 258, 260 (5th Cir. 1979), *rehearing den.*, 598 F.2d 620 (5th Cir. 1979), *cert. denied*, 444 U.S. 866 (1979); PI RFAAX 1, at 2. “A practitioner must establish and maintain a *bona fide* doctor-patient relationship in order to act ‘in the usual course of . . . professional practice’ and to issue

a prescription for a ‘legitimate medical purpose.’” *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010); PI RFAAX 1, at 2.

New York state law provides that “[a] practitioner, in good faith, and in the course of his or her professional practice only, may prescribe, administer and dispense” controlled substances. N.Y. Pub. Health Law § 3331(2); PI RFAAX 1, at 2. In addition, New York regulations provide that practitioners acting “in the course of their professional practice [] may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment.” N.Y. Comp. Codes R. & Regs. tit. 10, § 80.62(a); *see also id.* § 80.65 (“[a] prescription . . . shall be issued for a legitimate medical purpose only.”); PI RFAAX 1, at 3. Further, a practitioner's license “may be revoked . . . in whole or in part upon a finding that the licensee or certificate holder has . . . falsified any application, report, or record” or “failed to maintain effective control against diversion of controlled substances.” N.Y. Pub. Health Law § 3390; PI RFAAX 1, at 2.

Pursuant to New York regulations, a prescription for a schedule II controlled substance may not be refilled and may not exceed a 30-day supply. N.Y. Comp. Codes R. & Regs. tit. 10, § 80.67(a), (c); PI RFAAX 1, at 3. If a patient has received a 30-day supply of a schedule II controlled substance, the practitioner may not issue a new prescription for that same controlled substance until the patient has “exhausted all but a seven days’ supply of that controlled substance.” *Id.* In other words, a practitioner may not issue overlapping prescriptions for the same controlled substance until the patient has seven or fewer days’ supply remaining.

With respect to physician assistants, New York regulations state that a physician assistant may only prescribe controlled substances “in good faith and acting within his or her lawful scope of practice.” N.Y. Comp. Codes R. & Regs. tit. 10, § 94.2(e)(2); PI RFAAX 1, at 3. Further, prescriptions issued by a physician assistant must include “the name, address and telephone number of the supervising physician.” N.Y. Comp. Codes R. & Regs. tit. 10, § 94.2(e)(1); PI RFAAX 1, at 3.

C. Findings of Fact

In light of Registrant's default, the factual allegations in the OSC/ISO are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant, a physician assistant, admits that on January 7, 2025, and January 8, 2025, he issued two separate prescriptions for

oxycodone-acetaminophen ¹¹ 10–325 mg (a Schedule II opioid) to Patient N.A., both of which were for a 30-day supply of 59 tablets. PI RFAAX 1, at 4. Registrant admits that he issued these prescriptions without the name, address, and telephone number of his supervising physician. *Id.*

Registrant also admits that on February 6, 2025, he issued a prescription for promethazine with codeine 6.25–10 mg/5 ml (a Schedule V opioid) to Patient N.A. without the name, address, and telephone number of his supervising physician.¹² *Id.*

Moreover, Registrant admits that between February 7, 2025, and May 8, 2025, Registrant issued at least eight prescriptions for controlled substances to Patient N.A., including oxycodone-acetaminophen 10–325 mg, oxycodone 20 mg and 15 mg (a Schedule II opioid), and promethazine with codeine 6.25–10 mg/5ml. *Id.* Registrant admits that Patient N.A. was incarcerated by the New York City Department of Correction during the time Registrant issued these prescriptions. *Id.* Registrant admits that he issued these prescriptions without having conducted any assessment or examination of Patient N.A. *Id.* Further, Registrant admits that he failed to conduct any verification of Patient N.A.’s location, or note that Patient N.A. was incarcerated, despite Registrant’s patient charts claiming that Registrant saw Patient N.A. and that Patient N.A. was “evaluated at the clinic.” *Id.* Registrant also admits that, again, he issued the above prescriptions without the name, address, and telephone number of his supervising physician. *Id.* Registrant admits that the prescriptions issued to Patient N.A. did not result from a legitimate doctor-patient relationship. *Id.*

In consideration of all of the above, the Agency finds substantial record evidence that on two successive dates, Registrant issued overlapping prescriptions to N.A. for a 30-day supply of a schedule II controlled substance without having “exhausted

all but a seven days’ supply of that controlled substance” and that these prescriptions did not include the “name, address, and telephone number of the supervising physician.” The Agency finds substantial evidence that Registrant issued nine prescriptions for controlled substances to N.A. without the “name, address, and telephone number of the supervising physician.” The Agency also finds substantial evidence that Registrant issued eight prescriptions to N.A., while N.A. was incarcerated, without conducting an examination or establishing a legitimate doctor-patient relationship, and that Registrant falsified his patient records by noting that he evaluated N.A. “at the clinic.”

D. Discussion

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1), the Government’s evidence in support of its *prima facie* case primarily implicates Factors B and D. PI RFAAX 1, at 3–5. Evidence is considered under Factor B when it reflects experience dispensing controlled substances and under Factor D when it reflects compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). Although Factors B and D have some overlap, such that the Agency has frequently analyzed them together, Congress must have intended Factor B to encompass conduct that is not captured under Factor D. *See Kungys v. United States*, 485 U.S. 759, 778 (1988) (referencing the “cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant”).

i. Factor B

As already discussed, the CSA gives the Attorney General authority to revoke a registration if he determines that the registrant “has committed such acts as would render his registration . . . inconsistent with the public interest as determined under [section 823].” 21 U.S.C. 824(a). One of the five factors that the Attorney General must consider in making this determination is the registrant’s “experience in dispensing . . . controlled substances.” 21 U.S.C. 823(g)(1)(B) (Factor B). Neither the statute nor the implementing regulations define the term “experience” or places any limitations on the type of conduct that may be considered as “experience” under Factor B.¹³

¹³ The only limitation discussed in the legislative history on DEA’s authority under Factor B is that DEA should not “construe[this factor] in any way

Historically, the Agency’s Factor B ¹⁴ analysis considered “both the qualitative manner and quantitative volume of the [practitioner’s] experience . . . as expressed through his patients and employees,” and concluded that the record must contain quantitative evidence regarding the practitioner’s experience for the Agency to find that Factor B weighs against a practitioner. *E.g., Clair L. Pettinger*, 78 FR 61592, 61619 (2013). In 2015, the Agency abandoned this language, observing that the text of Factor B did not require DEA to consider the practitioner’s “quantity” of prescribing. *See JM Pharmacy Group, Inc.*, 80 FR 28667, 28667–68 (2015); *see also Wesley Pope, MD*, 82 FR 14944, 14982 (2017). The Agency reviewed dictionary definitions of “experience,” including:

(1) The “direct observation of or participation in events as a basis for knowledge,” (2) “the fact or state of having been affected by or gained knowledge through direct observation or participation,” (3) “practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,” and (4) “the length of such participation.”

80 FR at 28667 n.2 (citing *Webster’s Collegiate Dictionary* 409 (10th ed. 1998); *The Random House Dictionary of the English Language* 681 (2d ed. 1987)).

The word “dispense” means “to deliver a controlled substance[] to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing or administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.” 21 U.S.C. 802(10). This definition encompasses, among other things, practitioners who prescribe controlled substances and pharmacies who fill controlled substance prescriptions. *Id.* The term “controlled substance” simply means “a drug or other substance . . . included in schedule I, II, III, IV, or V” 21 U.S.C. 802(6). Thus, the phrase

to hinder registration of recent graduates of professional schools who may have no professional experience dispensing or conducting research with controlled substances.” H.R. REP. NO. 98–835, pt. 1, at 14 (1984).

¹⁴ Historically, the Agency referred to “Factor B” as “Factor Two.” Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the CSA and other statutes. Relevant to this matter, the MRA redesignated the public interest factors outlined at 21 U.S.C. 823(f)(1)–(5), which the Agency referred to as Factors One through Five, as 21 U.S.C. 823(g)(1)(A)–(E), which the Agency now refers to as Factors A through E. Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1)(B), “Factor B.”

¹¹ The OSC/ISO refers to Percocet, which is a brand name for oxycodone-acetaminophen. *See* PI RFAAX 1, at 4.

¹² The OSC/ISO alleges that on February 6, 2025, and February 7, 2025, Registrant issued two separate prescriptions for promethazine with codeine 6.25–10mg/5 ml to Patient N.A., both for a 30-day supply, in violation of N.Y. Pub. Health Law § 3390 and N.Y. Comp. Codes R. & Regs. tit. 10, § 80.67(c). *Id.* However, the cited regulation only imposes the 30-day restriction on Schedule II controlled substances and other controlled substances identified by name. Promethazine with codeine is a Schedule V controlled substance and it is not otherwise identified as a covered substance. Accordingly, the Agency does not sustain this allegation.

“experience in dispensing” means the direct participation in the act of delivering, prescribing, dispensing, or administering a controlled substance to an ultimate user.

The phrase “experience in dispensing” must be considered within the context of DEA’s broad mandate under 21 U.S.C. 824(a) to deregister practitioners who “ha[ve] committed such acts as would render [their] registration . . . inconsistent with the public interest.” 21 U.S.C. 824(a)(4). In other words, in determining what type of conduct is relevant under Factor B, DEA’s primary focus is to determine whether a registrant’s “experience in dispensing” is “inconsistent with the public interest” or whether a registrant’s dispensing constitutes “acts” that are inconsistent with the public interest. 21 U.S.C. 823(g)(1), 824(a)(4).

The word “inconsistent” is not defined in the CSA, but it is commonly defined as “lacking consistency: such as (a) not compatible with another fact or claim, [and] (b) containing incompatible elements.” *Inconsistent*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/inconsistent> (last visited on the date of signature). “Public interest” is a broad, discretionary term not explicitly defined in the CSA, but Congress identifies the primary goals in the CSA’s introductory section as ensuring access to controlled substances used for a “legitimate medical purpose” while protecting the public from the “illegal . . . distribution . . . and improper use of controlled substances[, which] have a substantial and detrimental effect on the health and general welfare of the American people.” 21 U.S.C. 801(1) & (2).

Considering these goals, DEA’s Factor B analysis primarily concerns whether a registrant’s “experience in dispensing” reflects illegal distribution or improper use of controlled substances that is inconsistent with the public interest. *Id.* In the context of a practitioner, this would require the Agency to evaluate whether he or she has dispensed controlled substances in a manner that is improper, illegal, or inconsistent with the public interest; for example, by issuing prescriptions without conducting a proper examination or developing a supported diagnosis; ignoring patient indications of abuse, diversion, or improper use; issuing a prescription in a manner that is inconsistent with state law or the state’s standards of practice; or issuing prescriptions for controlled substances

in a way that creates a risk of diversion.¹⁵

Of course, the Agency is not only concerned with acts of intentional diversion¹⁶ as DEA has explained that “[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .” *Samson K. Orusa, M.D.*, 87 FR 2986, 3018 (2022) (quoting *Paul J. Caragine, Jr.*, 63 FR 51592, 51602 (1998)); *Bradley H. Chesler, MD*, 87 FR 4917, 4929 (2022) (citing *Bienvenido Tan*, 76 FR 17673, 17689 (2011)); *Dewey C. MacKay, MD*, 75 FR 49956, 49974 n.35 (2010) (“Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.”). Indeed, neither 21 U.S.C. 824(a) nor 21 U.S.C. 823(g) requires DEA to find that a registrant has intentionally diverted controlled substances. Ultimately, a registrant whose dispensing practices create an environment that encourages or is indifferent to the abuse or diversion of controlled substances is acting outside the public’s interest. As the opioid epidemic surges and other controlled substances, such as amphetamines, ketamine, and benzodiazepines, are increasingly abused, DEA must remain vigilant to protect the public against registrants who fail to employ the CSA’s safeguards to ensure the health and general wellness of the American public.

Registrants “may continue to introduce evidence as to . . . lawful . . . dispensing activities.”¹⁷ However,

¹⁵ Analysis of whether a prescription is illegally filled, distributed, prescribed, or possessed also fit within Factor D, “Compliance with applicable State, Federal, or local laws relating to controlled substances.” 21 U.S.C. 823(g)(1)(D).

¹⁶ Only criminally unlawful conduct requires an act of intentional diversion such as proof that a physician “used ‘his authority to prescribe controlled substances . . . not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit’ or some other illegitimate purposes, such as his own ‘personal profit.’” *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006) (quoted in *Laurence T. McKinney*, 73 FR 43260, 43266 (2008)). Compare 21 U.S.C. 823 and 824, with 21 U.S.C. 841, 842, 843.

¹⁷ *Randall L. Wolff, M.D.*, 77 FR 5106, 5153 (2012) (finding that evidence of lawful prescribing is “entitled to some evidentiary weight only in cases where a practitioner credibly demonstrates an acceptance of responsibility and reform of past practices”); see also *Roberto Zayas, M.D.*, 82 FR 21410, 21422 n.27 (2017) (“[T]he Agency properly considers a [registrant’s] evidence of a lengthy history of compliance after the Government makes out its *prima facie* case, as determining what sanction is necessary to protect the public interest is the ultimate purpose of these provisions.”). In other words, this evidence may be relevant to the Agency’s sanctions analysis.

the Agency has found that “evidence that a practitioner has treated thousands of patients does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest.”¹⁸ *Krishna-Iyer*, 74 FR at 463. Accordingly, the Agency has consistently rejected registrants’ arguments that acts of unlawful prescribing were mitigated by years of lawful prescribing. See, e.g., *Syed-Jawed Akhtar-Zaidi*, 80 FR 42961, 42967 (2015), pet. for rev. denied, 841 F.3d 707, 713 (6th Cir. 2016) (rejecting respondent’s argument that he was denied a “fair adjudication” because the Government seized 400 patient files but only proved the illegality of a handful of prescriptions issued during undercover visits, and finding that “the physician’s prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which are inconsistent with the public interest”) (internal quotations and citations omitted).¹⁹

Here, as found above, Registrant is deemed to have admitted, and the Agency finds, that Registrant issued overlapping opioid prescriptions and failed to examine or otherwise establish a bona fide doctor-patient relationship with N.A. prior to prescribing controlled substances. Registrant’s prescribing reflects “experience in dispensing . . . controlled substances” that created an opportunity for the abuse or diversion of controlled substances and was outside the public interest. Registrant also falsified medical records which created further opportunities for abuse and diversion. Registrant did not request a hearing and thus did not provide the Agency with any evidence related to his “experience in dispensing” that served the public’s interest. Accordingly, the Agency finds that Factor B weighs

¹⁸ “[E]very registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [their] professional career.” *Krishna-Iyer*, 74 FR at 463. Accordingly, except where the Agency has found in its decision that a prescription was issued outside the public interest or in violation of law, the Agency assumes that all controlled substance prescriptions are dispensed or prescribed for a legitimate medical purpose and in accordance with relevant laws. See *Dewey C. Mackay, M.D.*, 75 FR at 49977.

¹⁹ In an unreported opinion, the Sixth Circuit affirmed DEA’s conclusion that the respondent’s acts of unlawful prescribing outweighed his years of work experience. *Orusa v. Drug Enf’t Admin.*, 2023 WL 3886403 at *5 (“Orusa’s credentials and years of work experience, which the agency acknowledged, do nothing to disturb the agency’s detailed review of his prescribing history—the relevant “experience in dispensing . . . controlled substances.”).

strongly against Registrant's continued registration.²⁰

ii. Factor D

Under Factor D, the Agency considers a registrant's "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. 823(g)(1)(D). Here, as found above, Registrant repeatedly violated state law by issuing overlapping prescriptions for a Schedule II opioid to N.A. (N.Y. Comp. Codes R. & Regs. tit. 10, § 80.67(c)) and failing to include the "the name, address and telephone number of the supervising physician" (N.Y. Comp. Codes R. & Regs. tit. 10, § 94.2(e)(1)). As found above, Registrant failed to examine N.A. or otherwise establish a bona fide doctor-patient relationship with N.A. prior to prescribing controlled substances. As such, the Agency finds that these controlled substance prescriptions were issued outside the usual course of professional practice, not for a legitimate medical purpose, and not in good faith, in violation of 21 CFR 1306.04(a) & 1306.06; N.Y. Pub. Health Law § 3331(2); N.Y. Comp. Codes R. & Regs. tit. 10, §§ 80.62(a), 80.65, 94.2(e)(1)–(2); *see Dewey C. MacKay*, 75 FR at 49973 ("A practitioner must establish and maintain a bona fide doctor-patient relationship in order to act 'in the usual course of . . . professional practice' and to issue a prescription for a 'legitimate medical purpose.'").

The Agency finds that after considering the public interest factors of 21 U.S.C. 23(g)(1), Factors B and D weigh in favor of revocation of Registrant's registrations. Accordingly, the Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). The Agency further finds that there is insufficient mitigating evidence to rebut the Government's *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Registrant can be trusted with a registration.

IV. Sanction

Where, as here, the Government has met its burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to Registrant to show why he can be entrusted with a registration. *Morall*, 412 F.3d at 174; *Jones Total Health Care Pharmacy*, 881 F.3d at 830; *Garrett Howard Smith, M.D.*, 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.*, 84 FR 46,968, 46,972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *See Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.*, 83 FR 29569, 29573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Stein*, 84 FR at 46972–73.

Here, Registrant did not request a hearing or answer the allegations in either the OSC/ISO or the OSC and was therefore deemed to be in default. *See supra* I. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to answer the allegations contained in either the OSC/ISO or the OSC and has not otherwise availed himself of the opportunity to refute the Government's case. Registrant's egregious misconduct involved unlawfully prescribing controlled substances to an individual with whom Registrant did not have a legitimate doctor-patient relationship, issuing

prescriptions to that person without conducting an evaluation or assessment despite claiming to have done so, issuing overlapping prescriptions to that person, and issuing prescriptions without providing the information for Registrant's supervising physician. *See supra* III.C. As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding his future compliance with the CSA, and has not demonstrated that he can be trusted with registration. Accordingly, the Agency will order the revocation of Registrant's registrations.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby revoke DEA Certificates of Registration Nos. MR2205602, MR6587919, and MR7746184 issued to Vladimir Romaniv, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending application of Vladimir Romaniv, P.A., to renew or modify this registration, as well as any other pending application of Vladimir Romaniv, P.A., for additional registration in New York, Massachusetts, or New Jersey.²¹ This Order is effective November 9, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 5, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters

²⁰ While the Agency has determined that Registrant's improper prescribing is relevant to Factors B and D, to the extent that the found conduct does not fall within these factors, it would nevertheless constitute "other conduct which may threaten the public health and safety." 21 U.S.C. 823(g)(1)(E). Registrant's repeated issuance of controlled substance prescriptions to a patient outside the usual course of professional practice and not for a legitimate medical purpose may threaten the public health and safety by creating the risk that controlled substances may leave the CSA's closed distribution system and be abused or diverted.

²¹ The Agency may revoke Respondent's Massachusetts registration based on Respondent's egregious misconduct in New York. *See, e.g., Roberto Zayas, M.D.*, 82 FR 21410, 21430 (2017) (revoking the physician's Florida registration and denying his Texas renewal application based on misconduct in Texas). The Administrator's determination that Registrant may not be trusted with a registration disqualifies him for current DEA registration in all states. *See Suntree Pharmacy and Suntree Medical Equipment, LLC*, 85 FR 73753, 73755 (2020) ("If a practitioner holding multiple registrations cannot be entrusted with one, it would be difficult to justify entrusting the same practitioner with another in a separate location.").

the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Alexandra R. Lovec, A.P.R.N.; Decision and Order

On December 22, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Alexandra Renee Lovec, A.P.R.N., of Ekalaka, Montana (Registrant). OSC, at 1, 6; Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 6. The OSC proposed the revocation of Registrant's DEA Certificate of Registration, No. ML4889347, alleging that Registrant's continued registration would be inconsistent with the public interest. OSC, at 1; RFAAX 1, at 1 (citing 21 U.S.C. 823(g)(1); 824(a)(4)).¹

The OSC alleged that from at least June 5, 2022, to at least January 16, 2025, Registrant repeatedly violated federal and Montana state law by issuing numerous prescriptions for Schedule II–IV controlled substances to a patient outside the usual course of professional practice and not for a legitimate medical purpose, in violation of 21 CFR 1306.04; Mont. Admin. R. § 24.159.1204(1)(a), 24.159.1464(1), (4), 24.159.2301(2).² OSC, at 2–4; RFAAX 1, at 2–4.³ Specifically, the OSC alleged that, among other things, Registrant failed to conduct or document adequate patient evaluations and histories necessary to establish an objective medical diagnosis justifying the necessity for the prescriptions and failed to adequately monitor patient progress. OSC, at 3–4; RFAAX 1, at 3–4.

On March 12, 2026, the Government submitted an RFAA requesting that the Agency issue a default final order

revoking Registrant's registration. RFAA, at 3. After carefully reviewing the entire record and conducting the analysis as set forth in more detail below, the Agency grants the Government's request for final agency action and revokes Registrant's registration.

I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request “within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default” unless “good cause” is established for the failure. 21 CFR 1301.43(a) & (c)(1). In the absence of a demonstration of good cause, a registrant who fails to timely file an answer also is “deemed to have waived their right to a hearing and to be in default.” 21 CFR 1301.43(c)(2). Unless excused, a default is deemed to constitute “an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

Here, the OSC notified Registrant of her right to file a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. OSC, at 5; RFAAX 1, at 5 (citing 21 CFR 1301.43). According to the Government's RFAA, Registrant failed to request a hearing. RFAA, at 2. Thus, the Agency finds that Registrant is in default and therefore has admitted to the factual allegations in the OSC. 21 CFR 1301.43(e).

II. Public Interest Determination

A. Overview of Law

The Attorney General “may deny, suspend, or revoke [a] registration if . . . the [registrant's] registration would be ‘inconsistent with the public interest.’” *Gonzales v. Oregon*, 546 U.S. 243, 251 (2006) (quoting 21 U.S.C. 824(a)(4)). The Attorney General's “discretion in exercising [the authority to register and deregister practitioners] is spelled out in very broad terms.” *Id.* at 292 (Scalia, J., dissenting); *see also Neumann's Pharmacy, L.L.C. v. Drug Enf't Admin.*, 167 F.4th 320, 323 (5th Cir. 2026) (“DEA unquestionably has broad authority to deregister pharmacies and substantial discretion to shape policy within statutory bounds.”). In executing this broad mandate, DEA must continuously balance the CSA's public interest goals of curbing the “illegal . . . distribution[] and possession[,] and improper use of controlled substances[, which has] a substantial and detrimental effect on the

health and general welfare of the American people,” while ensuring that the public has access to medications that “have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.” 21 U.S.C. 801(1), (2); *see* Joanna R. Lampe, Cong. Rsch. Serv., R45948, *The Controlled Substances Act (CSA): A Legal Overview for the 119th Congress* (2025), <https://www.congress.gov/crs-product/R45948>.

In the case of a practitioner, Congress directed the Attorney General to consider five factors in making the public interest determination. 21 U.S.C. 823(g)(1)(A)–(E).⁴ Just as the phrase “inconsistent with the public interest” is broad, the five factors that Congress directed DEA to consider in determining the public interest are similarly broad, suggesting that Congress intended for DEA to have discretion and flexibility to interpret this language as necessary to implement its critical mission to protect the public from drug abuse and diversion. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394–95 (2024) (noting that “[i]n a case involving an agency . . . the statute's meaning may well be that the agency is authorized to exercise a degree of discretion,” such as where the statute uses terms or phrases like “appropriate or reasonable” (internal citations omitted)). Indeed, courts have recognized the Agency's broad discretion to deny applications and deregister practitioners for a wide variety of conduct that the Agency has determined is inconsistent with the public interest. *See, e.g., Orusa v. Drug Enf't Admin.*, No. 22–3132, 2023 WL 3886403 (6th Cir. June 8, 2023) (physician issuing prescriptions outside the usual course of professional practice and beneath the standard of care); *St. Croix v. Drug Enf't Admin.*, No. 21–1116, 2022 WL 2092177 (D.C. Cir. June 10, 2022) (physician failing to maintain adequate records, prescribing controlled substances without a legitimate medical purpose, storing controlled substances at an unregistered location, failing to provide effective controls to guard

⁴ The five factors are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1)(A)–(E).

¹ Based on the Government's submissions in its RFAA dated March 16, 2026, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on January 7, 2026, the OSC was served to Registrant's counsel. RFAAX 2, at 2; *see also id.*, Appendices A–C.

² The Agency need not adjudicate the criminal violations alleged in the OSC. *Ruan v. United States*, 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

³ The OSC also alleged that Registrant violated Mont. Admin. R. § 24.159.1204(5), but the deemed-admitted facts were insufficient to find a violation regarding this allegation.

against theft or diversion of these substances); *Suntree Pharmacy v. Drug Enf't Admin.*, No. 20–14626, 2022 WL 444357 (11th Cir. Feb. 14, 2022), cert. denied, 143 S. Ct. 305 (2022) (pharmacy filling prescriptions outside the usual course of practice).

The CSA's five public interest factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. at 292–93 (Scalia, J., dissenting) (“It is well established that these factors are to be considered in the disjunctive,” quoting *In re Arora*, 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); see *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 181 (D.C. Cir. 2005) (describing the Agency's adjudicative process as “applying a multi-factor test through case-by-case adjudication,” quoting *LeMoyné-Owen Coll. v. N.L.R.B.*, 357 F.3d 55, 61 (D.C. Cir. 2004)). Any one factor, or combination of factors, may be decisive, *David H. Gillis, M.D.*, 58 FR at 37508, and the Agency “may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.” *Morall*, 412 F.3d. at 185 n.2 (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.*, 70 FR 33207, 33208 (2007)); see also *Penick Corp. v. Drug Enf't Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007).

Moreover, while the Agency is required to consider each of the factors, it “need not make explicit findings as to each one.” *MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. U.S. Drug Enf't Admin.*, 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). “In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(e), and the Agency must make its findings based on “substantial [record] evidence.” 5 U.S.C. 556(d); see

5 U.S.C. 706(2); 21 U.S.C. 877. If the Government meets its burden of establishing a *prima facie* case that Registrant's registration is not in the public interest, then the burden shifts to Registrant to rebut the Government's case. *Pharmacy Doctor Enters., Inc. v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 729 (11th Cir. 2019) (citing *Jones Total Health Care Pharmacy*, 881 F.3d at 830).

Registrant is registered in Montana, and the OSC has alleged violations of state laws in Montana. RFAAX 1, at 2–5. Accordingly, the Agency must evaluate the Government's evidence under Montana law. See *Henry Emery, M.D.*, 90 FR 46927, 46929 (2025) (explaining the Agency analyzes public interest allegations according to the laws in the state where registrant is registered with DEA); see also 21 U.S.C. 903 (“No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.”).

B. Applicable Federal and State Law

According to the CSA's implementing regulations, a lawful controlled substance prescription is one that is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a); see *Gonzales v. Oregon*, 546 U.S. at 274; *United States v. Hayes*, 595 F.2d 258 (5th Cir. 1979), rehearing den., 598 F.2d 620 (5th Cir. 1979), cert. denied, 444 U.S. 866 (1979); RFAAX 1, at 2. A “practitioner must establish and maintain a *bona fide* doctor-patient relationship in order to act ‘in the usual course of . . . professional practice’ and to issue a prescription for a ‘legitimate medical purpose.’” *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010).

As for state law, Montana regulations require nurses to “conduct and document nursing assessments of the health status of individuals and groups by: (a) collecting objective and subjective data from observations, examinations, interviews, and written records in an accurate and timely manner.” Mont. Admin. R. § 24.159.1204(1)(a). Further, Montana regulations require that all prescriptions must comply with all applicable state and federal laws and that an advanced practice registered nurse (APRN) with

prescriptive authority must comply with federal DEA requirements for controlled substances. *Id.* § 24.159.1464(1), (4). Finally, Montana regulations define unprofessional conduct of nurses as behavior “which fails to conform to the accepted standards of the nursing profession and which could jeopardize the health and welfare of the people” and includes “(i) diversion of a medication for any purpose; (j) violating state or federal laws relative to drugs; . . . [and] (v) violating a state or federal statute while performing or attempting to perform the practice of nursing.” *Id.* § 24.159.2301(2).

III. Findings of Fact

In light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). Accordingly, Registrant admits that from June 5, 2022, until as recently as January 16, 2025, Registrant unlawfully issued at least 109 prescriptions for Schedule II–V controlled substances to Patient M.S. that were not for a legitimate medical purpose. OSC, at 4. Registrant admits that these prescriptions included the following controlled substance medications: alprazolam, a Schedule IV sedative; lisdexamfetamine, a Schedule II stimulant; hydrocodone-acetaminophen 5–325 mg, a Schedule II narcotic; phentermine, a Schedule IV stimulant; and tramadol, a Schedule IV narcotic. *Id.*

Registrant admits that she issued the above controlled substance prescriptions to Patient M.S. despite failing to establish a medical condition sufficient to support the long-term use of these controlled substances. *Id.* Registrant admits that, among other things, she: failed to perform or document adequate physical examinations; failed to document an objective medical diagnosis, supported by examination or functional status, to support the on-going use of controlled substances; failed to conduct any urine drug screenings to test for controlled substances and non-controlled substances in order to verify compliance and otherwise discover noncompliance, abuse, or diversion, despite Patient M.S. consenting to random drug screenings; failed to execute a Controlled Medication Agreement with Patient M.S. outlining the dangers of dangerous drug combinations until one calendar year after Registrant began prescribing those medications to Patient M.S.; and failed to keep or maintain adequate notes or documents related to the treatment of Patient M.S. and treatment notes were often vague or incomplete. *Id.*

Registrant further admits that from at least March 2023 to October 2024, Registrant prescribed Patient M.S. a dangerous and potentially lethal drug combination of a stimulant, a sedative, and a narcotic. *Id.* Specifically, Registrant admits that she prescribed tramadol, alprazolam, lisdexamfetamine, and phentermine to Patient M.S. *Id.* Registrant admits that this combination put Patient M.S. at a substantial risk of adverse health consequences, including lifelong drug dependence and addiction, overdose, and fatal drug poisoning. *Id.*

DEA retained an independent medical expert who reviewed the prescribing history obtained from the Montana Prescription Drug Reporting system as well as the patient records for Patient M.S. *Id.* DEA's medical expert opined that Registrant's issuance of the above prescriptions fell below the standard of care applicable to the practice of medicine in Montana.

In consideration of the above, the Agency finds substantial record evidence that Registrant issued at least 109 controlled substance prescriptions to Patient M.S., in dangerous combinations, without adequate and accurate documentation, that lacked a legitimate medical purpose and were issued outside the usual course of professional practice in Montana.

IV. Discussion

While the Agency has considered all the public interest factors of 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case primarily implicates Factors B and D. RFAA, at 2–3; RFAAX 1, at 3–5. Evidence is considered under Factor B when it reflects experience dispensing controlled substances and under Factor D when it reflects compliance or non-compliance with laws related to controlled substances. *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022). Although Factors B and D have some overlap, such that the Agency has frequently analyzed them together, Congress must have intended Factor B to encompass conduct that is not captured under Factor D. *See Kungys v. United States*, 485 U.S. 759, 778 (1988) (referencing the “cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant”).

A. Factor B

As already discussed, the CSA gives the Attorney General authority to revoke a registration if he determines that the registrant “has committed such acts as would render his registration . . . inconsistent with the public interest as

determined under [section 823].” 21 U.S.C. 824(a). One of the five factors that the Attorney General must consider in making this determination is the registrant's “experience in dispensing . . . controlled substances.” 21 U.S.C. 823(g)(1)(B) (Factor B). Neither the statute nor the implementing regulations define the term “experience” or place any limitations on the type of conduct that may be considered as “experience” under Factor B.⁵

Historically, the Agency's Factor B⁶ analysis considered “both the qualitative manner and quantitative volume of the [practitioner's] experience . . . as expressed through his patients and employees,” and concluded that the record must contain quantitative evidence regarding the practitioner's experience for the Agency to find that Factor B weighs against a practitioner. *E.g., Clair L. Pettinger*, 78 FR 61592, 61619 (2013). In 2015, the Agency abandoned this language, observing that the text of Factor B did not require DEA to consider the practitioner's “quantity” of prescribing. *See JM Pharmacy Group, Inc.*, 80 FR 28667, 28667–68 (2015); *see also Wesley Pope, M.D.*, 82 FR 14944, 14982 (2017). The Agency reviewed dictionary definitions of “experience,” including:

(1) The “direct observation of or participation in events as a basis for knowledge,” (2) “the fact or state of having been affected by or gained knowledge through direct observation or participation,” (3) “practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,” and (4) “the length of such participation.”

80 FR at 28667 n.2 (citing *Webster's Collegiate Dictionary* 409 (10th ed. 1998); *The Random House Dictionary of the English Language* 681 (2d ed. 1987)).

The word “dispense” means “to deliver a controlled substance[] to an ultimate user or research subject by, or

pursuant to the lawful order of a practitioner, including the prescribing or administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery.” 21 U.S.C. 802(10). This definition encompasses, among other things, practitioners who prescribe controlled substances and pharmacies who fill controlled substance prescriptions. *Id.* The term “controlled substance” simply means “a drug or other substance . . . included in schedule I, II, III, IV, or V” 21 U.S.C. 802(6). Thus, the phrase “experience in dispensing” means the direct participation in the act of delivering, prescribing, dispensing, or administering a controlled substance to an ultimate user.

The phrase “experience in dispensing” must be considered within the context of DEA's broad mandate under 21 U.S.C. 824(a) to deregister practitioners who “ha[ve] committed such acts as would render [their] registration . . . inconsistent with the public interest.” 21 U.S.C. 824(a)(4). In other words, in determining what type of conduct is relevant under Factor B, DEA's primary focus is to determine whether a registrant's “experience in dispensing” is “inconsistent with the public interest” or whether a registrant's dispensing constitutes “acts” that are inconsistent with the public interest. 21 U.S.C. 823(g)(1), 824(a)(4).

The word “inconsistent” is not defined in the CSA, but it is commonly defined as “lacking consistency: such as (a) not compatible with another fact or claim, [and] (b) containing incompatible elements.” *Inconsistent*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/inconsistent> (last visited on the date of signature). “Public interest” is a broad, discretionary term not explicitly defined in the CSA, but Congress identifies the primary goals in the CSA's introductory section as ensuring access to controlled substances used for a “legitimate medical purpose” while protecting the public from the “illegal . . . distribution . . . and improper use of controlled substances[, which] have a substantial and detrimental effect on the health and general welfare of the American people.” 21 U.S.C. 801(1) & (2).

Considering these goals, DEA's Factor B analysis primarily concerns whether a registrant's “experience in dispensing” reflects illegal distribution or improper use of controlled substances that is inconsistent with the public interest. *Id.* In the context of a practitioner, this would require the Agency to evaluate whether he or she has dispensed

⁵ The only limitation discussed in the legislative history on DEA's authority under Factor B is that DEA should not “construe [this factor] in any way to hinder registration of recent graduates of professional schools who may have no professional experience dispensing or conducting research with controlled substances.” H.R. REP. NO. 98–835, pt. 1, at 14 (1984).

⁶ Historically, the Agency referred to “Factor B” as “Factor Two.” Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the CSA and other statutes. Relevant to this matter, the MRA redesignated the public interest factors outlined at 21 U.S.C. 823(f)(1)–(5), which the Agency referred to as Factors One through Five, as 21 U.S.C. 823(g)(1)(A)–(E), which the Agency now refers to as Factors A through E. Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1)(B), “Factor B.”

controlled substances in a manner that is improper, illegal, or inconsistent with the public interest; for example, by issuing prescriptions without conducting a proper examination or developing a supported diagnosis; ignoring patient indications of abuse, diversion, or improper use; issuing a prescription in a manner that is inconsistent with state law or the state's standards of practice; or issuing prescriptions for controlled substances in a way that creates a risk of diversion.⁷

Of course, the Agency is not only concerned with acts of intentional diversion,⁸ as DEA has explained that “[c]areless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .” *Samson K. Orusa, M.D.*, 87 FR 2986, 3018 (2022) (quoting *Paul J. Caragine, Jr.*, 63 FR 51592, 51602 (1998)); see also *MacKay*, 75 FR at 49974 n.35 (“Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.”). Indeed, neither 21 U.S.C. 824(a) nor 21 U.S.C. 823(g) requires DEA to find that a registrant has intentionally diverted controlled substances. Ultimately, a registrant whose dispensing practices create an environment that encourages or is indifferent to the abuse or diversion of controlled substances is acting outside the public’s interest. As the opioid epidemic surges and other controlled substances, such as amphetamines, ketamine, and benzodiazepines, are increasingly abused, DEA must remain vigilant to protect the public against registrants who fail to employ the CSA’s safeguards to ensure the health and general wellness of the American public.

Registrants “may continue to introduce evidence as to . . . lawful . . . dispensing activities.”⁹ However,

the Agency has found that “evidence that a practitioner has treated thousands of patients does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest.”¹⁰ *Krishna-Iyer*, 74 FR at 463. Accordingly, the Agency has consistently rejected registrants’ arguments that acts of unlawful prescribing were mitigated by years of lawful prescribing. See, e.g., *Syed-Jawed Akhtar-Zaidi*, 80 FR 42961, 42967 (2015), pet. for rev. denied, 841 F.3d 707, 713 (6th Cir. 2016) (rejecting respondent’s argument that he was denied a “fair adjudication” because the Government seized 400 patient files but only proved the illegality of a handful of prescriptions issued during undercover visits, and finding that “the physician’s prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which are inconsistent with the public interest”) (internal quotations and citations omitted).¹¹

Here, as found above, Registrant is deemed to have admitted, and the Agency finds, that Registrant issued at least 109 controlled substance prescriptions to a patient in dangerous combinations, without adequate and accurate documentation, that lacked a legitimate medical purpose and were issued outside the usual course of professional practice in Montana. RFAAX 1, at 2–4. The Agency finds that Registrant’s failure to adhere to the minimum standards governing Montana practice reflects “experience in dispensing . . . controlled substances” that created an opportunity for the

acceptance of responsibility and reform of past practices”); see also *Roberto Zayas, M.D.*, 82 FR 21410, 21422 n.27 (2017) (“[T]he Agency properly considers a [registrant’s] evidence of a lengthy history of compliance after the Government makes out its *prima facie* case, as determining what sanction is necessary to protect the public interest is the ultimate purpose of these provisions.”). In other words, this evidence may be relevant to the Agency’s sanctions analysis.

¹⁰ “[E]very registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [their] professional career.” *Krishna-Iyer*, 74 FR at 463. Accordingly, except where the Agency has found in its decision that a prescription was issued outside the public interest or in violation of law, the Agency assumes that all controlled substance prescriptions dispensed by a pharmacy are dispensed for a legitimate medical purpose and in accordance with relevant laws. See *Dewey C. Mackay, M.D.*, 75 FR at 49977.

¹¹ In an unreported opinion, the Sixth Circuit affirmed DEA’s conclusion that the respondent’s acts of unlawful prescribing outweighed his years of work experience. *Orusa v. Drug Enf’t Admin.*, 2023 WL 3886403 at *5 (“Orusa’s credentials and years of work experience, which the agency acknowledged, do nothing to disturb the agency’s detailed review of his prescribing history—the relevant ‘experience in dispensing . . . controlled substances.’”).

abuse or diversion of controlled substances and was outside the public interest. Registrant did not request a hearing and thus did not provide the Agency with any evidence related to her “experience in dispensing” that served the public’s interest. Accordingly, the Agency finds that Factor B weighs strongly against Registrant’s continued registration.¹²

B. Factor D

Under Factor D, the Agency considers a registrant’s “[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.” 21 U.S.C. 823(g)(1)(D). Here, as found above, Registrant is deemed to have admitted and the Agency finds that Registrant issued at least 109 controlled substance prescriptions that lacked a legitimate medical purpose and were issued outside the usual course of professional practice in Montana. Accordingly, the Agency finds substantial record evidence that Registrant violated 21 CFR 1306.04(a); Mont. Admin. R. § 24.159.1204(1)(a), 24.159.1464(1), (4), 24.159.2301(2).

The Agency finds that after considering the public interest factors of 21 U.S.C. 823(g)(1), Factors B and D weigh in favor of revocation of Registrant’s registration. Accordingly, the Government has satisfied its *prima facie* burden of showing that Registrant’s continued registration would be “inconsistent with the public interest.” 21 U.S.C. 824(a)(4). The Agency also finds that there is insufficient mitigating evidence to rebut the Government’s *prima facie* case. Thus, the only remaining issue is whether, in spite of the public interest determination, Registrant can be trusted with a registration.

V. Sanction

Where, as here, the Government has met the burden of showing that Registrant’s registration is inconsistent with the public interest, the burden shifts to Registrant to show why she can be entrusted with a registration. *Morall*,

¹² While the Agency has determined that Registrant’s dispensing conduct is relevant to Factors B and D, to the extent that the found conduct does not fall within these factors, it would nevertheless constitute “other conduct which may threaten the public health and safety.” 21 U.S.C. 823(g)(1)(E). Registrant’s repeated issuing of controlled substances to a patient in dangerous combinations, without adequate and accurate documentation, that lacked a legitimate medical purpose and were issued outside the usual course of professional practice in Montana, may threaten the public health and safety by threatening the health and safety of Registrant’s patient and by creating the risk that controlled substances may leave the CSA’s closed distribution system and be abused or diverted.

⁷ Analysis of whether a prescription is illegally dispensed also fits within Factor D, “Compliance with applicable State, Federal, or local laws relating to controlled substances.” 21 U.S.C. 823(g)(1)(D).

⁸ Only criminally unlawful conduct requires an act of intentional diversion such as proof that a physician “used ‘his authority to prescribe controlled substances . . . not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit’ or some other illegitimate purposes, such as his own ‘personal profit.’” *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006) (quoted in *Laurence T. McKinney*, 73 FR 43260, 43266 (2008)). Compare 21 U.S.C. 823 and 824, with 21 U.S.C. 841, 842, 843.

⁹ *Randall L. Wolff, M.D.*, 77 FR 5106, 5153 (2012) (finding that evidence of lawful prescribing is “entitled to some evidentiary weight only in cases where a practitioner credibly demonstrates an

412 F.3d. at 174; *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.*, 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, the Agency requires that a registrant who has committed acts inconsistent with the public interest accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *See Jones Total Health Care Pharmacy*, 881 F.3d at 833; *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995). The Agency requires a registrant's unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.*, 83 FR 29,569, 29,573 (2018); *see also Jones Total Health Care Pharmacy*, 881 F.3d at 830–31. In addition, a registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 830–31; *Hoxie*, 419 F.3d at 483–84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *See Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Jeffrey Stein, M.D.*, 84 FR at 46972–73.

Here, Registrant did not request a hearing or answer the allegations in the OSC and was therefore deemed to be in default. *See supra* I. To date, Registrant has not filed a motion with the Office of the Administrator to excuse the default. 21 CFR 1301.43(c)(1). Registrant has thus failed to answer the allegations contained in the OSC and has not otherwise availed herself of the opportunity to refute the Government's case. As such, Registrant has not accepted responsibility for the proven violations, has made no representations regarding her future compliance with the CSA, and has not demonstrated that she can be trusted with registration. Accordingly, the Agency will order the revocation of Registrant's registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(g)(1), I hereby

revoke DEA Certificate of Registration No. ML4889347 issued to Alexandra Renee Lovec, A.P.R.N. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending application of Alexandra Renee Lovec, A.P.R.N., to renew or modify this registration, as well as any other pending application of Alexandra Renee Lovec, A.P.R.N., for additional registration in Montana. This Order is effective November 9, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 5, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–20751 Filed 10–8–26; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

L Krenk DBA Maui Clinic Pharmacy; Decision and Order

On November 19, 2025, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to L Krenk DBA Maui Clinic Pharmacy of Kahului, Hawaii (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 6. The OSC proposed the revocation of Registrant's DEA registration, No. BL3161178, alleging that its continued registration would be inconsistent with the public interest. *Id.* at 1, 3 (citing 21 U.S.C. 823(g)(1), 824(a)(4)).

More specifically, the OSC alleged that Registrant and its owner, from March 2023 to July 9, 2024, violated federal and state law by dispensing controlled substance prescriptions from an unregistered location, and violated federal law by failing to comply with recordkeeping requirements as evidenced by “significant unexplained overages and shortages of controlled substances.” *Id.* at 4.

On April 16, 2026, the Government submitted an RFAA requesting that the Agency issue a default final order revoking Registrant's registration. RFAA, at 3. After carefully reviewing the entire record and conducting the analysis set forth below, the Agency grants the Government's RFAA and revokes Registrant's registration.

I. Default Determination

Under 21 CFR 1301.43, a registrant entitled to a hearing who fails to file a timely hearing request “within 30 days after the date of receipt of the [OSC] . . . shall be deemed to have waived their right to a hearing and to be in default” unless “good cause” is established for the failure. 21 CFR 1301.43(a), (c)(1). In the absence of a determination of good cause, a registrant who fails to timely file an answer also is “deemed to have waived their right to a hearing and to be in default.” 21 CFR 1301.43(c)(2). Unless excused, a default is deemed to constitute “an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

The OSC informed Registrant that it has a right to file a written request for hearing and answer, and that if it failed to file such a request and answer, it would be deemed to have waived its right to a hearing and to be in default.¹ RFAAX 1, at 5 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing or file an answer. RFAA, at 1–2. Further, the Agency notes that more than forty-five days have passed since the OSC was served on Registrant, yet the Agency has not received a motion by Registrant to be excused from default for good cause. 21 CFR 1301.43(c)(1). Thus, the Agency determines that Registrant is in default and, therefore, Registrant is deemed to admit the factual allegations in the OSC. 21 CFR 1301.43(c)(1), (e), (f)(1).

II. Public Interest Determination

A. Overview of Law

Congress enacted the Controlled Substances Act (CSA) “to conquer drug abuse and control the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Raich*, 545

¹ According to a Declaration that a DEA Special Agent (SA) signed under penalty of perjury, SA and a Task Force Officer personally served the OSC on the owner of Registrant, Mr. Leslie Krenk, at Registrant's registered address on November 21, 2025. RFAA, SA Declaration Attachment, at 1. The record also includes a signed Form DEA–12, which supports the content of the SA Declaration that the OSC was personally served on Registrant's owner on November 21, 2025. RFAA, Exhibit 2, at 1. The Agency, thus, determines that service of the OSC on Registrant was legally sufficient and took place on November 21, 2025. It is now more than thirty days since Registrant received service of the OSC.

U.S. 1, 12 (2005). A particular concern of Congress was “the need to prevent the diversion of drugs from legitimate to illicit channels,” and it “devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Id.* at 12–13.

The CSA requires, under this closed regulatory system, that “[e]very person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the [DEA] a registration.” 21 U.S.C. 822(a)(2); *Gonzales v. Raich*, 545 U.S. at 27–28. To protect the American people and ensure compliance with the CSA, Congress empowered the Agency to deny, suspend, or revoke a registration if granting or continuing a registration “would be inconsistent with the public interest.” 21 U.S.C. 823(g)(1), 824(a)(4); *Gonzales v. Oregon*, 546 U.S. 243, 251 (2006).

In determining whether a registrant’s registration would be inconsistent with the public interest, the Agency analyzes five statutorily established “public interest factors.” *Gonzales v. Oregon*, 546 U.S. at 251; 21 U.S.C. 823(g)(1)(A)–(E). The five factors are:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The [registrant]’s experience in dispensing, or conducting research with respect to controlled substances.

(C) The [registrant]’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

These five public interest factors are considered in the disjunctive. *Gonzales v. Oregon*, 546 U.S. at 292–93 (Scalia, J., dissenting); *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993). Any one factor, or combination of factors, may be decisive, *Gillis*, 58 FR at 37508, and the Agency “‘may give each factor the weight . . . deem[ed] appropriate in determining whether a registration should be revoked or an application for registration denied.’” *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 185 n.2 (D.C. Cir. 2005) (Henderson, J., concurring) (quoting *Robert A. Smith, M.D.*, 70 FR 33207, 33208 (2005)); see *Penick Corp., Inc. v. Drug Enf’t Admin.*, 491 F.3d 483, 490 (D.C. Cir. 2007). The Agency has taken

this approach for decades. See *Henry J. Schwarz, Jr., M.D.*, 54 FR 16422, 16424 (1989) (determining, in 1989, that “[t]he [Agency] need not make findings as to all of the factors . . . [and that the Agency] may give each factor the weight [it] deems appropriate,” and basing denial on only two factors); *Neveille H. Williams, D.D.S.*, 53 FR 23465, 23466 (1988) (holding, in 1988, and citing a 1986 case, that “[a]ll factors need not be present for the [Agency] to” issue a sanction and that the Agency “may accord each factor the weight [it] deems appropriate in determining the public interest” (citing *Paul Stepak, M.D.*, 51 FR 17556 (1986))).

While the Agency is required to consider each of the factors, it “need not make explicit findings as to each one.” *MacKay v. Drug Enf’t Admin.*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman v. U.S. Drug Enf’t Admin.*, 567 F.3d 215, 222 (6th Cir. 2009)); *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 830 (11th Cir. 2018); *Hoxie v. Drug Enf’t Admin.*, 419 F.3d 477, 482 (6th Cir. 2005). “In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009). Accordingly, Agency decisions have explained that findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

The Government has the burden of proof in this proceeding, 21 CFR 1301.44(e), and the Agency must make its findings based on “substantial [record] evidence.” 5 U.S.C. 556(d); see 5 U.S.C. 706(2); 21 U.S.C. 877. If the Government meets its burden of establishing a *prima facie* case that Registrant’s registration is not in the public interest, then the burden shifts to Registrant to rebut the Government’s case. *Pharmacy Doctor Enters., Inc. v. Drug Enf’t Admin.*, 789 Fed. Appx. 724, 729 (11th Cir. 2019) (citing *Jones Total Health Care Pharmacy*, 881 F.3d at 830).

In this matter, the Government’s evidence is confined to Factors B and D. RFAA, at 1–3. The Agency considers evidence under Factors B and D when the evidence concerns Registrant’s experience in dispensing controlled substances, and Registrant’s compliance with applicable State, Federal, or local laws relating to controlled substances, respectively. See *Ashraf v. United States*, 153 F.4th 1161, 1160–70 (11th

Cir. 2025); *Kareem Hubbard, M.D.*, 87 FR 21156, 21162 (2022).

The CSA also addresses the role of states in the enforcement of its provisions. According to 21 U.S.C. 903, “Application of State law,” “[n]o provision of . . . [Subchapter I] shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.” 21 U.S.C. 903 (the CSA’s non-preemption provision); *Gonzales v. Oregon*, 546 U.S. at 270–71.

The ramifications of the CSA’s non-preemption provision are significant for the Agency’s enforcement of the CSA. As the Supreme Court explains in *Gonzales v. Oregon*, in the context of physicians dispensing controlled substances, the CSA and Supreme Court case law “amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood.” *Id.* at 269–70. The Court continues, explaining that, “beyond this, however, the . . . [CSA] manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States ‘great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.’” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756, 105 S.Ct. 2380, 85 L.Ed.2d 728 (1985)).” *Id.* at 270 (citation modified).

The Supreme Court also states that the “structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States’ police powers.” *Id.* (citing the provisions of 21 U.S.C. 823(g)(1), formerly 21 U.S.C. 823(f), and pointing out that the “Attorney General can register a physician to dispense controlled substances ‘if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices’”). Further, the Supreme Court states, “[w]hen considering whether to revoke a physician’s registration, the Attorney General looks not just to violations of federal laws; but he ‘shall’ also consider

‘[t]he recommendation of the appropriate State licensing board or professional disciplinary authority’ and the registrant’s compliance with state and local drug laws.” *Id.* The Supreme Court also highlights the fact that the “very definition of a ‘practitioner’ eligible to prescribe [controlled substances] includes physicians ‘licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices’ to dispense controlled substances.” *Id.* (citing 21 U.S.C. 802(21)). Finally, the Supreme Court even presaged, cautioned against, and debunked, “conclusions that the CSA effectively displaces the States’ general regulation of medical practice.” *Id.*

As the Supreme Court stated, “[i]n the face of the CSA’s silence on the practice of medicine generally[,] and its recognition of state regulation of the medical profession[,] it is difficult to defend” a statement that state legal requirements for practitioners play no role in enforcement of the CSA. *Id.* at 272. Instead, the CSA’s non-preemption provision means that, except for one instance, the CSA respects, and enforces, state laws regulating the professional actions of federal controlled substance registration holders.²

As specifically relevant to this Registrant and this OSC, for example, the CSA’s non-preemption provision means that Hawaii legal provisions concerning the dispensing of controlled substances from registered locations apply to Registrant along with federal dispensing of controlled substances from registered location requirements. Further, if the alleged violations of Hawaii law are established, they may contribute to a *prima facie* case for revocation of Registrant’s registration. 21 U.S.C. 823(g)(1)(D).

B. Applicable Federal and State Law

The OSC alleges that Registrant (1) dispensed controlled substances from an unregistered location and (2) could

not account for controlled substances. RFAAX 1, at 4.

As for the unregistered location allegations, the CSA’s implementing regulations require every person to obtain a registration to dispense a controlled substance, absent an exemption. 21 CFR 1301.11(a). The CSA’s implementing regulations also require a separate registration for each principal place of business where controlled substances are dispensed. 21 CFR 1301.12(a).

Similarly, Hawaii law requires a separate registration for each principal place of business where Registrant dispenses controlled substances. Haw. Code R. Stat. 23–200–10 (2000).³ Hawaii law also requires a Board of Pharmacy permit before operating, or changing the location of, a pharmacy. Haw. Rev. Stat. 461–14(a) (2008). Further, Hawaii law requires registered pharmacists in charge of a pharmacy to comply with all laws and rules, including a requirement to notify the Pharmacy Board within ten days of changes of business address. Haw. Rev. Stat. 461–11 (2001).

As for the unaccounted-for controlled substances allegations, the CSA’s implementing regulations specify, among other things, requirements for inventories, including initial and biennial inventories.⁴ 21 CFR 1304.11(a)–(c). The CSA’s implementing regulations also state that registrants required to keep records shall maintain, on a current basis, a complete and accurate record of each controlled substance received, sold, or otherwise disposed of. 21 CFR 1304.21(a). Further, the CSA’s implementing regulations state that inventory and other required records must be kept and be available for at least two years for inspection and copying by DEA employees. 21 CFR 1304.04(a).

C. Findings of Fact

In light of Registrant’s default, the factual allegations in the OSC are deemed admitted and are proven by substantial evidence, indeed, proven incontrovertibly and unequivocally, as follows.⁵ 21 CFR 1301.43(e).

³ All but one of the alleged Hawaii legal authority violations involves a statute or regulation currently in effect. The exception is Hawaii Revised Statute 461–21, whose current iteration dates from May 27, 2025. Accordingly, due to the dates of Registrant’s OSC-alleged violations, the Agency is applying the previous iteration of this statute, effective from July 3, 2017, to May 26, 2025, to this adjudication.

⁴ The OSC does not identify a Hawaii legal authority specifically supporting the unaccounted-for controlled substances allegations.

⁵ Registrant is also deemed to admit that it is registered to handle controlled substances in Schedules II through V under DEA registration No. BL3161178, that its registered address is 22 Hana

Prior to mid-March of 2023, Registrant’s registered location was 53 S. Pruunene Street, Suite 120, Kahului, Hawaii 96732. RFAAX 1, at 4. In mid-March, Registrant ceased operations at 53 S. Pruunene Street and began operating from a new location at 22 Hana Highway, Suite B, Kahului, Hawaii 96732. *Id.* Prior to relocating, Registrant failed to inform the Hawaii Pharmacy Board and the State of Hawaii Narcotics Enforcement Board of its intent to move from the S. Pruunene Street location to the Hana Highway location. *Id.* Further, Registrant failed to notify the Hawaii Pharmacy Board of its new address within 10 days of the move. *Id.* Between April 1, 2023, and August 23, 2023, Registrant dispensed approximately 300 prescriptions for various controlled substances, including Schedule II opioids, from the new, unregistered location. *Id.*

For the inspection period of May 1, 2023, through July 9, 2024, Registrant had significant record keeping and inventory discrepancies, resulting in significant, unexplained overages and shortages of controlled substances. *Id.* at 4–5. Between July 9, 2024, and September 17, 2024, DEA collected the necessary documents to conduct an accountability audit of various controlled substances at Registrant for the period of May 1, 2023, through July 9, 2024. *Id.* at 4. The accountability audit revealed a significant number of record keeping and inventory discrepancies by Registrant totaling 4,779 unaccounted-for dosage units. *See id.* at 4–5. Of that total number, 1,804 dosage units are Schedule II (shortage of oxycodone 15 mg and overages of hydrocodone acetaminophen and oxycodone acetaminophen), 708 dosage units are Schedule III (shortage of buprenorphine/naloxone 8–2), and 2,267 dosage units are Schedule IV (shortage of alprazolam 1 mg as well as an overage of Tramadol).⁶ *See id.* at 5.

D. Conclusions of Law

The Agency determines that the OSC’s deemed-admitted factual allegations present *prima facie* cases that Registrant dispensed controlled substances from an unregistered location, in violation of 21 CFR 1301.11(a), 21 CFR 1301.12(a), Haw. Code R. Stat. 23–200–10 (2000), Haw.

Highway, Suite B, Kahului, Hawaii, 96732, that it is licensed in the State of Hawaii as a pharmacy with license number PHY–476, and that it is also licensed by the State of Hawaii Narcotics Enforcement Board with license number E17037. Given these deemed admissions, Registrant does not contest that it is subject to the Agency’s administrative enforcement of the CSA.

⁶ Tramadol is mis-labeled a Schedule V controlled substance in the OSC.

² The *only* circumstance in which Congress set such a uniform national standard in connection with the CSA is in 42 U.S.C. 290bb–2a, a provision concerning the “appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts.” *Gonzales v. Oregon*, 546 U.S. at 270–71. According to the Supreme Court’s analysis, the existence of this provision concerning the appropriate methods of professional practice in the medical treatment of classes of narcotic addicts “strengthens the understanding of the CSA as a statute combating recreational drug abuse,” and “also indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute.” *Id.* at 272 [emphasis added].

Rev. Stat. 461–14(a) (2008), and Haw. Rev. Stat. 461–11 (2001). *Supra* Section II.C. The Agency further determines that the OSC’s deemed-admitted factual allegations present *prima facie* cases that Registrant had unaccounted-for controlled substances, in violation of 21 CFR 1304.11(a–c), 21 CFR 1304.21(a), and 21 CFR 1304.04(a). *Id.*

E. Public Interest Conclusion

While the Agency considered all the public interest factors of 21 U.S.C. 823(g)(1), its determinations are relevant to Factor B (experience dispensing controlled substances) and Factor D (compliance with applicable State, Federal, or local laws relating to controlled substances). 21 U.S.C. 823(g)(1); *Pharmacy Doctors*, 789 Fed. App’x at 729–30, *accord Jones Total Health Care Pharmacy*, 881 F.3d at 829–30, *Hoxie v. Drug Enf’t Admin.*, 419 F.3d at 481–82; *Kareem Hubbard, M.D.*, 87 FR at 21162. Accordingly, the Agency determines that, after considering the public interest factors, and the facts deemed admitted by virtue of Registrant’s default, the Government satisfied its *prima facie* burden of showing that Registrant “has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest.” 21 U.S.C. 824(a)(4). The Agency further finds that, in light of Respondent’s failure to respond, there is no mitigating evidence to rebut the Government’s *prima facie* case. Thus, the only remaining issue is whether revocation of Registrant’s registration is the appropriate sanction.

III. Sanction

Where, as here, the Government presented a *prima facie* case that Registrant’s continued registration would be inconsistent with the public interest, the burden shifts to Registrant to show why it can be entrusted with a registration. *Morall*, 412 F.3d at 174; *Jones Total Health Care Pharmacy*, 881 F.3d at 830; *Garrett Howard Smith, M.D.*, 83 FR 18882, 18904 (2018). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant. *Jones Total Health Care Pharmacy*, 881 F.3d at 833; *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019). Moreover, as “past performance is the best predictor of future performance,” the Agency requires that a registrant who has committed acts inconsistent with the public interest accepts responsibility for those acts, understands the gravity and seriousness of the misconduct, and demonstrates that the registrant will not engage in

future misconduct. *ALRA Labs., Inc. v. Drug Enf’t Admin.*, 54 F.3d 450, 452 (7th Cir. 1995); *Jones Total Health Care Pharmacy*, 881 F.3d at 831–33. The Agency requires a registrant’s unequivocal acceptance of responsibility. *Janet S. Pettyjohn, D.O.*, 89 FR 82639, 82641 (2024); *Mohammed Asgar, M.D.*, 83 FR 29569, 29573 (2018); *Jones Total Health Care Pharmacy*, 881 F.3d at 830–31. In addition, a registrant’s candor during the investigation and hearing, if one is requested, is an important factor in determining acceptance of responsibility and the appropriate sanction. *Jones Total Health Care Pharmacy*, 881 F.3d at 830–31; *Hoxie*, 419 F.3d at 483–84. Further, the Agency considers the egregiousness and extent of the misconduct as significant factors in determining the appropriate sanction. *Jones Total Health Care Pharmacy*, 881 F.3d at 834 & n.4. The Agency also considers the need to deter similar acts by a registrant and by the community of registrants. *Stein*, 84 FR at 46972–73.

Here, Registrant did not timely request a hearing or timely answer the allegations, and is, therefore, deemed to have waived its right to a hearing and to be in default. 21 CFR 1301.43(c)(1), (e), (f)(1); RFAA, at 1–2. Thus, there is no record evidence that Registrant takes responsibility, let alone unequivocal responsibility, for the founded violations. Further, the record evidence is that, on or about September 30, 2019, Registrant and the United States Attorney’s Office for the District of Hawaii entered into a settlement agreement in which Registrant agreed to pay a fine and comply with the CSA and its implementing regulations. RFAAX 1, at 3. The existence of the OSC and this adjudication show that Registrant violated that settlement agreement. Accordingly, Registrant has not convinced the Agency that its future controlled-substance-related actions will comply with the CSA such that the Agency should continue to entrust it with a registration.

Further, the interests of specific and general deterrence weigh in favor of revocation. Registrant’s founded violations concern the CSA’s “strict requirements regarding registration” and, therefore, go to the heart of the CSA’s “closed regulatory system” specifically designed “to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances,” and to the heart of the Agency’s law enforcement mission. *Gonzales v. Raich*, 545 U.S. at 12–14. Registrant’s egregious violations also involve dispensing controlled substances from an unregistered

location, and a combined 4,779 unaccounted-for overages and shortages of controlled substance dosage units. If the Agency were to allow Registrant to maintain its registration under these circumstances, it would send an inaccurate message—that dispensing controlled substances according to minimal state standards and in compliance with state and federal law is not essential to maintaining a registration.

In sum, Registrant has not submitted any record evidence that rebuts the Government’s *prima facie* case for revocation of its registration, and that convinces the Agency that it should continue to entrust Registrant with a DEA registration. The record, thus, supports the imposition of a sanction. Accordingly, the Agency will order the revocation of Registrant’s registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BL3161178 issued to L Krenk DBA Maui Clinic Pharmacy. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of L Krenk DBA Maui Clinic Pharmacy to renew or modify this registration, as well as any other pending application of L Krenk DBA Maui Clinic Pharmacy for additional registration in Hawaii. This Order is effective November 9, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 5, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–20750 Filed 10–8–26; 8:45 am]

BILLING CODE 4410–09–P

LEGAL SERVICES CORPORATION**Sunshine Act Meetings**

TIME AND DATE: The Operations and Regulations, Delivery of Legal Services, and Institutional Advancement committees of the Legal Services Corporation (LSC) Board of Directors will meet on October 16 and October 21, 2026, respectively. The Operations and Regulations Committee meeting will begin on October 16 at 11:00 a.m. Eastern Time. The Delivery of Legal Services Committee meeting will begin on October 21 at 12:30 p.m. Eastern Time and Institutional Advancement Committee meeting will begin following the conclusion of the previous meeting. Each meeting will continue until the conclusion of the Committee's agenda.

PLACE: Public Notice of Virtual Meeting.

LSC will conduct its October 16 and October 21, 2026, meetings virtually via videoconference.

Public Observation: Unless otherwise noted herein, the committee meetings will be open to public observation via LSC's YouTube channel: <https://www.youtube.com/@LegalServicesCorp/streams>.

STATUS: Open, except as noted below.

Operations and Regulations Committee—Open.

Delivery of Legal Services Committee—Open.

Institutional Advancement Committee—Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to consider and act on the approval of invitees to the Leaders Council and Emerging Leaders Council.

Any portion of the closed sessions consisting solely of briefings does not fall within the Sunshine Act's definition of the term "meeting" and, therefore, the requirements of the Sunshine Act do not apply to such portion of the closed session.

A verbatim written transcript will be made of the closed session of the Institutional Advancement Committee. The transcript of any portions of the closed session falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6), (7), (9) and (10), will not be available for public inspection. A copy of the General Counsel's certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

Meeting Schedule*1. Friday, October 16, 2026*

a. Operations and Regulations Committee Meeting

Start Time—11:00 a.m. ET

i. Matters to be discussed include a briefing on performance management and talent management; considering and acting on the final rule for 45 CFR parts 1630—Cost Standards and Procedures and 1631—Purchasing and Property Management; and considering and acting on notice of proposed rulemaking for 45 CFR part 1631—Purchasing and Property Management.

2. Wednesday, October 21, 2026

a. Delivery of Legal Services Committee Meeting

Start Time—12:30 p.m. ET

i. Matters to be discussed include an update on performance areas 1 and 3; a panel conversation about impact litigation; and comments from the Client Leaders Council.

b. Institutional Advancement Committee Meeting

i. Matters to be discussed include Chairman's Report and update on the Leaders Council and Emerging Leaders Council; a development update; privately funded project highlights; and a communications update.

CONTACT PERSON FOR MORE INFORMATION:

Kimberly Little, Board and Executive Coordinator, at (202) 295-1500. Questions may also be sent by electronic mail to the Office of the Corporate Secretary at updates@lsc.gov.

Non-Confidential Meeting Materials: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at <https://www.lsc.gov/about-lsc/board-meeting-materials>.

(Authority: 5 U.S.C. 552b.)

Dated: October 7, 2026.

Stefanie Davis,

Deputy General Counsel, Legal Services Corporation.

[FR Doc. 2026-20788 Filed 10-7-26; 4:15 pm]

BILLING CODE 7050-01-P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 26-10]

Millennium Challenge Corporation Selection Criteria and Methodology Report for Fiscal Year 2027

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: The Millennium Challenge Act of 2003 (the "Act"), as amended, requires the Millennium Challenge Corporation ("MCC") to publish a report that identifies the criteria and methodology that MCC intends to use to determine which candidate countries may be eligible to be considered for assistance under the Act for fiscal year 2027. The report, described in 608(b)(1) of the Act, is set forth in full below. The Act further requires the Chief Executive Officer to accept public comment for the 30-day period beginning on the date of publication in the **Federal Register** of the information contained in the report set forth below, and to consider such comment for purposes of determining eligible countries under section 607 of the Act.

DATES: Comments are due by November 9, 2026.

ADDRESSES: Please send all written comments by email to developmentpolicy@mcc.gov.

FOR FURTHER INFORMATION CONTACT: Dan Barnes, 202-521-3600, developmentpolicy@mcc.gov.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: Each year MCC solicits and considers public comment for 30 days after publication of the country selection criteria and methodology. To submit a public comment, send an email to developmentpolicy@mcc.gov.

(Authority: 22 U.S.C. 7707(b)(2) and 22 U.S.C. 7707(c)(1))

Dated: October 6, 2026.

Brian Finkelstein,

Acting Vice President, General Counsel, and Corporate Secretary.

Millennium Challenge Corporation Selection Criteria and Methodology Report for Fiscal Year 2027

This document explains how the Board of Directors (the Board) of the Millennium Challenge Corporation (MCC) will identify, evaluate, and select eligible countries for fiscal year (FY) 2027. The document discusses the following:

- (I) Which countries MCC will evaluate
- (II) How the Board evaluates those countries

- A. Overall evaluation
- B. For selection of a country for a first compact
- C. For selection of a country for a subsequent compact
- D. For selection of a country for a concurrent compact
- E. For threshold program assistance
- F. A note on potential transition out of MCC's candidate pool after initial selection

This report is provided in accordance with section 608(b) of the Millennium Challenge Act of 2003, as amended (the Act), as more fully described in Appendix A.

(I) Which countries are evaluated?

MCC evaluates the policy performance of all candidate countries and statutorily-prohibited countries by dividing them into separate income categories for the purposes of creating "scorecards," which utilize objective and quantitative data to measure countries' policy performance on statutorily mandated criteria. These scorecard categories are used to account for the income bias that occurs when countries with more per capita resources perform better than countries with fewer. Appendix B lists all candidate countries and statutorily-prohibited countries for scorecard evaluation purposes and their income category. In FY 2027, those scorecard evaluation income categories¹ are:

- Countries with gross national income (GNI) per capita of \$2,225 or less;
- Countries with GNI per capita between \$2,226 and \$4,635; and
- Countries with GNI per capita between \$4,636 and \$8,105

(II) How does the Board evaluate these countries?

A. Overall evaluation

By statute, when evaluating candidate countries for compact eligibility, the Board assesses (1) performance on a set of statutorily mandated eligibility criteria; (2) the opportunity to invest in shared prosperity, promote economic growth, and reduce poverty; and (3) the availability of MCC funds.

(1) Policy Performance on Statutorily Mandated Eligibility Criteria

By statute, the Board relies, to the maximum extent possible, upon the

best-available objective and quantifiable policy performance indicators. These indicators evaluate country policy performance in a comparable, cross-country fashion. Comprised of 22 third-party indicators in the statutory categories of ruling justly, encouraging economic freedom, and investing in people, MCC scorecards are created for all candidate countries and statutorily-prohibited countries. Appendix C lists the 22 indicators that comprise the MCC scorecards and their relationship to the statutory criteria. MCC routinely conducts reviews of its indicators to ensure that current indicators remain relevant, effective, and transparent in measuring the statutorily mandated eligibility criteria, including ensuring that MCC is employing the best data available. MCC is committed to reviewing data annually to ensure continued alignment with statutory principles and administration priorities. To "pass" most indicators on the scorecard, a country's score on each indicator must be above the median score *in its income group* (as defined above for scorecard evaluation purposes). For the inflation, government accountability, and personal freedom indicators, however, MCC has established minimum or maximum scores for "passing." In particular, the Board considers whether a country:

- passes at least 11 of the 22 indicators,
- passes the Personal Freedom indicator; and
- passes either the Control of Corruption indicator or Government Accountability indicator.

While satisfaction of all three aspects means a country is termed to have "passed" the scorecard, the Board also considers whether the country performs "substantially worse" in any one policy category than it does on the scorecard overall.

The mandatory passing of the Personal Freedom indicator is called the Personal Freedom "hard hurdle" on the scorecard, while the mandatory passing of either the Control of Corruption or Government Accountability indicator is called the Control of Corruption and Accountability "hard hurdle." Not passing *either* "hard hurdle" results in not passing the scorecard overall, regardless of whether at least 11 of the 22 total indicators are passed.

- *Personal Freedom "hard hurdle:"*

This hurdle sets a minimum bar for personal freedom below which the Board will not consider a country for compact eligibility. This indicator creates an incentive for countries to undertake reform, recognizes the relationship between freedom and

prosperity, and holds MCC to the high standard of working with the best governed countries.

- *Control of Corruption and Accountability "hard hurdle:"* Corruption in any country is an unacceptable tax on economic growth and an obstacle to private sector investment. The Control of Corruption and Accountability "hard hurdle" helps ensure that MCC works with countries committed to combatting corruption and strengthening transparent and accountable governance. When a candidate country only passes one of the two indicators comprising the hurdle (instead of both), the Board is provided with information that closely examines the reason it is not passing one of the indicators to understand the broader governance environment and trajectory of the country. This includes consultation with U.S. Embassy officials, interagency partners, and other experts.

A country's scorecard performance is a key factor the Board uses to select countries for an MCC program. The Board, however, also recognizes that even the best-available data have inherent challenges. Data gaps, real-time events versus data lags, the absence of narratives and nuanced detail, and other data features affect each indicator. As a result, the Board uses its judgment to interpret policy performance as measured by the scorecards. The Board also consults other sources of information to enhance its understanding of country context (*e.g.*, specific policy issues related to trade, U.S. business opportunities, other U.S. engagement with the country, financial sector performance, and security/foreign policy concerns). The Board uses its judgement on how best to weigh such information in assessing overall policy performance and making a final determination.

(2) The Opportunity to Advance America First Priorities and Invest in Shared Prosperity

Beyond the scorecards, the Board considers a range of information sources depending on the country. Examples include sources that provide a better understanding of:

- a country's economy and business enabling environment;
- market fundamentals, trade dynamics, and opportunities to facilitate strategic U.S. business investments and exports;
- the potential to strengthen supply chains critical to shoring up the American industrial base including critical minerals and reduce reliance on strategic competitors; the potential for

¹ The first two income groups align with the definition of low income and lower middle income countries using the historical International Development Association (IDA) threshold published by the World Bank. The third category was added in FY 2025 by the passage of the Millennium Challenge Corporation Candidate Country Reform Act and includes a subset of upper middle income countries.

the private sector to lead investment and growth, including the potential for an MCC program to unlock strategic investment opportunities for interagency partners, including the International Development Finance Corporation, the U.S Trade and Development Agency, and the Export-Import Bank of the United States; and

- the control of corruption and rule of law.

Where applicable, the Board also considers MCC's own experience and ability to work with a country to promote investments that provide mutual benefit, including by considering MCC's core areas of expertise and skills versus a country's needs, and MCC's capacity to work with a country.

This information provides greater clarity regarding the opportunity for MCC investments to advance the foreign policy objectives described in the National Security Strategy of the United States and make America safer, stronger, and more prosperous.

(3) The Availability of MCC Funds

The Board considers the availability of funds when evaluating countries. This includes consideration of MCC's pipeline of countries in program development, implementation, and closure. Consequently, the Board factors in MCC's overall portfolio when making its selection decisions given current and projected funding availability.

* * *

The following subsections describe how the Board applies each of these three statutorily-mandated factors to: selection of countries for compacts, selection of countries for subsequent compacts, selection of countries for the threshold program, and selection of countries for concurrent compacts. A note follows on considerations for countries that might transition out of MCC's candidate pool after initial selection.

B. Evaluation for Selection of a Country for a First Compact

When selecting countries for a compact, the Board looks at the statutorily-mandated aspects described in the previous section, including a country's performance on the MCC scorecard, evidence of a country's commitment to working in areas that advance shared prosperity, including by ensuring a positive enabling environment for economic growth and private sector investment (including specifically strategic investment and export opportunities for U.S. businesses), and the availability of funding.

At a minimum, the Board considers whether a country passes its scorecard. Where applicable, previous threshold program information is also considered. For those countries currently developing or implementing a threshold program, the Board examines the progress the country has made toward substantial implementation.

C. Evaluation for Selection of a Country for a Subsequent Compact

Section 609(l) of the Act authorizes MCC to enter into "one or more subsequent Compacts. . . after the expiration of the existing Compact." MCC does not consider the eligibility of a country for a subsequent compact until 18 months before the existing compact's end date. Selection for a subsequent compact is not automatic and is intended for countries that (1) exhibit successful performance on their previous compact(s); (2) exhibit improved policy performance on the eligibility criteria assessed by the scorecard during the partnership; and (3) exhibit a commitment to further sector reform.

(1) Successful implementation of the previous compact(s)

To evaluate any previous compact's success, the Board examines whether the compact succeeded within its budget and time limits, in particular by looking at three aspects of each compact program:

- *The degree to which there is evidence of strong political will and management capacity;*
- *The degree to which the country has exhibited commitment and capacity to achieve program results; and*
- *The degree to which the country has implemented the compact in accordance with MCC's core policies and standards.*

Appendix D provides details regarding the information types examined and sources used.

(2) Improved policy performance

The Board also expects the country to improve its overall policy performance on the eligibility criteria assessed by the scorecard during the partnership and to pass the scorecard in the year of selection for the subsequent compact. The Board considers the trajectory of a country's overall policy performance on key indicators over time.

While the Board expects the country to be passing its scorecard, the Board also examines other sources of information to understand the nuance and reasons behind scorecard performance over time. The Board also consults other information sources to

look at policy performance over time in areas not covered by the scorecard, but that the Board deems to be important (such as trade, strategic U.S. business opportunities, supply chains critical for domestic manufacturing including critical minerals, and foreign policy concerns).

(3) A commitment to further sector reform

The Board expects subsequent compacts to endeavor to tackle policy reforms necessary to unlock an identified constraint to economic growth. Consequently, the Board considers MCC's own experience during the previous compact in considering how committed the country is to advancing investments in shared prosperity and economic growth. This includes assessing:

- The country's delivery of policy reform during the previous compact (as described above);
- Expectations of the country's ability and willingness to continue sector policy reform;
- The opportunity to invest in shared prosperity and advance America First priorities (as outlined in A.2 above);
- The prior compact's relative success overall (as discussed above), and how well future funding can be leveraged for impact, given the country's experience in the previous compact.

D. Evaluation for Concurrent Compacts

Section 609(k) of the Act authorizes MCC to enter into one additional concurrent compact with a country if one or both of the compacts with the country is for the purpose of regional economic integration, increased regional trade, or cross-border collaboration.

The fundamental criteria and process for the selection of countries for such compacts remains the same as those for the selection of countries for non-concurrent compacts: countries continue to be evaluated and selected individually, as described in sections II.A, II.B, II.C, and II.F.

Section 609(k) also requires as a precondition for a concurrent compact that the Board determine that the country is making "considerable and demonstrable progress in implementing the terms of the existing Compact and supplementary agreements thereto." This statutory requirement is consistent with prior Board practice regarding the selection of a country for a non-concurrent compact. For a country where a concurrent compact is contemplated, the Board will take into account whether there is clear evidence of success, as relevant to the phase of the current compact. Among other

information, the Board will examine the evaluation criteria described in Section II.C.1 above.

In addition to providing information to the Board so it can make its determination regarding the country's progress in implementing its current compact, MCC provides the Board with additional information relating to the potential for regional economic integration, increased regional trade, or cross-border collaboration for any country being considered for a concurrent compact. This information may include items such as:

- The current state of a country's regional integration, such as common financial and political dialogue frameworks, integration of productive value chains, and cross-border flows of people, goods, and services.
- The current and potential level of trade between a country and its neighbors, including analysis of trade flows and unexploited potential for trade, and an assessment of the extent and significance of tariff and non-tariff barriers, including information regarding the patterns of trade.
- The potential gains from cross-border cooperation between a country and its neighbors to alleviate bilateral and regional bottlenecks to economic growth, such as through physical infrastructure or coordinated policy and institutional reforms.

E. Evaluation for Threshold Program Assistance

The Board also evaluates countries for participation in the threshold program. Threshold programs provide assistance to candidate countries exhibiting a significant commitment to meeting the criteria described in the previous subsections but failing to meet such requirements. Specifically, in examining a candidate country's policy performance, the opportunity to advance shared prosperity and unlock economic growth, and available funds, the Board will consider whether a country appears to be on a trajectory to becoming viable for compact eligibility in the medium or short term.

F. A Note on Potential Transition out of MCC's Candidate Pool After Initial Selection

Some candidate countries may have a high enough per capita income or a high growth rate that implies there is a chance they could transition out of MCC's candidate pool during the life of an MCC partnership. It is not possible to accurately predict if or when such a transition may occur.

Nonetheless, such countries may have more resources at their disposal for

funding their own growth. As a result, in addition to using the regular selection criteria described in the previous sections, the Board will use its discretion to assess both the need and the opportunity presented by partnering with such a country, in order to ensure that MCC's scarce grant funds are directed appropriately.

Accordingly, if a candidate country with a high probability of transitioning out of MCC's candidate pool is under consideration for selection, the Board will examine additional data and information related to:

- Whether the country faces significant challenges accessing other sources of development financing (such as international capital, domestic resources, and other donor assistance) and, if so, whether MCC grant financing would be an appropriate tool;
- Whether there is a clear and strategic opportunity for MCC to assist the country through investments that spur economic growth and shared prosperity, including unlocking strategic U.S. private sector opportunities, securing critical minerals, or advancing other strategic priorities;
- Whether the country demonstrates particularly strong policy performance; and
- Whether MCC can reasonably expect that the country would contribute a significant amount of funding to the compact.

Should a country eventually transition out of MCC's candidate pool during compact development, continuing compact development beyond that point would then be at the Board's discretion.

Appendix A: Statutory Basis for This Report

This report to Congress is provided in accordance with section 608(b) of the Millennium Challenge Act of 2003, as amended (the Act), 22 U.S.C. 7707(b).

Section 605 (22 U.S.C. 7704) of the Act authorizes the provision of assistance to countries that enter into a Millennium Challenge Compact with the United States to support policies and programs that advance the progress of such countries in achieving lasting economic growth and poverty reduction. The Act requires MCC to take a number of steps in selecting countries for compact assistance for FY 2027 based on the countries' demonstrated commitment to just and democratic governance, economic freedom, and investing in their people, MCC's opportunity to generate economic growth in the country and reduce poverty, and the availability of funds. These steps include the submission of reports to the congressional committees specified in the Act and publication of information in the **Federal Register** that identify:

(1) The countries that are "candidate countries" for assistance for FY 2027 based on per capita income levels and eligibility to receive assistance under U.S. law and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act; 22 U.S.C. 7707(a));

(2) The criteria and methodology that MCC's Board of Directors (Board) will use to measure and evaluate policy performance of the candidate countries consistent with the requirements of subsections (a) and (b) of section 607 of the Act (22 U.S.C. 7706) in order to determine "eligible countries" from among the "candidate countries" (section 608(b) of the Act; 22 U.S.C. 7707(b)); and

(3) The list of countries determined by the Board to be "eligible countries" for FY 2027, with justification for eligibility determination and selection for compact negotiation, including those eligible countries with which MCC will seek to enter into compacts (section 608(d) of the Act; 22 U.S.C. 7707(d)).

This report satisfies item 2 above.

Appendix B: Lists of all Candidate Countries and Statutorily-Prohibited Countries for Evaluation Purposes

Income Groups for Scorecards

Since MCC was created, it has relied on the *World Bank's gross national income (GNI) per capita income data* (Atlas method) and the historical ceiling for eligibility as set by the World Bank's International Development Association (IDA) to divide countries into separate income categories for purposes of creating scorecards. These categories are used to account for the income bias that occurs when countries with more per capita resources perform better than countries with fewer. Using the historical IDA eligibility ceiling for the scorecard evaluation groups ensures that the poorest countries compete with their income level peers and are not compared against countries with more resources to mobilize. Following the passage of the Millennium Challenge Corporation Candidate Country Reform Act in FY 2025, MCC began grouping the countries newly added into the income pool by this legislation (countries with GNI per capita above the World Bank's lower middle income/upper middle income country threshold but below the threshold for initiating the International Bank for Reconstruction and Development (IBRD) graduation process) in a third group to maintain this principle of countries competing with their income peers.

In FY 2027, MCC will continue to use the historical IDA classifications for eligibility and the lower middle income/upper middle income country threshold to categorize countries in groups for purposes of FY 2027 scorecard comparisons:

- Countries with GNI per capita equal to or less than IDA's historical ceiling for eligibility (*i.e.*, \$2,225 for FY 2027);
- Countries with GNI per capita above IDA's historical ceiling for eligibility but below the World Bank's lower middle income/upper middle income country threshold (*i.e.*, \$2,226 and \$4,635 for FY 2027); and

• Countries with GNI per capita above the World Bank's lower middle income/upper middle income country threshold but below the threshold for initiating the IBRD graduation process (*i.e.*, \$4,636 and \$8,105 for FY 2027).

The list of countries for FY 2027 scorecard assessments is set forth below:

Countries With GNI per Capita of \$2,225 or Less

1. Afghanistan
2. Benin
3. Burkina Faso
4. Burma
5. Burundi
6. Cameroon
7. Central African Republic
8. Chad
9. Comoros
10. Congo, Dem. Rep.
11. Dem. People's Republic of Korea
12. Eritrea
13. Ethiopia
14. Gambia, The
15. Guinea
16. Guinea-Bissau
17. Haiti
18. Kenya
19. Lao PDR
20. Lesotho
21. Liberia
22. Madagascar
23. Malawi
24. Mali
25. Mauritania
26. Mozambique
27. Nepal
28. Niger
29. Nigeria
30. Pakistan
31. Rwanda
32. Senegal
33. Sierra Leone
34. Solomon Islands
35. Somalia
36. South Sudan
37. Sudan
38. Syrian Arab Republic
39. Tajikistan
40. Tanzania
41. Timor-Leste
42. Togo
43. Uganda
44. Yemen, Rep.
45. Zambia

Countries With GNI per Capita Between \$2,226 and \$4,635

1. Angola
2. Bangladesh
3. Bhutan
4. Bolivia
5. Cambodia
6. Congo, Rep.
7. Cote d'Ivoire
8. Djibouti
9. Egypt, Arab Rep.
10. Eswatini
11. Ghana
12. Honduras
13. India
14. Kiribati
15. Kyrgyz Republic
16. Lebanon
17. Morocco

18. Namibia
19. Nicaragua
20. Papua New Guinea
21. Sao Tome and Principe
22. Tunisia
23. Uzbekistan
24. Vanuatu
25. Venezuela
26. Zimbabwe

Countries With GNI per Capita Between \$4,636 and \$8,105

1. Algeria
2. Azerbaijan
3. Belize
4. Botswana
5. Cabo Verde
6. Colombia
7. Ecuador
8. El Salvador
9. Equatorial Guinea
10. Fiji
11. Gabon
12. Guatemala
13. Indonesia
14. Iran, Islamic Rep.
15. Iraq
16. Jamaica
17. Jordan
18. Kosovo
19. Libya
20. Micronesia, Fed. States
21. Moldova
22. Mongolia
23. Paraguay
24. Philippines
25. Samoa
26. South Africa
27. Sri Lanka
28. Suriname
29. Thailand
30. Tonga
31. Turkmenistan
32. Ukraine
33. Vietnam

Statutorily-Prohibited Countries

1. Afghanistan
2. Burkina Faso
3. Burma
4. Chad
5. Dem. People's Republic of Korea
6. Eritrea
7. Iran
8. Mali
9. Nicaragua
10. Niger
11. South Sudan
12. Sudan
13. Zimbabwe

Appendix C: Indicator Definitions

The following indicators will be used to measure candidate countries' demonstrated commitment to the criteria found in section 607(b) of the Act. The indicators are intended to assess the degree to which the political and economic conditions in a country serve to promote broad-based sustainable economic growth and reduction of poverty and thus provide a sound environment for the use of MCC funds. The indicators are not goals in themselves; rather, they are proxy measures of policies that are linked to broad-based economic growth. The indicators were selected based on (i) their relationship to the

statutorily defined eligibility criteria; (ii) the number of countries they cover; (iii) transparency and availability; and (iv) relative soundness and objectivity. Where possible, the indicators are developed by independent sources.

Ruling Justly

1. Control of Corruption: An index of surveys and expert assessments that rate countries on: "grand corruption" in the political arena; the frequency of petty corruption; the effects of corruption on the business environment; and the tendency of elites to engage in "state capture," among other things. Pass: Score must be above the median score for the income group.

2. Government Accountability: Independent experts rate countries on government accountability and transparency; freedom from domination by the military, foreign powers, totalitarian parties, religious hierarchies, and economic oligarchies; the prevalence of free and fair electoral processes; and political pluralism and participation of all stakeholders, among other things. Pass: Score must be above the minimum score of 17 out of 40.

3. Personal Freedom: Independent experts rate countries on their freedom of expression and belief; association and organizational rights; rule of law and human rights, including religious freedom; and economic rights, among other things. Pass: Score must be above the minimum score of 25 out of 60.

4. Freedom of Information: Measures the legal and practical steps taken by a government to enable or allow information to move freely through society; this includes measures of press freedom, national freedom of information laws, and freedom of speech as measured by the extent to which a country is shutting down social media or the internet. Pass: Score must be above the median score for the income group.

5. Government Effectiveness: An index of surveys and expert assessments that rate countries on the quality of public service provision; civil servants' competency and independence from political pressures; and the government's ability to plan and implement sound policies, among other things. Pass: Score must be above the median score for the income group.

6. Rule of Law: An index of surveys and expert assessments that rate countries on the extent to which the public has confidence in and abides by the rules of society; the incidence and impact of violent and nonviolent crime; the effectiveness, independence, and predictability of the judiciary; the protection of property rights; and the enforceability of contracts, among other things. Pass: Score must be above the median score for the income group.

Encouraging Economic Freedom

1. Business Start-Up: An index that rates countries on the time and cost of complying with all procedures officially required for an entrepreneur to start up and formally operate an industrial or commercial business as well as the overall business environment in a country. Pass: Score must be above the median score for the income group.

2. *Inflation*: The most recent average annual change in consumer prices. Pass: Score must be 15 percent or less.

3. *Regulatory Quality*: An index of surveys and expert assessments that rate countries on the burden of regulations on business; price controls; the government's role in the economy; and foreign investment regulation, among other areas. Pass: Score must be above the median score for the income group.

4. *Trade Policy*: A measure of a country's openness to international trade based on weighted average tariff rates and non-tariff barriers to trade. Pass: Score must be above the median score for the income group.

5. *Women in the Economy*: An index that measures the extent to which laws provide men and women equal capacity to generate income or participate in the economy, including factors such as the capacity to access institutions, get a job, register a business, sign a contract, open a bank account, choose where to live, to travel freely, property rights protections, and protections against domestic violence, among others. Pass: Score must be above the median score for the income group.

6. *Property and Land Rights*: An index that rates countries on the extent to which the institutional, legal, and market framework provides secure land tenure and access to land in rural areas and the extent to which all individuals have the right to private property in practice and in law, including measures of intellectual property rights, risk of expropriation, and the quality of contract enforcement. Pass: Score must be above the median score for the income group.

7. *Access to Credit*: An index that ranks countries based on access and use of formal and informal financial services as measured by the number of bank branches and ATMs per 100,000 adults and the share of adults that have an account at a formal or informal financial institution. Pass: Score must be above the median score for the income group.

8. *Employment Opportunity*: Measures the rights of people to work. Pass: Score must be above the median score for the income group.

9. *International Market Access*: Measures a country government's commitment to the free movement of capital, citizen access to international capital markets, and the barriers to global market access through import or export controls. Pass: Score must be above the median score for the income group.

10. *Market Competitiveness*: Measures a country government's commitment to strengthening market forces in the economy by promoting a business environment that allows for innovation and open competition while limiting expropriation, and monopolies. Pass: Score must be above the median score for the income group.

Investing in People

1. *Health Expenditures*: Total current expenditures on health by government (excluding funding sourced from external donors) at all levels divided by GDP. Pass: Score must be above the median score for the income group.

2. *Chronic Disease*: An indicator measuring the prevalence of chronic diseases. Measures the likelihood of dying between ages 30 and 70 due to cardiovascular disease, cancer,

diabetes, or chronic respiratory disease. Pass: Score must be above the median score for the income group.

3. *Child Health*: An index made up of three indicators: (i) access to improved water, (ii) access to improved sanitation, and (iii) child (ages 1–4) mortality. Pass: Score must be above the median score for the income group.

4. *Natural Resource Protection*: Assesses a country government's commitment to preserving biodiversity and natural habitats, responsibly managing ecosystems and fisheries, and engaging in sustainable agriculture. Pass: Score must be above the median score for the income group.

5. *Workforce Development*: An indicator measuring education within the workforce. This indicator measures the proportion of youth and adults enrolled in training, non-formal education, and formal education in the last 12 months. Pass: Score must be above the median score for the income group.

6. Girls' Education:

a. *Girls' Primary Completion Rate*: The number of female students enrolled in the last grade of primary education minus repeaters divided by the population in the relevant age cohort (gross intake ratio in the last grade of primary). Countries with a GNI/capita of \$2,225 or less are assessed on this indicator. Pass: Score must be above the median score for the income group.

b. *Girls' Lower Secondary Completion Rate*: Countries with a GNI/capita between \$2,226 and \$4,635 are assessed on the number of female pupils that have completed the last grade of lower secondary education divided by the population within three to five years of the intended age of completion, expressed as a percentage of the total population of females in the same age group. Pass: Score must be above the median score for the income group.

c. *Girls' Upper Secondary Completion Rate*: Countries with a GNI/capita of between \$4,636 and \$8,105 are assessed on the number of female pupils that have completed the last grade of upper secondary education divided by the population within three to five years of the intended age of completion, expressed as a percentage of the total population of females in the same age group. Pass: Score must be above the median score for the income group.

Relationship to Statutory Criteria

Within each policy category, the Act sets out a number of specific selection criteria. A set of objective and quantifiable policy indicators is used to inform eligibility decisions for assistance and to measure the relative performance by candidate countries against these criteria. Performance against each of these criteria is assessed by at least one of the objective indicators. Most are addressed by multiple indicators. The specific indicators appear in parentheses next to the corresponding criterion set out in the Act. MCC's statute specifically directs the agency to take into account and assess the role of women and girls across these policy criteria, where appropriate.

Section 607(b)(1): Just and democratic governance, including a demonstrated commitment to—

(A) promote political pluralism, equality and the rule of law (*Government*

Accountability, Personal Freedom, Rule of Law, and Women in the Economy);

(B) respect human and civil rights, including the rights of people with disabilities (*Government Accountability, Personal Freedom, Women in the Economy, Employment Opportunity, and Freedom of Information*);

(C) protect private property rights (*Personal Freedom, Regulatory Quality, Rule of Law, and Property and Land Rights, Women in the Economy*);

(D) encourage transparency and accountability of government (*Government Accountability, Personal Freedom, Freedom of Information, Control of Corruption, Rule of Law, Government Effectiveness, and Employment Opportunity*);

(E) combat corruption (*Control of Corruption, Government Accountability, Personal Freedom, Rule of Law, and Freedom of Information*); and

(F) the quality of civil society enabling environment (*Personal Freedom, Freedom of Information, Employment Opportunity, and Rule of Law*).

Section 607(b)(2): Economic freedom, including a demonstrated commitment to economic policies that—

(A) encourage citizens and firms to participate in global trade and international capital markets (*International Market Access, Inflation, Trade Policy, and Regulatory Quality*);

(B) promote private sector growth (*Market Competitiveness, Inflation, Business Start-Up, Property and Land Rights, Access to Credit, Women in the Economy, and Regulatory Quality*);

(C) strengthen market forces in the economy (*Market Competitiveness, Business Start-Up, Inflation, Trade Policy, Property and Land Rights, Access to Credit, and Regulatory Quality*); and

(D) respect worker rights, including the right to form labor unions (*Employment Opportunity, Personal Freedom, and Women in the Economy*).

Section 607(b)(3): Investments in the people of such country, particularly women and children (*Women in the Economy*), including programs that—

(A) promote broad-based primary education (*Girls' Primary Education Completion Rate, Girls' Lower Secondary Education Completion Rate, Workforce Development, and Employment Opportunity*);

(B) strengthen and build capacity to provide quality public health and reduce child mortality (*Chronic Disease, Health Expenditures, and Child Health*); and

(C) promote the protection of biodiversity and the transparent and sustainable management and use of natural resources (*Natural Resource Protection*).

Appendix D: Subsequent and Concurrent Compact Considerations

MCC reporting and data in the following chart are used to assess threshold program performance, compact performance of MCC compact countries nearing the end of compact implementation (*i.e.*, within 18 months of compact end date), or for current MCC compact countries under consideration

for a concurrent compact, where appropriate. Some reporting used for assessment may contain sensitive information and adversely affect implementation or MCC-partner country relations. This information is therefore for MCC's internal use and is not made public. However, key implementation information is summarized in compact status and results reports that are published quarterly on MCC's website under MCC country programs (www.mcc.gov/where-we-work) and monitoring and evaluation (www.mcc.gov/our-impact/m-and-e) web pages.

For completed compacts, additional information is used to assess compact performance and is found in a country's "Star Report." The Star Report captures key information to provide a framework for results and improve the ability to disseminate learning and evidence throughout the lifecycle of an MCC investment from selection to final evaluation. For each compact and threshold program, evidence is collected on performance indicators, evaluation results, partnerships, sustainability efforts, and learning, among other elements.

In addition to the Star Reports, MCC also surveys staff on topics related to the quality of the partnership during design and implementation of programs, progress toward program results, a partner country's commitment to undertaking policy and institutional reforms, and compliance with MCC standards. Additional information on the survey can be found in the Guide to the Program Surveys: <https://www.mcc.gov/resources/doc/guide-to-the-program-surveys/>.

Topic	MCC reporting/ data source	Published documents
COUNTRY PARTNERSHIP Political Will • Status of major conditions precedent • Program oversight/implementation - o project restructures - o partner response to accountable entity capacity issues • Political independence of the accountable entity Management Capacity • Project management capacity • Project performance • Level of MCC intervention/oversight • Relative level of resources required PROGRAM RESULTS Financial Results • Commitments—including contributions to compact and threshold funding • Disbursements Project Results • Output, outcome, objective targets • Accountable entity commitment to 'focus on results' • Accountable entity cooperation on impact evaluation • Percent complete for process/outputs • Relevant outcome data • Details behind target delays Target Achievements ADHERENCE TO STANDARDS • Fraud and corruption • Procurement • Program closure • IFC Performance Standards • Monitoring and evaluation • All other legal provisions COUNTRY SPECIFIC Sustainability • Implementation entity • MCC investments Role of private sector or other donors • Trajectory of private sector involvement going forward • Other relevant investors/investments • Other donors/programming • Status of related reforms	• Quarterly implementation reporting • Quarterly results reporting • MCC Star Reports • Indicator tracking tables • Quarterly financial reporting • Quarterly implementation reporting • Quarterly results reporting • Impact evaluations • MCC Star Reports • Audits (GAO and OIG) • Quarterly implementation reporting • MCC Star Reports • Quarterly implementation reporting • Quarterly results reporting • MCC Star Reports	• Quarterly results published as "Table of Key Performance Indicators" (available by country): https://www.mcc.gov/itt. • Star Reports (available by country): https://www.mcc.gov/starreport/. • Monitoring and Evaluation Plans (available by country): https://www.mcc.gov/meplan/. • Quarterly results published as "Table of Key Performance Indicators" (available by country): https://www.mcc.gov/itt. • Star Reports (available by country): https://www.mcc.gov/starreport/. • Published OIG and GAO audits • Star Reports (available by country): https://www.mcc.gov/starreport/. • Quarterly results published as "Table of Key Performance Indicators" (available by country): https://www.mcc.gov/itt. • Star Reports (available by country): https://www.mcc.gov/starreport/.

[FR Doc. 2026-20704 Filed 10-8-26; 8:45 am]

BILLING CODE 9211-03-P

NATIONAL CREDIT UNION ADMINISTRATION

Proposed Agency Information Collection Activities; Comment Request

AGENCY: National Credit Union
Administration (NCUA).

ACTION: Notice and request for comment.

SUMMARY: The NCUA has approved the publication of a proposal to revise the NCUA Call Report (Form 5300), which

is a currently approved information collection, for public comment. Revisions include the collection of data on a credit union's involvement with payment stablecoin activities. The NCUA is submitting the following revised form and instructions of a currently approved information collection to the OMB for review and clearance. The revised form and instructions are proposed to take effect with the March 31, 2027, report date.

DATES: Comments must be received on or before December 8, 2026.

ADDRESSES: You may submit written comments on the information collection by any of the following methods:

Federal Register Portal: <https://www.federalregister.gov>. Find this information collection by searching for "National Credit Union Administration", then selecting "Past 90 days", and scrolling through the list of documents.

Regulations.gov: <https://www.regulations.gov/search?filter=ncua>. Find this information collection by scrolling through the search results and looking for NCUA Call Report 2027-Q1.

Rulemakings and Proposals for Comment: <https://ncua.gov/regulation-supervision/rulemakings-proposals-comment>. NCUA will post a link to the [regulations.gov](https://www.regulations.gov) web page where you can

submit a comment by selecting Comment.

Mail: 1775 Duke Street, Suite 6055, Alexandria, Virginia 22314.

Fax: 703-519-8161.

Email: PRAComments@NCUA.gov.

Instructions: All submissions must be identified by the OMB Control Number 3133-0004 or by Document Number (Please send comments by one method only).

FOR FURTHER INFORMATION CONTACT:

Copies of the submission may be obtained by contacting Dacia Rogers at (703) 518-6547. You may also view the entire information collection request at www.reginfo.gov. Enhanced content is also available from the Notice on the **Federal Register** website (www.federalregister.gov). In addition, copies of the Call Report Form and Instructions can be obtained at the NCUA's website (<https://ncua.gov/regulation-supervision/regulatory-reporting/cuonline>).

SUPPLEMENTARY INFORMATION: The NCUA is proposing a revision of the NCUA Form 5300 Call Report and Instructions.

OMB Number: 3133-0004.

Title: NCUA Form 5300 Call Report.

Type of Review: Revision of a currently approved collection.

Abstract: Sections 106 and 202 of the Federal Credit Union Act require federally insured credit unions (FICUs) to make financial and other reports to the NCUA. Section 741.5 describes the submission method FICUs must use to provide information to NCUA. NCUA Form 5300, Call Report, is used to file quarterly financial and statistical data through NCUA's online portal, CUOnline. The financial and statistical information provided by credit unions is essential to NCUA in carrying out its responsibility for supervising federal credit unions. This information facilitates NCUA monitoring credit unions with share accounts insured by the National Credit Union Share Insurance Fund (Share Insurance Fund).

Affected Public: Private sector: Not-for-profit institutions.

Respondents: All federally insured credit unions.

Estimated Number of Respondents: 4,224.

Estimated Average Burden per Response: 47.0 hours.

Estimated Total Annual Burden Hours: 794,112.

Reason for Change: The estimated average burden per response increased based on recent feedback received from the public.

The proposed revisions to Form 5300 and Instructions in this notice would

not have a material impact on the existing burden estimates. The estimated average burden per response figure was updated based on feedback received from the *Request for Information Regarding Enhancing and Streamlining Data Collection from Credit Unions* issued to the public in April 2026.

Legal Basis and Need for Collections: The Call Report Form 5300 information collections are mandatory under 12 U.S.C. 1756, 1766, and 1782. Except for selecting sensitive items, the Call Report Form 5300 is not given confidential treatment.

The credit unions report on the Call Report is essential to the NCUA's supervision and regulation of federal credit unions. This information also facilitates the NCUA's monitoring of other credit unions with Share Insurance Fund coverage for share accounts.

Credit unions submit quarterly Call Report data to the NCUA. Call Report data serves a regulatory or public policy purpose by assisting the NCUA in fulfilling its mission of ensuring the safety and soundness of individual credit unions and the credit union system, protecting consumer financial rights, as well as agency-specific missions affecting federal and state-chartered credit unions, such as ensuring financial stability and administering share insurance.

Form 5300 Call Report—Proposed Changes

Schedule J, Payment Stablecoin Activities (New Schedule)

(1) Adding eight new accounts for reporting custody of reserve assets for permitted payment stablecoin issuer (PPSI) third parties. This information will enhance NCUA's offsite supervision.

(2) Adding nine new accounts for reporting cryptographic key custody and control. This information will enhance NCUA's offsite supervision.

(3) Adding five new accounts for reporting direct exposure to PPSIs. This information will enhance NCUA's offsite supervision.

(4) Adding four new accounts for reporting payment stablecoins held on the credit union's balance sheet. This information will enhance NCUA's offsite supervision.

Request for Comment

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of

public record. The public is invited to submit comments concerning: (a) whether the proposed revisions to the instructions for the collection of information that are the subject of this notice are necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information as proposed to be revised, including the validity of the methodology and 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 the respondents, including the use of automated collection techniques or other forms of information technology.

By the National Credit Union Administration Board.

Melane Conyers-Ausbrooks,
Secretary of the Board.

[FR Doc. 2026-20729 Filed 10-8-26; 8:45 am]

BILLING CODE 7535-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will convene a virtual meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on October 26-27, 2026. Agenda items to be discussed during the public session include: a presentation on the outcome of the pilot on exploring using AI to search data in the Nuclear Materials Event Database (NMED), recommendations from ACMUI's subcommittee on radiopharmaceutical production and distribution safety, a presentation on radiological health at the U.S. Food and Drug Administration (FDA), and a presentation on recent medical events. *The agenda is subject to change.* The current agenda and any updates will be available on the ACMUI's Meetings and Related Documents web page at ACMUI Meetings and Related Documents: 2026 | Nuclear Regulatory Commission or by emailing Ms. Sarah Hoenig at the contact information below. *Purpose:* Discuss issues related to 10 CFR part 35 Medical Use of Byproduct Material.

DATES: *Date and Time for Open Session:* October 26, 2026, from 10:00 a.m. to 2:45 p.m. EDT.

Date and Time for Closed Session: October 27, 2026, from 11:00 a.m. to 12:30 p.m. EDT. This session will be

closed to conduct the ACMUI's required annual training.

ADDRESSES:

Date	Webinar information (Microsoft Teams)
October 26, 2026	Link: https://teams.microsoft.com/meet/213166283153366?p=5pGC3QyZeNAhXyq69K . Meeting ID: 213 166 283 153 366. Passcode: 85E2QM7g. Call in number (audio only): +1 301-576-2978, United States, Silver Spring. Phone conference ID: 739 970 19#.

Public Participation: Any member of the public who wishes to participate in the meeting via Microsoft Teams or via phone should contact Ms. Sarah Hoenig using the information below.

FOR FURTHER INFORMATION CONTACT: Ms. Sarah Hoenig, email: sarah.hoenig@nrc.gov phone: 301-415-3284.

SUPPLEMENTARY INFORMATION:

Conduct of the Meeting

The ACMUI Chair, Hossein Jadvar, MD, Ph.D., will preside over the meeting. Dr. Jadvar will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Sarah Hoenig using the contact information listed above. All submittals must be received by the close of business on October 19, 2026, and must only pertain to the topics on the agenda.
2. Questions and comments from members of the public will be permitted during the meeting, at the discretion of the ACMUI Chair.
3. The draft transcript and meeting summary will be available on ACMUI's website ACMUI Meetings and Related Documents: 2026 | Nuclear Regulatory Commission on or about November 27, 2026.
4. Persons who require special services, such as those for the hearing impaired, should notify Ms. Sarah Hoenig of their planned participation.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily 42 U.S.C. 2201(a)); the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*); and the Commission's regulations in Title 10 of the *Code of Federal Regulations*, Part 7.

Dated at Rockville, Maryland this 7th day of October 2026.

For the U.S. Nuclear Regulatory Commission.

Russell E. Chazell,

Federal Advisory Committee Management Officer.

[FR Doc. 2026-20733 Filed 10-8-26; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2026-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of October 12, 19, 26, and November 2, 9, 16, 2026. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: <https://www.nrc.gov/public-involve/public-meetings/schedule.html>.

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please contact the Reasonable Accommodations Resource by email at Reasonable_Accommodations.Resource@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301-415-1969, or by email at Betty.Thweatt@nrc.gov or Samantha.Miklaszewski@nrc.gov.

MATTERS TO BE CONSIDERED:

Week of October 12, 2026

Thursday, October 15, 2026

9:00 a.m. CDT Nuclear Regulatory Commission Reorganization First 100 Days: Enhancing Reactor and Materials Oversight Integration and Performance (Public Meeting) (Contact: Wesley Held: 301-287-3591)

Additional Information: The meeting will be held in the NRC Region IV offices at 1600 East Lamar Boulevard, Arlington, Texas 76011-4511. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—<https://video.nrc.gov/>.

Week of October 19, 2026—Tentative

There are no meetings scheduled for the week of October 19, 2026.

Week of October 26, 2026—Tentative

There are no meetings scheduled for the week of October 26, 2026.

Week of November 2, 2026—Tentative

There are no meetings scheduled for the week of November 2, 2026.

Week of November 9, 2026—Tentative

There are no meetings scheduled for the week of November 9, 2026.

Week of November 16, 2026—Tentative

There are no meetings scheduled for the week of November 16, 2026.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Wesley Held at 301-287-3591 or via email at Wesley.Held@nrc.gov.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: October 7, 2026.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2026-20755 Filed 10-7-26; 4:15 pm]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 05200051, 05200052, 05200053, and 05200054; NRC–2026–0100]

Fermi America LLC (dba Fermi America); Project Matador Advanced Energy and Intelligence Campus AP1000 Units 1–4; Project Matador Nuclear Units 1–4; Draft Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft Environmental Impact Statement (EIS). The draft EIS is in response to a Combined License (COL) application submitted by Fermi America for the proposed construction and operation of four AP1000 advanced passive pressurized-water reactors—designated as Project Matador Nuclear Units 1–4 (PMN Units 1–4). PMN Units 1–4 would be located at the Project Matador Advanced Energy and Intelligence Campus (Project Matador campus). The draft EIS evaluates the environmental impacts of the proposed action of issuing a COL that would allow the construction of PMN Units 1–4, as well as the environmental impacts of the no-action alternative (*i.e.*, denying the COL application).

DATES: Submit comments on the draft EIS by November 23, 2026. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–0100. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email:* Comments may be submitted to the NRC electronically using the email address

FermiAmericaEnvironmental@nrc.gov.

- *Mail comments to:* Office of Nuclear Material Safety and Safeguards, Mail Stop: TWFN–5–A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Guidance and Publication Branch.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Lance Rakovan, Office of Advanced Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2589; email: Lance.Rakovan@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–0100 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–0100.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The draft EIS is available in ADAMS under Accession No. ML26261A417.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2026–0100 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit

comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

On June 17, 2025, Fermi America submitted the initial portion of its COL application for four AP1000 reactors, PMN Units 1–4 (ADAMS Package Accession No. ML25169A395). The proposed reactors would be located at the Project Matador campus in Carson County, Texas, adjacent to the U.S. Department of Energy’s Pantex Plant. The initial submittal included general, financial, and environmental information. The NRC acknowledged receipt of the initial submittal in a letter dated July 7, 2025 (ADAMS Accession No. ML25182A087). Fermi America’s submission initiated the proposed Federal action of determining whether to issue the requested COL. On August 20, 2025, Fermi America provided a second submittal of the COL application (ADAMS Accession No. ML25232A199), which included non-site-specific technical chapters of the Final Safety Analysis Report. In an acceptance letter dated September 5, 2025, (ADAMS Accession No. ML25240A918), the NRC acknowledged, among other things, Fermi America’s commitment to participate in the pilot program for environmental review under the National Environmental Policy Act of 1969, as amended (NEPA). This pilot involves the preparation of an applicant-prepared draft EIS, under NRC supervision. A notice of intent to prepare an EIS and to conduct a scoping process was published on March 20, 2026 (91 FR 13641).

This notice is being published in accordance with the NEPA, and the NRC’s regulations implementing NEPA under part 51 of title 10 of the *Code of Federal Regulations* (10 CFR), “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” In addition, pursuant to 36 CFR 800.8(c), the NRC is using the process and documentation for the preparation of the draft EIS to comply with section 106 of the National Historic Preservation Act of 1966, as

amended, in lieu of the procedures set forth in 36 CFR 800.3 through 800.6.

III. Discussion

The NRC is issuing the draft EIS for public comment. The draft EIS includes the evaluation of the environmental impacts of the proposed action of issuing a COL that would allow the construction of PMN Units 1–4, as well as the environmental impacts of the no-action alternative. In the draft EIS, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, the preliminary recommendation is that the NRC issue the requested COL to Fermi America contingent upon successful completion of the safety review and unless safety issues mandate otherwise. The NRC staff based its preliminary recommendation on the NRC staff's independent environmental review, the NRC staff's assessment of the applicant-prepared EIS, the NRC staff's consultation with Federal, State, and local agencies and Indian Tribes, and the NRC staff's consideration of public comments received during the scoping process.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: October 5, 2026.

For the Nuclear Regulatory Commission.

Michelle Hayes,

Chief, Advanced Reactor Licensing Branch 2, Division of Advanced Reactor Licensing, Office of Advanced Reactors.

[FR Doc. 2026–20742 Filed 10–8–26; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. K2025–1687; MC2027–2 and K2027–2; MC2027–3 and K2027–3]

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.

DATES: *Comments are due:* October 15, 2026.

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:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

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 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.

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).

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)

1. *Docket No(s):* K2025–1687; *Filing Title:* Request of the United States Postal Service Concerning Modification One to Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 91, Which Includes an Extension of That Agreement; *Filing Acceptance Date:* October 6, 2026; *Filing Authority:* 39 CFR 3041.505, and 3041.515; *Public Representative:* Maxine Bradley; *Comments Due:* October 15, 2026.

III. Summary Proceeding(s)

1. *Docket No(s):* MC2027–2 and K2027–2; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1106, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 6, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

2. *Docket No(s):* MC2027–3 and K2027–3; *Filing Title:* USPS Request to Add New Mid-Market Standardized Distinct Product, PM–GA Contract 1107, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 6, 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. 2026–20739 Filed 10–8–26; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106607; File No. SR–NASDAQ–2026–086]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Transaction Fees at Nasdaq Equity 7, Section 118, To Establish a Tier of Credit for Non-Displayed Orders (Other Than Supplemental Orders) That Provide Liquidity

October 6, 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 September 30, 2026, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “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 Exchange's transaction fees at Nasdaq Equity 7, Section 118, to establish a tier of credit for non-displayed orders (other than Supplemental Orders) that provide liquidity.

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on October 1, 2026.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rulefilings>, 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 purpose of the proposed rule change is to amend the Exchange's schedule of credits, at Equity 7, Section 118(a)(1), which applies to the use of the order execution and routing services of the Nasdaq Market Center for all securities priced at \$1 or more. Until the end of August 2026, the Exchange provided a credit to members for non-displayed orders (other than Supplemental Orders) that provide liquidity. Specifically, the Exchange provided a credit tier (“Old Credit Tier”) of \$0.0015 per share executed in Tape A or Tape B, and \$0.0010 per share executed in Tape C. The Old Credit Tier was available to a member that (i) provided 0.10% or more of Consolidated Volume³ though non-displayed orders (other than midpoint orders) and (ii) increased providing non-displayed liquidity (other than midpoint orders) by 30% or more relative to the member's February 2026 Consolidated Volume provided through non-displayed orders (other than midpoint orders). The Old Credit Tier expired at the end of August 2026.⁴

The Exchange proposes to institute a new version of this credit tier (“New Credit Tier”). The amounts of the New Credit Tier will remain as they were under the expired Old Credit Tier (*i.e.*: \$0.0015 per share executed in Tape A or Tape B, and \$0.0010 per share executed in Tape C). However, the criteria to qualify for the New Credit Tier will change in three ways when compared to the criteria to qualify for the Old Credit Tier: (1) setting the reference month to qualify for the credit tier to August 2026, (2) setting at 5% the level of increased non-displayed liquidity provided (other than midpoint orders) to qualify for the credit tier, and (3) setting a new expiration date of February 2027.

³ Equity 7, Section 118(a) defines Consolidated Volume as the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot.

⁴ See Securities Exchange Act Release No. 105149 (Apr. 3, 2026), 91 FR 17821 (Apr. 8, 2026) (File No. SR–NASDAQ–2026–024) (“Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Transaction Fees at Nasdaq Equity 7, Section 118, To Update and Extend a Tier of Credit for Non-Displayed Orders (Other Than Supplemental Orders) That Provide Liquidity”).

The Exchange believes that the New Credit Tier will incentivize members to increase their non-displayed liquidity (other than midpoint orders) providing activity on the Exchange, which will improve overall market quality.

The Exchange has designated these amendments to Equity 7, Section 118, to be operative on October 1, 2026. Therefore, in accordance with the Rule of Interpretation⁵ in Equity 7, Section 118, the Exchange will begin to apply the New Credit Tier on October 1, 2026, based on a member's qualifying transaction volume during the month of September 2026.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed change to its schedule of credits is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has 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’”⁸

⁵ “Rule of Interpretation: In compliance with Reg NMS Rule 610(d), effective February 2, 2026, for purposes of determining quoting or transaction volumes for fees and incentives qualifications under Section 118(a), (d), (j), and (k), all volume figures will be derived from quoting or trading activity in the prior month. Consequently, new members will receive the base rates in their first month of trading.”

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(4) and (5).

⁸ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, 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.”⁹

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange believes that it is reasonable, equitable, and not unfairly discriminatory to establish the New Credit Tier. This New Credit Tier will encourage members to increase their non-displayed liquidity (other than midpoint orders) providing activity on the Exchange, which will improve overall market quality, to the benefit of all market participants. Instituting a 6-month sunset for the comparative baseline ensures that the baseline being used for the credit tier does not become outdated. To the extent that the Exchange succeeds in increasing the levels of liquidity and activity on the Exchange, then the Exchange will experience improvements in its market quality, which stands to benefit all market participants. The Exchange notes that the New Credit Tier is voluntary. The Exchange further believes that the New Credit Tier is not unfairly discriminatory because it will be

applied uniformly to all members that meet the specified criteria.

The Exchange notes that if there are market participants who are dissatisfied with the proposal, they are free to shift their order flow to competing venues that may offer them more generous pricing or less stringent qualifying criteria.

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.

In terms of intermarket competition, 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 or credit opportunities available at other venues to be more favorable. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. In such an environment, the Exchange must continually adjust its fees and credits to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory and regulatory standards applicable to national securities exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which the New Credit Tier in this market may impose any burden on competition is extremely limited.

In terms of intramarket competition, the Exchange does not believe that its proposal will place any category of Exchange participant at a competitive disadvantage. In this instance, the New Credit Tier is intended to incentivize liquidity-adding activity on the Exchange, and it does not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. By offering the New Credit Tier to market participants that meet certain criteria, the Exchange is enhancing its appeal as a trading venue and encouraging increased participation in its order execution and routing processes, while maintaining a competitive pricing structure. An increase in the activity of these market participants—particularly in response to pricing—facilitates

tighter spreads. This may cause an additional corresponding increase in order flow from other market participants, which would be to the benefit of all market participants.

In sum, if the change proposed herein is unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

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.¹⁰

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: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) 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-NASDAQ-2026-086 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-NASDAQ-2026-086. This

⁹ 59039 (Dec. 2, 2008), 73 FR 74770, 74782-83 (Dec. 9, 2008) (SR-NYSEArca-2006-21)).

¹⁰ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

¹⁰ 15 U.S.C. 78s(b)(3)(A)(ii).

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-NASDAQ-2026-086 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-20711 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106602; File No. SR-MEMX-2026-32]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

October 6, 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 September 30, 2026, MEMX LLC ("MEMX" or the "Exchange") 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

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule

applicable to Members³ (the "Fee Schedule") pursuant to Exchange Rules 15.1(a) and (c). As is further described below, the Exchange proposes to amend the MEMX Options Fee Schedule (the "Options Fee Schedule") by modifying the Volume Tier. The Exchange proposes to implement the changes to the Options Fee Schedule pursuant to this proposal on October 1, 2026. The text of the proposed rule change is provided in Exhibit 5.

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 purpose of the proposed rule change is to amend the Options Fee Schedule by re-naming the existing Volume Tier the "Customer (contra Non-Customer) Volume Tier" and limiting the executions eligible to receive the enhanced rebate under such tier to Customer⁴ capacity executions that add liquidity⁵ in Penny⁶ options where the contra-party is a Non-Customer (*i.e.* a Market Maker,⁷

Professional,⁸ Firm,⁹ Away Market Maker¹⁰ or Broker-Dealer¹¹), as further described below.

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. The Exchange is one of only 18 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than approximately 18.8% of the market share and currently the Exchange represents only approximately 4.0% of the market share.¹² In such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, discontinue, or reduce use of certain categories of products in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange's Fee Schedule sets forth standard rebates and rates applied per contract.

Currently, the Exchange provides a base rebate of \$0.49 per contract for executions made in a Customer capacity that add liquidity in Penny options ("Added Customer Penny Volume").

⁸ As set forth on the Fee Schedule, "Professional" applies to any order for the account of a Professional. The term "Professional" means any person or entity that (A) is not a broker or dealer in securities; and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members. See Exchange Rule 16.1. MEMX Options provides fee qualifier "p" for professional transactions.

⁹ As set forth on the Fee Schedule, "Firm" applies to any order for the proprietary account of an OCC clearing member. MEMX Options provides fee qualifier "f" for firm transactions.

¹⁰ As set forth on the Fee Schedule, "Away Market Maker" applies to any order for the account of a market maker on another options exchange. MEMX Options provides fee qualifier "a" for away market maker transactions.

¹¹ As set forth on the Fee Schedule, "Broker Dealer" applies to any order for the account of a broker-dealer, including a foreign broker dealer. MEMX Options provides fee qualifier "b" for broker-dealer transactions.

¹² Market share percentage calculated as of September 24, 2026. The Exchange receives and processes data made available through the consolidated data feeds (*i.e.*, OPRA).

¹¹ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Rule 1.5(p).

⁴ Customer capacity applies to any order for the account of a Priority Customer. "Priority Customer" means any person or entity that is neither a broker or dealer in securities nor a Professional. See Rule 16.1 of the MEMX Rulebook. MEMX Options provides fee qualifier "c" for Customer transactions.

⁵ MEMX Options provides Fee Code "D" for transactions that add liquidity to the MEMX Options Book.

⁶ MEMX Options provides Fee Code "P" for transactions in Penny options.

⁷ As set forth on the Fee Schedule, "Market Maker" applies to any order for the account of a registered Market Maker. MEMX Options provides fee qualifier "m" for market maker transactions.

Additionally, it offers the Volume Tier, whereby Members are eligible to receive an enhanced rebate of \$0.53 per contract for a qualifying Member's executions of Added Customer Penny Volume by achieving an ADAV¹³ in the Customer capacity in Penny and Non-Penny options that is equal to or greater than 1.2% of the equity and ETF option TCV.¹⁴ As noted on the Fee Schedule, ADAV is calculated on a monthly basis, and Members that qualify for the Volume Tier by achieving the specified ADAV threshold in a particular month will receive the proposed enhanced rebate of \$0.53 per contract for all executions of Added Customer Penny Volume in that month.

Now, the Exchange wishes to modify this tier by limiting the executions eligible to receive the enhanced rebate under this tier to executions of Added Customer Penny Volume that have a contra-party that is a Non-Customer (*i.e.* a Market Maker, Firm, Away Market Maker, or Broker Dealer). Said another way, under the current proposal, executions of Added Customer Penny volume that have a contra-party that is also a Customer will not be eligible to receive the enhanced rebate under the tier, and will receive the base rebate of \$0.49 per contract even if that Member meets the required criteria under the tier. Given this new application, the Exchange proposes to rename the tier the "Customer (contra Non-Customer) Volume Tier" and to make clear on the Fee Schedule which executions are eligible to receive the enhanced rebate under this tier. The Exchange is not proposing to amend the required criteria or the rebate provided under the tier, and as such, all of a Member's Added Customer Penny Volume and Added Customer Non-Penny Volume, regardless of contra-party, shall still continue to count towards the ADAV criteria required to receive the enhanced rebate.

The Exchange believes that the proposed Customer (contra Non-Customer) Volume Tier continues to provide an incremental incentive for Members to strive for higher ADAV on the Exchange to receive the proposed enhanced rebate for executions of Added Customer Penny Volume with a Non-Customer contra-party. As such, the proposed tier is designed to decrease

the Exchange's expenditures, while continuing to incentivize market participants to direct additional order flow to the MEMX Options platform, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants. Further, the Exchange notes that other options exchanges maintain tiered pricing structures whereby enhanced rebates are provided for members that meet certain volume requirements, and other exchanges similarly offer pricing structures for rebates/fees that are dependent upon the contra-party capacity.¹⁵

2. Statutory Basis

The Exchange believes that its proposal to amend the Options Fee Schedule is consistent with the provisions of Section 6 of the Act,¹⁶ in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,¹⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among Members and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act 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, or dealers.

MEMX Options operates in a highly fragmented and 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, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their 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."¹⁸

Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants.

The Exchange believes that the proposed change to modify the category of executions eligible to receive the enhanced rebate under the newly named Customer (contra Non-Customer) Volume Tier is reasonable because competing options exchanges offer similar distinctions between the fees and rebates applicable to executions based on the market participant on the contra-side, and while Customer to Customer transactions will no longer be eligible to receive the enhanced rebate under the proposed tier, they will still receive the standard rebate for all executions of Added Customer Penny Volume, a rebate which is not provided on some competing options exchanges.¹⁹ The Exchange further believes that the proposed change is equitable and not unfairly discriminatory because the enhanced rebate will continue to apply equally to all similarly situated market participants.

For the reasons discussed above, the Exchange submits that its proposed change to the Options Transaction Fee Schedule satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act²⁰ in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding burden on competition, the Exchange

¹³ As set forth on the Fee Schedule, the term "ADAV" means the average daily added volume calculated as the number of contracts added per day. ADAV is calculated on a monthly basis.

¹⁴ As set forth on the Fee Schedule, the term "TCV" means the total consolidated volume calculated as the volume reported by all exchanges to the consolidated transaction reporting plan for the month for which the fees apply.

¹⁵ See, e.g. the MIAx Sapphire Fee Schedule (available at: https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAx_Sapphire_Fee_Schedule_09012026.pdf), and the BOX Options Fee Schedule, (available at: <https://boxexchange.com/regulatory/fees/>) which set forth standard transaction fees and rebates based on the member's capacity as well as the contra-party capacity. On both exchanges, Customer to Customer executions are neither charged nor rebated. BOX Options also provides Public Customer Tiered Volume rebates, and like the Exchange is proposing herein, Customer to Customer executions are exempted from the per contract enhanced rebate provided under such tiers.

¹⁶ 15 U.S.C. 78f.

¹⁷ 15 U.S.C. 78f(b)(4) and (5).

¹⁸ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

¹⁹ See *supra* note 15.

²⁰ 15 U.S.C. 78f(b)(4) and (5).

believes that its transaction pricing is subject to significant competitive forces, and that the proposed tier described herein is appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to decrease the Exchange's expenditures, while continuing to incentivize market participants to direct additional order flow to the MEMX Options platform, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants. Further, MEMX Options' proposed renamed and amended Customer (contra Non-Customer) Volume Tier continues to be in line with the tiered rebates and fees assessed by other options exchanges.²¹ As a result, the Exchange believes that the proposal 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."²²

Intramarket Competition

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed amended tier will apply to all Members uniformly. The opportunity to qualify for the Customer (contra Non-Customer) Volume Tier and thus received an enhanced rebate for executions of Added Customer Penny Volume with a Non-Customer contra party would be available to all Members that meet the associated volume requirement in any month. As described above, the Exchange believes that after giving effect to the change proposed herein, the Customer (contra Non-Customer) Volume Tier continues to be commensurate with the corresponding enhanced rebate under such tier and reasonably related to the enhanced liquidity and market quality that such tier is designed to promote. As such, the Exchange does not believe the proposed changes would impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange does not believe that 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 previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 17 other options exchanges and off-exchange venues. Therefore, no exchange possesses significant pricing power in the execution of option order flow. To the contrary, the proposed change represents a competitive proposal through which the Exchange is seeking to decrease its expenditures, while continuing to incentivize market participants to direct additional order flow to the MEMX Options platform, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members. Accordingly, the Exchange believes that the proposal would not burden, but rather promote, intermarket competition by enabling it to compete with other exchanges that offer similar pricing incentives to market participants.

Additionally, 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."²³ The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition v. SEC*, 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'. . . ."²⁴ Accordingly, the

Exchange does not believe its proposed pricing changes impose 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)(ii) of the Act²⁵ and Rule 19b-4(f)(2)²⁶ 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 shall 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-MEMX-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-MEMX-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

No. 59039 (December 2, 2008), 73 FR 74770, 74782-83 (December 9, 2008) (SR-NYSE-2006-21)).

²⁵ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁶ 17 CFR 240.19b-4(f)(2).

²³ *Id.*

²⁴ *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release

²¹ See *supra* note 15.

²² See *supra* note 18.

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-MEMX-2026-32 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-20707 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106610; File No. 600-47]

Cboe Clear U.S., LLC; Notice of Filing of an Amendment to Application for Registration as a Clearing Agency Under Section 17A of the Securities Exchange Act of 1934

October 6, 2026.

On October 1, 2026, Cboe Clear U.S., LLC ("CCUS") filed with the Securities and Exchange Commission ("Commission") an amendment ("Amendment") to its application on Form CA-1 ("Application") seeking to register as a clearing agency pursuant to Section 17A of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 17Ab2-1 thereunder.¹ CCUS originally filed its Application on June 30, 2026.² CCUS previously amended its Application on July 7 and 17, August 18, and September 4, 2026.³

The Commission is publishing this notice ("Notice of Amendment") to solicit comments on the Amendment.⁴

The Commission will consider any comments received in response to this Notice of Amendment prior to taking any action on the Application with respect to permanent registration. A summary of the Application exhibits modified by the Amendment appears below.

I. Discussion

The Amendment adds two exhibits: (i) in new Exhibit E-6, CCUS provides its Certificate of Good Standing from the state of Delaware, and (ii) in new Exhibit J-2, CCUS provides its most recent disclosure under the CPMI-IOSCO *Principles for Financial Market Infrastructures*.⁵ The Amendment also modifies existing Exhibits A, E-2, E-3, J, L, O, and S of the Application, as described below.

In its amendment to Exhibit A, CCUS has added a table describing the composition of CCUS's current Board of Directors ("Board"), and CCUS has included a note that CCUS's ultimate parent, Cboe Global Markets, Inc. ("CGM"), will evaluate adopting a governance policy providing that it will give due regard to the principles reflected in Articles Fourteenth through Sixteenth of the CGM Third Amended and Restated Certificate of Incorporation with respect to any registered securities clearing agency it controls, including CCUS, in the same manner as those principles apply to its "Regulated Securities Exchange Subsidiaries" (as defined in that document).⁶

In its amendment to Exhibit E-2 ("CCUS Rules"), CCUS has amended CCUS Rules by adding processes for appeal or review of decisions, revising Rule 405 to include portions of the Default Financial Resources Policy, and making other edits for clarity and consistency.

In its amendment to Exhibit E-3 ("LLC Agreement"), CCUS has modified its proposed Ninth Amended and Restated LLC Agreement to include a new section to place limitations on Cboe Clear Digital Holdings, LLC ("Member")'s exercise of reserved authorities to ensure that the Member shall not exercise its reserved authority

in a manner that: (i) impairs the Board's authority to direct the operations of the clearing agency consistent with Section 17A of the Exchange Act; (ii) denies or impairs the fair representation of participants of the clearing agency pursuant to Section 17A(b)(3)(C) of the Exchange Act; or (iii) prevents the Board from being composed or operating in a manner required by the Exchange Act or applicable SEC regulations, including Rule 17Ad-25. CCUS has also added a new definition of "director" that refers to the definition of "director" in Section 3(a)(7) of the Exchange Act, to ensure consistency with Exchange Act requirements. The modifications to the LLC Agreement also require CCUS's annual budget plan to be first reviewed and approved by the Board before going to the Member for written consent and require any auditors of CCUS to be first recommended by the Audit Committee and approved by the Board before going to the Member for written consent.

In its amendment to Exhibit J, CCUS has added description of CCUS's "Open Access Model," which is based on CCUS's open-access framework.

In its amendment to Exhibit L, CCUS has added reference to CCUS's \$25 million in contributed equity or "skin in the game."

In its amendment to Exhibit O, CCUS has added a description of Direct Clearing Members. Exhibit O explains that Direct Clearing Members are entities, not individuals, including proprietary trading firms, commercial firms, corporations, institutional investors or other market participants that trade for their own proprietary accounts "and do not carry customer accounts or otherwise engage in customer-facing brokerage activities." Direct Clearing Member applicants are subject to CCUS's membership and approval process which includes an evaluation of the firm's financial condition, governance, operational capabilities, risk management framework, legal authority and ability to satisfy its obligations to CCUS.⁷

In its amendment to Exhibit S, CCUS has removed its exemption requests related to Regulation Systems Compliance and Integrity.⁷

II. Request for Comment

Interested persons are invited to submit written data, views, and arguments concerning the Application as amended, including whether the Application as amended is consistent with the Exchange Act and the rules and regulations thereunder applicable to clearing agencies (e.g., Exchange Act

²⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78q-1; 17 CFR 240.17ab2-1.

² Notice of filing of the Application was published for comment in the *Federal Register* on July 24, 2026. Release No. 34-105960 (July 21, 2026), 90 FR 46817 (July 24, 2026) ("Notice").

³ On August 18 and September 4, 2026, CCUS amended its application to update certain exhibits for which confidential treatment had been requested. The amendments filed on July 7 and 17 were filed prior to the Notice and included as part of the description of the Application set forth in the Notice.

⁴ Non-confidential aspects of the Application exhibits modified by the Amendment, including any exhibits cited in this Notice of Amendment, are

available on the Commission's website together with the previously filed Application at: <https://www.sec.gov/rules-regulations/commission-orders-notices/other-commission-orders-notices-information/ccus-form-ca-1>.

⁵ See CPMI-IOSCO, *Public quantitative disclosure standards for central counterparties* (Rev. May 2026), <https://www.iosco.org/library/pubdocs/pdf/IOSCOPD819.pdf>; CPMI-IOSCO, *Principles for financial market infrastructures* (Apr. 2012), <https://www.bis.org/publications/principles-financial-market-infrastructures.pdf>.

⁶ Capitalized terms not defined in this Notice of Amendment are defined in the Application.

⁷ 17 CFR 242.1000 through 242.1007.

Rules 17Ad-22, 17Ad-25, 17Ad-26, and Regulation Systems Compliance and Integrity).⁸

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules-regulations/how-submit-comment>); or
- Send an email to rule-comments@sec.gov. Please include File Number 600-47 on the subject line.

Paper Comments

- Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number 600-47. 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-regulations/commission-orders-notices/other-commission-orders-notices-information>).

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 600-47 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-20714 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106603; File No. SR-IEX-2026-39]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Pursuant to IEX Rule 15.110(a) and (c) To Amend the IEX Equities Fee Schedule

October 6, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on September 30, 2026, the Investors Exchange LLC ("IEX" or the "Exchange") 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 self-regulatory organization. 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

Pursuant to the provisions of Section 19(b)(1) of the Act,⁴ and Rule 19b-4 thereunder,⁵ the Exchange is filing with the Commission a proposed rule change to amend the Exchange's equities fee schedule applicable to Members⁶ (the "IEX Equities Fee Schedule")⁷ pursuant to IEX Rule 15.110(a) and (c) to modify some of the criteria to qualify for displayed liquidity adding rebates, modify certain of the rebate amounts, and introduce a new displayed liquidity adding rebate tier. Changes to the IEX Equities Fee Schedule pursuant to this proposal are effective upon filing,⁸ and will be operative on November 1, 2026.

The text of the proposed rule change is available at the Exchange's website at <https://www.iexexchange.io/resources/regulation/rule-filings> and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization 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 self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the IEX Equities Fee Schedule, pursuant to IEX Rule 15.110(a) and (c), to modify some of the criteria to qualify for the Displayed Liquidity Adding Rebate Tiers,⁹ modify certain of the rebate amounts, and introduce a ninth Displayed Liquidity Adding Rebate Tier for executions priced at or above \$1.00 per share.¹⁰ Specifically, IEX proposes to: (i) increase the volume of displayed adding activity on the Exchange required to qualify for five of the Displayed Liquidity Adding Rebate Tiers; (ii) remove Tier 7's alternative qualifying criteria (added at least 25,000,000 ADV of displayed liquidity and traded at least 50,000,000 non-displayed ADV); (iii) establish maximum levels of displayed adding activity for Tiers 7 and 8 of the Displayed Liquidity Adding Rebate tiers; (iv) modify the rebate amounts payable under Tiers 7 and 8; and (v) introduce a ninth Displayed Liquidity Adding Rebate Tier.

Displayed Liquidity Adding Rebate Tiers

IEX currently offers Members eight Displayed Liquidity Adding Rebate Tiers based on the Member's trading or quoting activity in the immediately preceding month.¹¹ These rebates,

⁹ See footnote 4 to the Transaction Fees, Base Rates table and Fee Code Combinations and Associated Fees table of the IEX Equities Fee Schedule, *supra* note 7.

¹⁰ Nothing in this rule filing affects trades below \$1.00 per share ("sub-dollar trades"), which will continue to receive a rebate equal to 0.15% of the total dollar value of the execution ("TDV") for displayed liquidity adding executions. Sub-dollar trades will continue to have no impact on any of the rebate or fee tier calculations for trades with an execution price of \$1.00 per share or more.

¹¹ IEX Equities Fee Schedule, *supra* note 7, Base Rates table (Base Fee Code ML) and Fee Code Combinations and Associated Fees table, footnote 4. Pursuant to Rule 610(d) of Regulation NMS, all IEX Equities transaction fees and rebates are determinable at the time of execution. Accordingly, all transaction fees and rebates that depend on a Member's trading or quoting activity are based on that activity in the immediately preceding month.

⁸ See 17 CFR 240.17ad-22 ("Rule 17Ad-22"), 240.17ad-25 ("Rule 17Ad-25"), and 240.17ad-26 ("Rule 17Ad-26"); 17 CFR 242.1000 through 242.1007 ("Regulation Systems Compliance and Integrity").

⁹ 17 CFR 200.30-3(a)(16).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b-4.

⁶ See IEX Rule 1.160(s).

⁷ See IEX Equities Fee Schedule, available at <https://www.iex.io/resources/trading/fee-schedule>.

⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

which apply equally to executions of Tape A, Tape B, and Tape C securities, are as follows:

- *Tier 1*: provides Member the Exchange's base fee of FREE for all displayed liquidity adding executions priced at or above \$1.00 per share ("Added Displayed Liquidity") if the Member added less than 3,000,000 ADV¹² of displayed liquidity.

- *Tier 2*: provides Member a rebate of \$0.0010 per share for all Added Displayed Liquidity if the Member traded at least 10,000,000 non-displayed ADV¹³ and less than 20,000,000 non-displayed ADV.

- *Tier 3*: provides Member a rebate of \$0.0014 per share for all Added Displayed Liquidity if the Member: (1) added at least 3,000,000 ADV of displayed liquidity and less than 10,000,000 ADV of displayed liquidity; or (2) traded at least 20,000,000 non-displayed ADV; or (3) had an NBBO Time¹⁴ of at least 50% in at least 250 ETPs.

- *Tier 4*: provides Member a rebate of \$0.0016 per share for all Added

Displayed Liquidity if the Member: (1) added at least 10,000,000 ADV of displayed liquidity and less than 15,000,000 ADV of displayed liquidity; or (2) had an NBBO Time of at least 50% in at least 750 ETPs.

- *Tier 5*: provides Member a rebate of \$0.0018 per share for all Added Displayed Liquidity if the Member: (1) added at least 15,000,000 ADV of displayed liquidity and less than 20,000,000 ADV of displayed liquidity; or (2) traded at least 30,000,000 non-displayed ADV.

- *Tier 6*: provides Member a rebate of \$0.0020 per share for all Added Displayed Liquidity if the Member: (1) added at least 20,000,000 ADV of displayed liquidity and less than 30,000,000 ADV of displayed liquidity; or (2) traded at least 40,000,000 non-displayed ADV.

- *Tier 7*: provides Member a rebate of \$0.0022 per share for all Added Displayed Liquidity if the Member: (1) added at least 30,000,000 ADV of displayed liquidity; or (2) added at least 25,000,000 ADV of displayed liquidity and traded at least 50,000,000 non-displayed ADV.

- *Tier 8*: provides Member a rebate of \$0.0023 per share for all Added Displayed Liquidity if the Member added at least 40,000,000 ADV of displayed liquidity.

As set forth above, there are several ways a Member can qualify for the Displayed Liquidity Adding Rebate Tiers 3, 4, 5, and 6, including by exceeding threshold volumes of displayed adding ADV in the prior month. IEX proposes to increase the displayed adding ADV thresholds required to qualify for those specific rebate tiers.¹⁵ IEX also proposes to modify the rebate amounts and qualification criteria applicable to Tiers 7 and 8, and to introduce a new Tier 9, as set forth below.

Specifically, IEX proposes to make the following changes to (i) the displayed adding ADV criteria to qualify for Displayed Liquidity Adding Rebate Tiers 1, 3, 4, 5, 6, 7, and 8; (ii) the displayed adding ADV criteria and rebate amounts for Tiers 7 and 8; and (iii) new proposed Tier 9 in both the Base Rates table description of Fee Code ML and the Displayed Liquidity Adding Rebates Tiers set forth in footnote 4 to the Fee Code Combinations and Associated Fees table:

- *Tier 1*: increase the displayed liquidity adding ADV maximum from less than 3,000,000 to less than 5,000,000 ADV in order to qualify for the fee of "FREE" on displayed liquidity adding executions.

- *Tier 3*: increase the displayed liquidity adding ADV minimum from at least 3,000,000 to at least 5,000,000 ADV and the maximum displayed liquidity adding from less than 10,000,000 ADV to less than 15,000,000 ADV in order to qualify for the rebate of \$0.0014 per share on displayed liquidity adding executions.

- *Tier 4*: increase the displayed liquidity adding ADV minimum from at least 10,000,000 to at least 15,000,000 ADV and the maximum displayed liquidity adding from less than 15,000,000 ADV to less than 20,000,000 ADV in order to qualify for the rebate of \$0.0016 per share on displayed liquidity adding executions.

- *Tier 5*: increase the displayed liquidity adding ADV minimum from at least 15,000,000 to at least 20,000,000 ADV and the maximum displayed liquidity adding from less than 20,000,000 ADV to less than 25,000,000 ADV in order to qualify for the rebate of \$0.0018 per share on displayed liquidity adding executions.

- *Tier 6*: increase the displayed liquidity adding ADV minimum from at least 20,000,000 to at least 25,000,000 ADV in order to qualify for the rebate of \$0.0020 per share on displayed liquidity adding executions. The current maximum displayed liquidity adding of less than 30,000,000 ADV would remain unchanged.

- *Tier 7*: reduce the rebate amount from \$0.0022 to \$0.0021 and establish a maximum displayed liquidity adding of less than 40,000,000 ADV in order to qualify for the proposed rebate of \$0.0021 per share on displayed liquidity adding executions. The current minimum displayed liquidity adding of at least 30,000,000 ADV would remain unchanged. The Exchange also proposes to further modify Tier 7 by removing the alternative qualification criteria of adding at least 25,000,000 ADV of displayed liquidity and traded at least 50,000,000 non-displayed ADV.

- *Tier 8*: reduce the rebate amount from \$0.0023 to \$0.0022, and establish a maximum displayed liquidity adding of less than 50,000,000 ADV in order to qualify for the proposed rebate of \$0.0022 per share on displayed liquidity adding executions. The current minimum displayed liquidity adding of at least 40,000,000 ADV would remain unchanged.

- *New Tier 9*: a Member would be required to add at least 50,000,000 ADV

See Securities Exchange Act Release No. 104541 (January 5, 2026), 91 FR 737 (January 8, 2026) (SR-IEX-2025-39) (amending the Exchange's fee schedule applicable to Members to comply with Rule 610(d) of Regulation NMS).

¹² The IEX Equities Fee Schedule defines "ADV" as average daily volume calculated as the number of shares added or removed (as applicable) that execute at or above \$1.00 per share, per day. ADV is calculated on a monthly basis, based on trading activity in the immediately preceding month, unless otherwise indicated in the Fee Schedule. Routed shares executed away from IEX, and shares executed in auctions and the Opening Process, are not included in the ADV calculation. The Exchange also excludes from its calculation of ADV any trading day on which the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Market Hours and any day with a scheduled early market close. With prior notice to the Exchange, a Member may aggregate its ADV with other Members with which it is affiliated pursuant to Rule 12b-2 under the Act. See IEX Equities Fee Schedule, *supra* note 7, Transaction Fees, Definitions and Notes.

¹³ "Non-displayed ADV" refers to executions with the following Fee Code Combinations: MI, MIB, TI, TIB, TIY, TIYB, TIR, TLW, TLWB, and MIA. See IEX Equities Fee Schedule, *supra* note 7, Transaction Fees, Definitions.

¹⁴ "NBBO Time" means the Member's Percent Time at NBB plus the Member's Percent Time at NBO. "Percent Time at NBB" and "Percent Time at NBO" mean, respectively, the aggregate of the percentage of time during Regular Market Hours in which a Member has a displayed order of at least one round lot at the national best bid ("NBB") or the national best offer ("NBO"). When applied to transaction fees or rebates, NBBO Time is calculated using the Member's quoting activity in the immediately preceding month. For tiers that include NBBO Time as a required criterion, the Exchange determines on a daily basis the number of securities in which the Member met the NBBO Time threshold for that day and, at the end of the month, takes the average (rounded to the nearest whole number) of those daily counts. See IEX Equities Fee Schedule, *supra* note 7, Transaction Fees, Definitions and Notes.

¹⁵ Nothing in this filing changes the other qualification criteria for these rebates. For example, a Member can still qualify for Displayed Liquidity Adding Rebate Tier 3 if the Member had traded at least 20,000,000 non-displayed ADV or had an NBBO Time of at least 50% in at least 250 ETPs.

of displayed liquidity in order to qualify for the proposed rebate of \$0.0023 per share on displayed liquidity adding executions.

Accordingly, the Exchange proposes to amend the description of Base Fee Code ML (“Add displayed liquidity”) in the Base Rates table to revise, in pertinent part, the following criteria:

- “(Member added less than 5,000,000 ADV of displayed liquidity)” with a fee of “FREE” in the “Executions at or above \$1.00” column.

- “(Member: (1) added at least 5,000,000 ADV of displayed liquidity and less than 15,000,000 ADV of displayed liquidity . . .)” with a rebate of “(\$0.0014)” in the “Executions at or above \$1.00” column.

- “(Member: (1) added at least 15,000,000 ADV of displayed liquidity and less than 20,000,000 ADV of displayed liquidity . . .)” with a rebate of “(\$0.0016)” in the “Executions at or above \$1.00” column.

- “(Member: (1) added at least 20,000,000 ADV of displayed liquidity and less than 25,000,000 ADV of displayed liquidity . . .)” with a rebate of “(\$0.0018)” in the “Executions at or above \$1.00” column.

- “(Member: (1) added at least 25,000,000 ADV of displayed liquidity . . .)” with a rebate of “(\$0.0020)” in the “Executions at or above \$1.00” column.

- “(Member added at least 30,000,000 ADV of displayed liquidity and less than 40,000,000 ADV of displayed liquidity)” with a rebate of “(\$0.0021)” in the “Executions at or above \$1.00” column.

- “(Member added at least 40,000,000 ADV of displayed liquidity and less than 50,000,000 ADV of displayed liquidity)” with a rebate of “(\$0.0022)” in the “Executions at or above \$1.00” column.

- “(Member added at least 50,000,000 ADV of displayed liquidity)” with a rebate of “(\$0.0023)” in the “Executions at or above \$1.00” column.

The Exchange also proposes to amend Footnote 4 (Displayed Liquidity Adding Rebate Tiers (Applicable to Executions at or above \$1 for Tape A, B, or C Securities)), which applies to Base Fee Code ML and to Fee Code Combinations ML, MLB, MLY, and MLYB, to reflect the modified qualification criteria and rebates for Tiers 1, 3, 4, 5, 6, 7, and 8, and the criteria and the applicable rebate for proposed Tier 9, as set forth above.

IEX is making no other changes to the IEX Equities Fee Schedule. As noted above, changes to the IEX Equities Fee Schedule pursuant to this proposal are

effective upon filing and will be operative on November 1, 2026.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)¹⁶ of the Act in general, and furthers the objectives of Sections 6(b)(4)¹⁷ and 6(b)(5)¹⁸ of the Act in particular, in that 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, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. For the reasons set forth below, the Exchange believes that the proposed rule change is reasonable, equitable, and not designed to permit unfair discrimination.

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. Based upon informal discussions with market participants, IEX believes that Members and other market participants may be more incentivized to send displayed orders to IEX if the proposed fee structure were adopted. Accordingly, IEX has designed the proposed rebate changes to attract and incentivize displayed orders while providing a fee structure that is fair, equitable, and not designed to permit unfair discrimination because the proposed changes will apply equally to all Members who satisfy the criteria.

The Exchange believes that the proposed amended Displayed Liquidity Adding Rebate Tiers and the proposed new Displayed Liquidity Adding Rebate Tier 9 are reasonable because they are designed to incentivize Members to add a meaningful volume of displayed liquidity on IEX by paying a higher rebate to Members that added progressively more displayed liquidity in the immediately preceding month. The proposed modifications to the displayed adding ADV qualifying criteria for seven of the Displayed Liquidity Adding Rebate Tiers, the proposed modified rebates for Tiers 7 and 8, and the proposed Tier 9, are within the range of rebates offered by competing exchanges, and thus the Exchange does not believe that the proposal raises any new or novel issues not already considered by the Commission in the context of other exchanges’ fees.

The Exchange also believes it is consistent with the Act to base the criteria to qualify for the proposed amended tiers and proposed Tier 9 on the Member’s trading activity on IEX in the immediately preceding month in order to comply with Rule 610(d) of Regulation NMS.

Finally, to the extent this proposed fee change is successful in incentivizing the entry and execution of displayed orders on IEX, such greater liquidity will benefit all market participants by increasing price discovery and price formation as well as market quality and execution opportunities. And, as discussed above, IEX does not believe that any aspect of this proposal raises new or novel issues not already considered by the Commission.

B. Self-Regulatory Organization’s Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that 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. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if fee schedules at other venues are viewed as more favorable. Consequently, the Exchange believes that the degree to which IEX fees could impose any burden on competition is extremely limited, and does not believe that such fees would burden competition between Members or competing venues. Moreover, as noted in the Statutory Basis section, the Exchange does not believe that the proposed changes raise any new or novel issues not already considered by the Commission.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different rebates and fees are assessed on Members, these rebate and fee tiers are not based on the type of Member entering the orders that match, but rather on the Member’s own trading activity on the Exchange. Further, the proposed fee change is intended to encourage market participants to bring increased order flow to the Exchange and contribute to the public price discovery process, which benefits all market participants.

¹⁶ 15 U.S.C. 78f(b).

¹⁷ 15 U.S.C. 78f(b)(4).

¹⁸ 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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) ¹⁹ of the Act.

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 shall institute proceedings under Section 19(b)(2)(B) ²⁰ of the Act 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-IEX-2026-39 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-IEX-2026-39. 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-IEX-2026-39 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-20708 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36356; File No. 813-00421]

DPP Investors 2025 LP and DLA Piper LLP (US)

October 7, 2026.

AGENCY: Securities and Exchange Commission ("Commission" or "SEC").

ACTION: Notice.

Notice of application for an order ("Order") under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the "Act") granting an exemption from all provisions of the Act, except sections 9, 17, 30, and 36 through 53, and the rules and regulations under the Act (the "Rules and Regulations"). With respect to sections 17(a), (d), (f), (g), and (j) of the Act, sections 30(a), (b), (e), and (h) of the Act and the Rules and Regulations and rule 38a-1 under the Act, Applicants request a limited exemption as set forth in the application.

SUMMARY OF APPLICATION: Applicants request an order to exempt certain limited liability companies, partnerships, trusts, corporations or other entities ("Investment Funds") formed for the benefit of eligible employees of DLA Piper LLP (US) and its affiliates from certain provisions of the Act. Each Investment Fund will be an "employees' securities company" within the meaning of section 2(a)(13) of the Act.

APPLICANTS: DPP Investors 2025 LP and DLA Piper LLP (US).

FILING DATES: The application was filed on February 28, 2025, and amended on February 26, 2026 and September 30, 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 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 November 2, 2026, and should be accompanied by proof of service on Applicant, 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. Applicant: Rita Patel, Rita.Patel@dlapiper.com, and Bradley E. Phipps, Bradley.Phipps@dlapiper.com, DLA Piper LLP (US).

FOR FURTHER INFORMATION CONTACT: Stephan N. Packs, Senior Counsel, or Matthew Cook, Branch Chief, at (202) 551-6720 or IMOCC@sec.gov (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended application, dated September 30, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for Applicants 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. 2026-20772 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

¹⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁰ 15 U.S.C. 78s(b)(2)(B).

²¹ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106608; File No. SR–NYSEAMER–2026–89]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the NYSE American Options Proprietary Market Data Fee Schedule To Adopt Fees for One-Minute Intra-Day Volume Reports

October 6, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on September 30, 2026, NYSE American LLC (“NYSE American” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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 [sic] to amend the NYSE American Options Proprietary Market Data Fee Schedule (“Fee Schedule”) to adopt fees for a version of the NYSE Options Open-Close Volume Summary market data product known as the One-Minute Interval Intra-Day Report (the “1-Minute Report”) and make clarifying changes to the Fee Schedule to differentiate between the 1-Minute Report and the version of the NYSE Options Open-Close Volume Summary known as the Ten-Minute Interval Intra-Day Report (the “10-Minute Report”). The proposed rule change is available on the Exchange’s website at www.nyse.com 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 self-regulatory organization 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 those 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 parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt fees for the 1-Minute Report and make clarifying changes to the Fee Schedule to differentiate between the 1-Minute Report and the 10-Minute Report. The Exchange recently adopted the 1-Minute Report as a new data product and the Exchange now proposes to adopt fees for this product.⁴ This proposal is based on similar fee filings by the Cboe Exchange, Inc. (“Cboe”), Cboe C2 Exchange, Inc. (“C2”), Cboe BZX Exchange, Inc. (“Cboe BZX”), Cboe EDGX Exchange, Inc. (“Cboe EDGX”), Miami International Securities Exchange, LLC (“MIAX”), MIAX PEARL, LLC (“MIAX PEARL”), MIAX Sapphire, LLC (“MIAX Sapphire”), and MIAX Emerald, LLC (“MIAX Emerald”) to establish fees for their open-close reports that provide substantively similar data sets as proposed herein, albeit based on the trading activity on those exchanges.⁵

The Exchange proposes to implement fees for the 1-Minute Report on October 1, 2026.

Background

By way of background, the Exchange currently offers two versions of the NYSE Options Open-Close Volume Summary, an End of Day (“EOD”) Volume Summary product and the 10-Minute Report. The EOD Volume Summary provides a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-

Dealer, and Market Maker⁶), side of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The EOD Volume Summary provides proprietary Exchange trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

The Exchange also offers the 10-Minute Report, which provides similar information to that of EOD Volume Summary, except that it is produced and updated every 10 minutes during the trading day. Data is captured in “snapshots” taken every 10 minutes throughout the trading day and is available to subscribers within five minutes of the conclusion of each 10-minute period. The 10-Minute Report provides a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The 10-Minute Report also provides proprietary Exchange trade data and does not include trade data from any other exchange. All open-close data products are completely voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and that potential customers may purchase it only if they voluntarily choose to do so.

As noted above, the Exchange recently adopted the 1-Minute Report, which is the same as the existing 10-Minute Report, except that it is produced and updated every minute during the trading day. The 1-Minute Report is captured in “snapshots” taken every 1 minute throughout the trading day and would be available to subscribers within five minutes of the conclusion of each one-minute period. Similar to the 10-Minute Report, the 1-Minute Report provides a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker), side

⁴ See Securities Exchange Act Release No. 106075 (August 11, 2026), 91 FR 52753 (August 14, 2026) (SR–NYSEAMER–2026–72) (Notice of Filing and Immediate Effectiveness of Proposed Change To Introduce the New One-Minute Interval Intra-Day Report).

⁵ See Securities Exchange Act Release Nos. 104796 (February 10, 2026), 91 FR 6931 (February 13, 2026) (SR–CBOE–2026–011); 103761 (August 21, 2025), 90 FR 41619 (August 26, 2025) (SR–C2–2025–023); 103760 (August 21, 2025), 90 FR 41624 (August 26, 2026) (SR–CboeBZX–2025–116); 104211 (November 18, 2025), 90 FR 52744 (November 21, 2025) (SR–CboeEDGX–2025–075); 104823 (February 11, 2026), 91 FR 7322 (February 17, 2026) (SR–MIAX–2026–06); 104826 (February 11, 2026), 91 FR 7317 (February 17, 2026) (SR–PEARL–2026–05); 104824 (February 11, 2026), 91 FR 7341 (February 17, 2026) (SR–SAPPHIRE–2026–04); and 104825 (February 11, 2026), 91 FR 7346 (February 17, 2026) (SR–EMERALD–2026–03).

⁶ See Exchange Rule 900.2.NY for the definitions of the terms Customer, Professional Customer, Firm, and Market Maker.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The 1-Minute Report would provide proprietary Exchange trade data and would not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Proposed Rule Change

The Exchange proposes to amend the Fee Schedule to provide that market participants may purchase the 1-Minute Report on a subscription basis or by ad-hoc request for a specified month or series of months (historical file). The Exchange proposes a fee of \$8,000 per month for subscribing to the 1-Minute Report. The Exchange also proposes a fee of \$4,000 per request per month for an ad-hoc request of historical data for the 1-Minute Report covering all Exchange-listed securities. An ad-hoc request can be for any number of months beginning with October 2026 for which the data is available. As is the case currently for subscribers of the 10-Minute Report, for mid-month subscriptions of the 1-Minute Report, new subscribers will be charged for the full calendar month for which they subscribe and will be provided with the 1-Minute Report for each trading day of the calendar month in which they subscribed.

The Exchange notes that while the 1-Minute Report is priced higher than its existing pricing for the 10-Minute Report, this is to be expected as a participant subscribing to the 1-Minute Report receives 10x the data points than a subscriber of the 10-Minute Report. The proposed higher pricing for the 1-Minute Report is also in line with other exchanges that offer substantively similar open-close report data based on the trading activity on those exchanges and the pricing they charge for similar ten-minute and one-minute open-close data products.⁷ Other exchanges charge

4–5x for their one-minute open-close data products compared to the ten-minute version. The Exchange proposes to similarly charge 4x the amount for monthly subscription to the 1-Minute Report as compared to the 10-Minute Report, *i.e.*, \$8,000 per month vs. \$2,000 per month.

The Exchange also proposes to make a clarifying change to the Fee Schedule by adding the qualifier “(10-Minute Interval)” to the Intra-Day Volume Summary text priced currently at \$2,000 per month and to the Intra-Day Volume Summary text for Ad-hoc Requests priced currently at \$1,000 per month. The purpose for the clarifying edits to the Intra-Day Volume Summary in the Fee Schedule is to distinguish between the pricing for the ten-minute intraday data and the one-minute intraday data.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁹ in particular, in that it is 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 to protect investors and the

\$1,000 per month); Cboe EDGX Fee Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data (charging 5x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$5,000 per month vs. \$1,000 per month). Cboe, Cboe BZX, C2 and Cboe EDGX Fee Schedules are available at https://www.cboe.com/us/options/membership/fee_schedule/. See also MIAX Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$9,000 per month vs. \$3,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Options_Fee_Schedule_09012026.pdf; MIAX PEARL Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$2,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Options_Fee_Schedule_08012026.pdf; MIA X Sapphire Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$2,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Sapphire_Fee_Schedule_09012026.pdf; and MIAX Emerald Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$2,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Emerald_Fee_Schedule_08012026.pdf.

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal to adopt fees for the 1-Minute Report is consistent with Section 6(b) of the Act¹⁰ in general and furthers the objectives of Section 6(b)(4) of the Act¹¹ in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (“SROs”) and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to users and consumers of such data and also spur innovation and competition for the provision of market data. Particularly, the 1-Minute Report further broadens the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of 1-Minute Report data. The proposed rule change would benefit investors by making the 1-Minute Report available for purchase, which may promote better informed trading. Particularly, information regarding opening and closing activity across different options series may indicate investor sentiment, which can be helpful trading information. Subscribers to the data may also be able to enhance their ability to analyze options trade and volume data on an intraday basis and create and test trading models and analytical strategies. The Exchange believes the 1-Minute Report would provide a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading. The Exchange believes that market participants may find it beneficial to receive additional data based on these shorter intervals as opposed to the existing data intervals provided in the 10-Minute Report. While use cases are the same as the existing 10-Minute Report, the increased frequency of data intervals in the 1-Minute Report provides more current information and more data reporting intervals throughout the trading day to gain knowledge of the trading activity by origin for subscribers. The Exchange further notes that it created the 1-Minute Report in response to customer feedback.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4).

⁷ See Cboe Fee Schedule, Cboe Livevol Fees, Open-Close Data (charging 4x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$12,000 per month vs. \$3,000 per month; Cboe BZX Fee Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data (charging 4x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$1,500 per month); C2 Fee Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data (charging 5x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$5,000 per month vs.

The Exchange believes the proposed fees are reasonable as they reflect a modest increase in price relative to the additional data points being offered in the new 1-Minute Report. As discussed above, a participant who subscribes to the 1-Minute Report receives ten times the data points that they would receive in comparison to the 10-Minute Report and are only seeing an increase of four times in the cost for ten times the amount of data.

The Exchange believes the proposed fees for the 1-Minute Report are reasonable because the proposed higher pricing is in line with other exchanges that offer substantively similar open-close report data products based on the trading activity on those exchanges and the pricing they charge for similar ten-minute and one-minute open-close data products.¹² As noted above, other exchanges charge 4–5x for their one-minute open-close data products compared to the 10-minute version. Accordingly, the Exchange believes the proposed pricing of \$8,000 per month for subscribing to the 1-Minute Report, which is 4x the cost of subscribing to the 10-Minute Report, is reasonable.

Furthermore, proposing fees that are excessively higher than established fees for similar data products offered by other exchanges would simply serve to reduce demand for the Exchange's data product, which as noted, is entirely optional. Like the 10-Minute Report and similar data products offered at other exchanges, the 1-Minute Report provides insight into trading on a specific market and may likewise aid in assessing investor sentiment. Although each of these similar data products provide only proprietary trade data and not trade data from other exchanges, it is possible investors are still able to gauge overall investor sentiment across different option series based on open and closing interest on any one exchange. Similarly, market participants may be able to analyze option trade and volume data and create and test trading models and analytical strategies using only the 10-Minute Report data. As such, if a market participant views the 10-Minute Report data as a more attractive offering for its specific business needs, then such market participant can merely choose to purchase the 10-Minute Report for the lower price. Alternatively, if a market participant views another exchange's data as more attractive than the Exchange's data product, then such market participant can merely choose not to purchase the Exchange's data product and instead purchase another

exchange's product, which offer similar data points, albeit based on that other market's trading activity.

The Exchange also believes the proposed fees are reasonable as they would support the introduction of a new historic market data product that is designed to aid investors by providing insight into trading on the Exchange. Once the 1-Minute Report is made available, it will provide options market participants with valuable information about opening and closing transactions executed on the Exchange throughout the trading day, like other trade data products offered by competing options exchanges. In turn, this data would assist market participants in gauging investor sentiment and trading activity, resulting in potentially better-informed trading decisions. As noted above, subscribers may also use such data to create and test trading models and analytical strategies. The Exchange also believes the proposed fees are equitable and not unfairly discriminatory as the fees would apply equally to all subscribers who choose to purchase such data. The Exchange believes the proposal does not differentiate between subscribers that purchase the 1-Minute Report and would allow any interested market participant to purchase such data based on their business needs.

The Exchange anticipates a wide variety of market participants to purchase the Exchange's data product, including but not limited to, individual customers, buy-side investors and investment banks. The Exchange reiterates that the decision as to whether or not to purchase the 1-Minute Report is entirely optional for all potential subscribers. Indeed, no market participant is required to purchase the data product, and the Exchange is not required to make the data product available to market participants. Rather, the Exchange is voluntarily making the 1-Minute Report available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential subscribers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intermarket competition as other

exchanges are free to introduce their own comparable historic data product and adopt fees to better compete with the Exchange's offering. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to sell a data product similar to those offered by other competitor options exchanges.¹³ The Exchange is offering the 1-Minute Report in order to keep pace with changes in the industry and evolving customer needs and believes the data product will contribute to robust competition among national securities exchanges. Several other U.S. options exchanges offer a market data product that is substantially similar to the Exchange's offering.¹⁴ As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

Furthermore, the Exchange operates in a highly competitive environment, and its ability to price the 1-Minute Report is constrained by competition among exchanges that offer similar data products to their customers. As discussed above, there are several U.S. options exchanges [sic] offer a market data product that is substantially similar to the Exchange's offering, which the Exchange must consider in its pricing discipline in order to compete effectively.¹⁵ For example, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as discussed, market participants are under no obligation to utilize or purchase. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposed fees would apply uniformly to any subscriber, in that the

¹³ See Securities Exchange Act Release Nos. 103323 (June 25, 2025), 90 FR 27884 (June 30, 2025) (SR-CBOE-2025-042); 103324 (June 25, 2025), 90 FR 27890 (June 30, 2025) (SR-C2-2025-012); 103322 (June 25, 2025), 90 FR 27887 (June 30, 2025) (SR-CboeBZX-2025-079); 103321 (June 25, 2025), 90 FR 27894 (June 30, 2025) (SR-CboeEDGX-2025-047); 103908 (September 8, 2025), 90 FR 44123 (September 11, 2025) (SR-MIAX-2025-39); 103907 (September 8, 2025), 90 FR 44120 (September 11, 2025) (SR-PEARL-2025-40); 103905 (September 8, 2025), 90 FR 44113 (September 11, 2025) (SR-SAPPHIRE-2025-33); and 103906 (September 8, 2025), 90 FR 44126 (September 11, 2025) (SR-EMERALD-2025-18).

¹⁴ *Id.*

¹⁵ See, note 7, *supra*.

¹² See, note 7, *supra*.

Exchange would not differentiate between subscribers that purchase the 1-Minute Report. The Exchange believes the proposed fees are set at a modest level that would allow interested subscribers to purchase such data based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) ¹⁶ of the Act and subparagraph (f)(2) of Rule 19b-4 ¹⁷ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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 under Section 19(b)(2)(B) ¹⁸ of the Act 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-NYSEAMER-2026-89 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-NYSEAMER-2026-89. 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-NYSEAMER-2026-89 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-20712 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106609; File No. SR-NYSEARCA-2026-102]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the NYSE Arca Options Proprietary Market Data Fee Schedule To Adopt Fees for One-Minute Intra-Day Volume Reports

October 6, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 ("Act"),² and Rule 19b-4 thereunder,³ notice is hereby given that on September 30, 2026, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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 NYSE Arca Options Proprietary Market Data Fee Schedule ("Fee Schedule") to adopt fees for a version of the NYSE Options Open-Close Volume Summary market data product known as the One-Minute Interval Intra-Day Report (the "1-Minute Report") and make clarifying changes to the Fee Schedule to differentiate between the 1-Minute Report and the version of the NYSE Options Open-Close Volume Summary known as the Ten-Minute Interval Intra-Day Report (the "10-Minute Report"). The proposed rule change is available on the Exchange's website at www.nyse.com 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 self-regulatory organization 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 those 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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to adopt fees for the 1-Minute Report and make clarifying changes to the Fee Schedule to differentiate between the 1-Minute Report and the 10-Minute Report. The Exchange recently adopted the 1-Minute Report as a new data product and the Exchange now proposes to adopt fees for this product.⁴ This proposal is based on similar fee filings by the Cboe Exchange, Inc. ("Cboe"), Cboe C2 Exchange, Inc. ("C2"), Cboe BZX Exchange, Inc. ("Cboe BZX"), Cboe EDGX Exchange, Inc. ("Cboe EDGX"), Miami International Securities Exchange, LLC ("MIAX"), MIAX PEARL, LLC ("MIAX PEARL"), MIAX

⁴ See Securities Exchange Act Release No. 106076 (August 11, 2026), 91 FR 52770 (August 14, 2026) (SR-NYSEARCA-2026-84) (Notice of Filing and Immediate Effectiveness of Proposed Change To Introduce the New One-Minute Interval Intra-Day Report).

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(2).

¹⁸ 15 U.S.C. 78s(b)(2)(B).

¹⁹ 17 CFR 200.30-3(a)(12).

¹⁵ U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

Sapphire, LLC (“MIAX Sapphire”), and MIAX Emerald, LLC (“MIAX Emerald”) to establish fees for their open-close reports that provide substantively similar data sets as proposed herein, albeit based on the trading activity on those exchanges.⁵

The Exchange proposes to implement fees for the 1-Minute Report on October 1, 2026.

Background

By way of background, the Exchange currently offers two versions of the NYSE Options Open-Close Volume Summary, an End of Day (“EOD”) Volume Summary product and the 10-Minute Report. The EOD Volume Summary provides a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker⁶), side of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The EOD Volume Summary provides proprietary Exchange trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

The Exchange also offers the 10-Minute Report, which provides similar information to that of EOD Volume Summary, except that it is produced and updated every 10 minutes during the trading day. Data is captured in “snapshots” taken every 10 minutes throughout the trading day and is available to subscribers within five minutes of the conclusion of each 10-minute period. The 10-Minute Report provides a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), contract volume, and transaction type (opening or closing).

The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The 10-Minute Report also provides proprietary Exchange trade data and does not include trade data from any other exchange. All open-close data products are completely voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and that potential customers may purchase it only if they voluntarily choose to do so.

As noted above, the Exchange recently adopted the 1-Minute Report, which is the same as the existing 10-Minute Report, except that it is produced and updated every minute during the trading day. The 1-Minute Report is captured in “snapshots” taken every 1 minute throughout the trading day and would be available to subscribers within five minutes of the conclusion of each one-minute period. Similar to the 10-Minute Report, the 1-Minute Report provides a volume summary of trading activity on the Exchange at the option level by origin (Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The 1-Minute Report would provide proprietary Exchange trade data and would not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Proposed Rule Change

The Exchange proposes to amend the Fee Schedule to provide that market participants may purchase the 1-Minute Report on a subscription basis or by ad-hoc request for a specified month or series of months (historical file). The Exchange proposes a fee of \$8,000 per month for subscribing to the 1-Minute Report. The Exchange also proposes a fee of \$4,000 per request per month for an ad-hoc request of historical data for the 1-Minute Report covering all Exchange-listed securities. An ad-hoc request can be for any number of months beginning with October 2026 for which the data is available. As is the case currently for subscribers of the 10-Minute Report, for mid-month subscriptions of the 1-Minute Report, new subscribers will be charged for the full calendar month for which they

subscribe and will be provided with the 1-Minute Report for each trading day of the calendar month in which they subscribed.

The Exchange notes that while the 1-Minute Report is priced higher than its existing pricing for the 10-Minute Report, this is to be expected as a participant subscribing to the 1-Minute Report receives 10x the data points than a subscriber of the 1-Minute Report. The proposed higher pricing for the 1-Minute Report is also in line with other exchanges that offer substantively similar open-close report data based on the trading activity on those exchanges and the pricing they charge for similar ten-minute and one-minute open-close data products.⁷ Other exchanges charge 4–5x for their one-minute open-close data products compared to the ten-minute version. The Exchange proposes to similarly charge 4x the amount for monthly subscription to the 1-Minute

⁷ See Cboe Fee Schedule, Cboe LiveVol Fees, Open-Close Data (charging 4x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$12,000 per month vs. \$3,000 per month); Cboe BZX Fee Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data (charging 4x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$1,500 per month); C2 Fee Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data (charging 5x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$5,000 per month vs. \$1,000 per month); Cboe EDGX Fee Schedule, Cboe LiveVol, LLC Market Data Fees, Open-Close Data (charging 5x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$5,000 per month vs. \$1,000 per month). Cboe, Cboe BZX, C2 and Cboe EDGX Fee Schedules are available at https://www.cboe.com/us/options/membership/fee_schedule/. See also MIAX Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$9,000 per month vs. \$3,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Options_Fee_Schedule_09012026.pdf; MIAX PEARL Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$2,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_PEARL_Options_Fee_Schedule_08012026.pdf; MIAX Sapphire Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$2,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Sapphire_Fee_Schedule_09012026.pdf; and MIAX Emerald Options Fee Schedule (charging 3x the amount for a monthly subscription to the one-minute intra-day open close report as compared to the ten-minute intra-day open close report—\$6,000 per month vs. \$2,000 per month) available at https://www.miaxglobal.com/sites/default/files/fee_schedule-files/MIAX_Emerald_Fee_Schedule_08012026.pdf.

⁵ See Securities Exchange Act Release Nos. 104796 (February 10, 2026), 91 FR 6931 (February 13, 2026) (SR-CBOE-2026-011); 103761 (August 21, 2025), 90 FR 41619 (August 26, 2025) (SR-C2-2025-023); 103760 (August 21, 2025), 90 FR 41624 (August 26, 2026) (SR-CboeBZX-2025-116); 104211 (November 18, 2025), 90 FR 52744 (November 21, 2025) (SR-CboeEDGX-2025-075); 104823 (February 11, 2026), 91 FR 7322 (February 17, 2026) (SR-MIAX-2026-06); 104826 (February 11, 2026), 91 FR 7317 (February 17, 2026) (SR-PEARL-2026-05); 104824 (February 11, 2026), 91 FR 7341 (February 17, 2026) (SR-SAPPHIRE-2026-04); and 104825 (February 11, 2026), 91 FR 7346 (February 17, 2026) (SR-EMERALD-2026-03).

⁶ The terms Customer, Professional Customer, Firm and Market Maker are defined in Rule 1.1.

Report as compared to the 10-Minute Report, *i.e.*, \$8,000 per month vs. \$2,000 per month.

The Exchange also proposes to make a clarifying change to the Fee Schedule by adding the qualifier “(10-Minute Interval)” to the Intra-Day Volume Summary text priced currently at \$2,000 per month and to the Intra-Day Volume Summary text for Ad-hoc Requests priced currently at \$1,000 per month. The purpose for the clarifying edits to the Intra-Day Volume Summary in the Fee Schedule is to distinguish between the pricing for the ten-minute intraday data and the one-minute intraday data.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁸ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁹ in particular, in that it is 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 to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal to adopt fees for the 1-Minute Report is consistent with Section 6(b) of the Act¹⁰ in general and furthers the objectives of Section 6(b)(4) of the Act¹¹ in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (“SROs”) and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to users and consumers of such data and also spur innovation and competition for the provision of market data. Particularly, the 1-Minute Report further broadens the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The proposal also promotes increased transparency through the dissemination of 1-Minute Report data. The proposed rule change would benefit investors by making the 1-Minute Report available for purchase, which may promote better informed trading. Particularly,

information regarding opening and closing activity across different options series may indicate investor sentiment, which can be helpful trading information. Subscribers to the data may also be able to enhance their ability to analyze options trade and volume data on an intraday basis and create and test trading models and analytical strategies. The Exchange believes the 1-Minute Report would provide a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading. The Exchange believes that market participants may find it beneficial to receive additional data based on these shorter intervals as opposed to the existing data intervals provided in the 10-Minute Report. While use cases are the same as the existing 10-Minute Report, the increased frequency of data intervals in the 1-Minute Report provides more current information and more data reporting intervals throughout the trading day to gain knowledge of the trading activity by origin for subscribers. The Exchange further notes that it created the 1-Minute Report in response to customer feedback.

The Exchange believes the proposed fees are reasonable as they reflect a modest increase in price relative to the additional data points being offered in the new 1-Minute Report. As discussed above, a participant who subscribes to the 1-Minute Report receives ten times the data points that they would receive in comparison to the 10-Minute Report and are only seeing an increase of four times in the cost for ten times the amount of data.

The Exchange believes the proposed fees for the 1-Minute Report are reasonable because the proposed higher pricing is in line with other exchanges that offer substantively similar open-close report data products based on the trading activity on those exchanges and the pricing they charge for similar ten-minute and one-minute open-close data products.¹² As noted above, other exchanges charge 4–5x for their one-minute open-close data products compared to the 10-minute version. Accordingly, the Exchange believes the proposed pricing of \$8,000 per month for subscribing to the 1-Minute Report, which is 4x the cost of subscribing to the 10-Minute Report, is reasonable.

Furthermore, proposing fees that are excessively higher than established fees for similar data products offered by other exchanges would simply serve to reduce demand for the Exchange’s data

product, which as noted, is entirely optional. Like the 10-Minute Report and similar data products offered at other exchanges, the 1-Minute Report provides insight into trading on a specific market and may likewise aid in assessing investor sentiment. Although each of these similar data products provide only proprietary trade data and not trade data from other exchanges, it is possible investors are still able to gauge overall investor sentiment across different option series based on open and closing interest on any one exchange. Similarly, market participants may be able to analyze option trade and volume data and create and test trading models and analytical strategies using only the 10-Minute Report data. As such, if a market participant views the 10-Minute Report data as a more attractive offering for its specific business needs, then such market participant can merely choose to purchase the 10-Minute Report for the lower price. Alternatively, if a market participant views another exchange’s data as more attractive than the Exchange’s data product, then such market participant can merely choose not to purchase the Exchange’s data product and instead purchase another exchange’s product, which offer similar data points, albeit based on that other market’s trading activity.

The Exchange also believes the proposed fees are reasonable as they would support the introduction of a new historic market data product that is designed to aid investors by providing insight into trading on the Exchange. Once the 1-Minute Report is made available, it will provide options market participants with valuable information about opening and closing transactions executed on the Exchange throughout the trading day, like other trade data products offered by competing options exchanges. In turn, this data would assist market participants in gauging investor sentiment and trading activity, resulting in potentially better-informed trading decisions. As noted above, subscribers may also use such data to create and test trading models and analytical strategies. The Exchange also believes the proposed fees are equitable and not unfairly discriminatory as the fees would apply equally to all subscribers who choose to purchase such data. The Exchange believes the proposal does not differentiate between subscribers that purchase the 1-Minute Report and would allow any interested market participant to purchase such data based on their business needs.

The Exchange anticipates a wide variety of market participants to purchase the Exchange’s data product,

⁸ 15 U.S.C. 78f(b).

⁹ 15 U.S.C. 78f(b)(5).

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4).

¹² See, note 7, *supra*.

including but not limited to, individual customers, buy-side investors and investment banks. The Exchange reiterates that the decision as to whether or not to purchase the 1-Minute Report is entirely optional for all potential subscribers. Indeed, no market participant is required to purchase the data product, and the Exchange is not required to make the data product available to market participants. Rather, the Exchange is voluntarily making the 1-Minute Report available, as requested by customers, and market participants may choose to receive (and pay for) this data based on their own business needs. Potential subscribers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange also does not believe the proposed fees would cause any unnecessary or inappropriate burden on intramarket competition as other exchanges are free to introduce their own comparable historic data product and adopt fees to better compete with the Exchange's offering. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to sell a data product similar to those offered by other competitor options exchanges.¹³ The Exchange is offering the 1-Minute Report in order to keep pace with changes in the industry and evolving customer needs and believes the data product will contribute to robust competition among national securities exchanges. Several other U.S. options exchanges offer a market data product that is substantially similar to the Exchange's offering.¹⁴ As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

Furthermore, the Exchange operates in a highly competitive environment,

and its ability to price the 1-Minute Report is constrained by competition among exchanges that offer similar data products to their customers. As discussed above, there are several U.S. options exchanges [sic] offer a market data product that is substantially similar to the Exchange's offering, which the Exchange must consider in its pricing discipline in order to compete effectively.¹⁵ For example, proposing fees that are excessively higher than established fees for similar data products would simply serve to reduce demand for the Exchange's data product, which as discussed, market participants are under no obligation to utilize or purchase. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges.

The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposed fees would apply uniformly to any subscriber, in that the Exchange would not differentiate between subscribers that purchase the 1-Minute Report. The Exchange believes the proposed fees are set at a modest level that would allow interested subscribers to purchase such data based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) ¹⁶ of the Act and subparagraph (f)(2) of Rule 19b-4 ¹⁷ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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 under Section 19(b)(2)(B) ¹⁸ of the Act 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-NYSEARCA-2026-102 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-NYSEARCA-2026-102. 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-NYSEARCA-2026-102 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-20713 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

¹³ See Securities Exchange Act Release Nos. 103323 (June 25, 2025), 90 FR 27884 (June 30, 2025) (SR-CBOE-2025-042); 103324 (June 25, 2025), 90 FR 27890 (June 30, 2025) (SR-C2-2025-012); 103322 (June 25, 2025), 90 FR 27887 (June 30, 2025) (SR-CboeBZX-2025-079); 103321 (June 25, 2025), 90 FR 27894 (June 30, 2025) (SR-CboeEDGX-2025-047); 103908 (September 8, 2025), 90 FR 44123 (September 11, 2025) (SR-MIAX-2025-39); 103907 (September 8, 2025), 90 FR 44120 (September 11, 2025) (SR-PEARL-2025-40); 103905 (September 8, 2025), 90 FR 44113 (September 11, 2025) (SR-SAPPHIRE-2025-33); and 103906 (September 8, 2025), 90 FR 44126 (September 11, 2025) (SR-EMERALD-2025-18).

¹⁴ *Id.*

¹⁵ See, note 7, *supra*.

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(2).

¹⁸ 15 U.S.C. 78s(b)(2)(B).

¹⁹ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106601; File No. SR–MEMX–2026–31]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

October 6, 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 September 30, 2026, MEMX LLC (“MEMX” or the “Exchange”) 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

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members³ (the “Fee Schedule”) pursuant to Exchange Rules 15.1(a) and (c). As is further described below, the Exchange proposes to amend the required criteria under the Tape B Volume Tier 2. The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal immediately. The text of the proposed rule change is provided in Exhibit 5.

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 purpose of the proposed rule change is to amend the Fee Schedule to modify the required criteria under the Tape B Volume Tier 2.

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 18 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 14% of the total market share of executed volume of equities trading.⁴ Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents approximately 1.6% of the overall market share.⁵ The Exchange in particular operates a “Maker-Taker” model whereby it provides rebates to Members that add liquidity to the Exchange and charges fees to Members that remove liquidity from the Exchange. The Fee Schedule sets forth the standard rebates and fees applied per share for orders that add and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or lower 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.

Currently, the Exchange provides a standard rebate of \$0.0015 per share for executions of orders in securities priced at or above \$1.00 per share that add displayed liquidity to the Exchange (such orders, “Added Displayed

Volume”).⁶ The Exchange also currently offers Tape B Volume Tiers 1 and 2 under which a Member may receive an additive rebate for a qualifying Member's executions of Added Displayed Volume (other than Retail Orders⁷) in Tape B securities priced over \$1.00 per share by achieving certain criteria. Currently under Tape B Volume Tier 2, the Exchange provides an additive rebate of \$0.0002 per share for a qualifying Member's executions of Added Displayed Volume (other than Retail Orders) in Tape B securities priced over \$1.00 per share by achieving a Tape B ADAV⁸ that is equal to or greater than 0.25% of the Tape B TCV⁹ (excluding Retail Orders).¹⁰ Now, the Exchange proposes to modify the required criteria such that a Member would now qualify for such tier by achieving a Tape B ADAV that is equal to or greater than 0.20% of the Tape B TCV (excluding Retail Orders). Thus, such proposed change reduces the Tape B ADAV threshold by 0.05%. The Exchange is not proposing to change the additive rebate provided under such tier.

The proposed modified criteria is intended to encourage Members to maintain or increase their order flow, including the in form of orders that add liquidity on the Exchange in Tape B securities, in order to qualify for the additive rebate provided under the Tape B Volume Tier 2, which may contribute to a more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members.

⁶ The base rebate for executions of Added Displayed Volume is referred to by the Exchange on the Fee Schedule under the existing description “Added displayed volume” with a Fee Code of “B”, “D” or “J”, as applicable, on execution reports.

⁷ A “Retail Order” means an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization (“RMO”), provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. See Exchange Rule 11.21(a).

⁸ As set forth on the Fee Schedule, “ADAV” means the average daily added volume calculated as the number of shares added per day, which is calculated on a monthly basis.

⁹ As set forth on the Fee Schedule, “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.

¹⁰ The pricing for the Tape B Volume Tier 2 is referred to by the Exchange on the Fee Schedule under the existing description “Tape B Volume Tier 2” with a Fee Code of “b2” to be appended to the otherwise applicable Fee Code assigned by the Exchange on the monthly invoices for qualifying executions.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Exchange Rule 1.5(p).

⁴ Market share percentage calculated as of September 29, 2026. The Exchange receives and processes data made available through consolidated data feeds (*i.e.*, CTS and UTDF).

⁵ *Id.*

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹¹ in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,¹² in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and 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, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their 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.”¹³

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange’s transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to direct additional order flow, including displayed, liquidity-adding orders to the Exchange, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange to the benefit of all Members and market participants.

The Exchange believes that the Tape B Volume Tier 2, as modified by the

proposed change to the required criteria under such tier, is reasonable, equitable and not unfairly discriminatory for these same reasons, as such tier continues to provide Members with an incremental incentive to achieve a certain volume threshold on the Exchange, is available to all Members on an equal basis, and is designed to encourage Members to maintain or increase their order flow, including liquidity-adding orders, to the Exchange in order to qualify for the additive rebate for executions of Added Displayed Volume (excluding Retail Orders) in Tape B securities, thereby contributing to a deeper and more liquid market to the benefit of all Members. The Exchange believes that the additive rebate under the Tape B Volume Tier 2 remains commensurate with the required criteria under such tier, as modified, and is reasonably related to the market quality benefits that such tier is designed to achieve.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act¹⁴ in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange’s statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees described herein are appropriate to address such forces.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to incentivize market participants to direct additional order flow to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members and market participants. As a result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal 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.”¹⁵

Intramarket Competition

As discussed above, the Exchange believes that the proposal would incentivize Members to submit additional order flow, including displayed, liquidity-adding orders in Tape B securities to the Exchange, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members, as well as enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants.

The Exchange does not believe that the proposed change to amend the required criteria under the Tape B Volume Tier 2 would impose any burden on intramarket competition because such change will apply to all Members uniformly, and the opportunity to qualify for that additive rebate is available to all Members. As described above, the Exchange believes that, after giving effect to the change proposed herein, the required criteria under the Tape B Volume Tier 2 is commensurate with the corresponding additive rebate under such tier and reasonably related to the enhanced liquidity and market quality that such tier is designed to promote. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

As noted 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. Members have numerous alternative venues that they may participate on and direct their order flow to, including 17 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 14% of the total market share of

¹¹ 15 U.S.C. 78f.

¹² 15 U.S.C. 78f(b)(4) and (5).

¹³ Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

¹⁴ 15 U.S.C. 78f(b)(4) and (5).

¹⁵ See *supra* note 13.

executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market.

Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, including with respect to Added Displayed Volume and market 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. As described above, the proposed change represents a competitive proposal through which the Exchange is seeking to generate additional revenue with respect to its transaction pricing and to encourage the submission of additional order flow to the Exchange through volume and quoting-based tiers, which have been widely adopted by exchanges, including the Exchange. Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar pricing incentives to market participants.

Additionally, 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."¹⁶ The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition v. SEC*, 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'. . . ."¹⁷ Accordingly, the Exchange does not believe its proposed pricing changes impose 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)(ii) of the Act¹⁸ and Rule 19b-4(f)(2)¹⁹ 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 shall 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-MEMX-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.

¹⁷ *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-NYSE-2006-21)).

¹⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁹ 17 CFR 240.19b-4(f)(2).

All submissions should refer to file number SR-MEMX-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-MEMX-2026-31 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-20706 Filed 10-8-26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106606; File No. SR-IEX-2026-40]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Pursuant to IEX Rule 15.110(a) and (c) To Modify the Required Criteria To Qualify for the Reduced Incremental Fee

October 6, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the "Act")² and Rule 19b-4 thereunder,³ notice is hereby given that, on September 30, 2026, the Investors Exchange LLC ("IEX" or the "Exchange") 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

¹⁶ *Id.*

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,⁴ and Rule 19b-4 thereunder,⁵ the Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members⁶ (the "Fee Schedule"⁷) pursuant to IEX Rule 15.110(a) and (c) to modify the required criteria to qualify for the reduced Incremental Fee. Changes to the Fee Schedule pursuant to this proposal are effective upon filing,⁸ and will be implemented on November 1, 2026.

The text of the proposed rule change is available at the Exchange's website at <https://www.iexexchange.io/resources/regulation/rule-filings> and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization 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 self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

IEX proposes to modify the required criteria to qualify for Incremental Fee Tier 2, which is applicable to certain executions of non-displayed orders.⁹ Specifically, IEX proposes to increase by 5,000,000 the threshold volume required to qualify for the reduced fees of Incremental Fee Tier 2, unless the Member qualified for one of the Exchange's two highest displayed liquidity adding rebate tiers in the prior month. This fee change proposal is effective on filing and will be implemented on November 1, 2026.¹⁰

IEX's Incremental Fee Tiers are a volume-based fee incentive designed to incentivize Members to increase their Incremental Fee eligible ADV¹¹ on the Exchange by charging a reduced fee of \$0.0001 per share¹² to Members that qualify for Incremental Fee Tier 2 for applicable executions of non-displayed orders.¹³ A Member qualifies for the reduced fee (*i.e.*, Incremental Fee Tier 2) for a portion of its Incremental Fee eligible ADV¹⁴ in the current month if in the prior (*i.e.*, immediately preceding) month, its Incremental non-displayed ADV¹⁵ exceeded its Baseline non-displayed ADV¹⁶ by at least 15,000,000.¹⁷

trades would not impact the Incremental Fee Tier calculations and would not be eligible for any of the Incremental Fee Tiers described herein.

¹¹ "Incremental Fee eligible ADV" means executions with any of the Fee Code Combinations MI, MIB, TI, TIB, TIY, or TIYB. Unless otherwise specified, Incremental Fee eligible ADV refers to executions in the current month. *See* Fee Schedule, *supra*, note 7, Transaction Fees, Definitions.

¹² IEX's base rate for transactions that add or remove non-displayed liquidity is \$0.0010 per share. *See* IEX Fee Schedule, *supra*, note 7, Transaction Fees, Base Rates table.

¹³ The fee codes to which the Incremental Fee Tiers apply are "MI" (Adds non-displayed liquidity); "MIB" (Adds non-displayed liquidity in Tape B securities); "TIY" (Post Only order removes non-displayed liquidity); "TIYB" (Post Only order removes non-displayed liquidity in Tape B securities); "TI" (Removes non-displayed liquidity); and "TIB" (Removes non-displayed liquidity in Tape B securities).

¹⁴ The amount of Incremental Fee eligible ADV that is eligible for the reduced fee of \$0.0001 per share is capped at the Baseline non-displayed ADV, unless the Member qualified for Incremental Fee Tier 2 for at least three immediately preceding months. *See* IEX Fee Schedule, *supra*, note 7, footnote 6 to the Transaction Fees, Base Rates table and Fee Code Combinations and Associated Fees table.

¹⁵ "Incremental non-displayed ADV" means executions in the immediately preceding month of Incremental Fee eligible ADV that exceeded the Baseline non-displayed ADV. *See* IEX Fee Schedule, *supra*, note 7, Transaction Fees, Definitions.

¹⁶ "Baseline non-displayed ADV" is calculated by taking the average of the Member's Incremental Fee eligible ADV in the three months with the lowest Incremental Fee eligible ADV between March 1, 2025 and February 28, 2026. For Members that joined IEX after March 1, 2025, the Baseline non-displayed ADV is calculated by taking the average of the Member's Incremental Fee eligible ADV in its first three full months of trading on the Exchange. *See* IEX Fee Schedule, *supra*, note 7, Transaction Fees, Definitions.

¹⁷ Unless the Member has qualified for Incremental Fee Tier 2 in at least the three immediately preceding months, IEX caps the volume that is eligible for the reduced \$0.0001 fee at the Member's Baseline non-displayed ADV, and any additional Incremental Fee eligible ADV is charged the regular fee of \$0.0010 for either adding or removing non-displayed liquidity. For Members that qualified for Incremental Fee Tier 2 in at least the three immediately preceding months, IEX doubles the cap on the amount of Incremental Fee eligible ADV that qualifies for the \$0.0001 reduced fee, and any additional Incremental Fee eligible ADV in excess of the two-times Baseline non-

IEX proposes to increase the threshold volume by which Members must exceed their Baseline non-displayed ADV to qualify for Incremental Fee Tier 2 from 15,000,000 to 20,000,000 Incremental Fee eligible ADV, unless the Members qualified for one of the Exchange's two highest displayed liquidity adding rebate tiers in the prior month. This proposed increase is designed to reflect changes to trading volumes in securities priced at or above \$1.00 compared to when these tiers were set, as well as the increased trading activity of IEX Members; these changes add liquidity to the Exchange and make the threshold volume requirement easier to reach. The Exchange believes that the proposed change to the threshold volume requirement will continue to incentivize Members to grow their non-displayed volume on the Exchange. Moreover, IEX notes that increased volume on the Exchange contributes to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

With respect to a Member who qualified for one of the Exchange's two highest displayed liquidity adding rebate tiers in the prior month, IEX proposes to continue applying the lower qualification requirement, meaning the Member's Incremental non-displayed ADV must exceed its Baseline non-displayed ADV by at least 15,000,000. To qualify for Tier 8 in the current month, in the prior month a Member must have added at least 40,000,000 ADV of displayed liquidity. To qualify for Tier 9 in the current month, in the prior month a Member must have added at least 50,000,000 ADV of displayed liquidity.¹⁸

IEX proposes applying the lower qualification requirement for Members who qualified for Tiers 8 or 9 in the prior month to expand access to the Incremental Fee Tiers. This proposed change, working in tandem with the Displayed Liquidity Adding Rebate Tiers, is designed to incentivize Members to add both displayed and non-displayed liquidity to the Exchange by making it easier for Members that add substantial amounts of displayed liquidity to benefit from the Incremental Fee Tier 2 reduced fees.

displayed ADV cap on the \$0.0001 reduced fee is assessed a reduced fee of \$0.0004.

¹⁸ On September 30, 2026, IEX filed a proposed rule change that made a few modifications to the Displayed Liquidity Adding Rebate Tiers, including introducing a new top-level tier, Tier 9. *See* SR-IEX-2026-39. The fee changes in both SR-IEX-2026-39 and this filing will be operative on November 1, 2026.

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b-4.

⁶ *See* IEX Rule 1.160(s).

⁷ *See* Investors Exchange Fee Schedule, available at <https://www.iex.io/resources/trading/fee-schedule>.

⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

⁹ *See* Footnote 6 to the Transaction Fees section of the Fee Schedule, *supra*, note 7.

¹⁰ Nothing in this rule filing affects trades below \$1.00 per share ("sub-dollar trades"). Sub-dollar

To reflect the changed threshold to qualify for Incremental Fee Tier 2 (for Members who did not qualify for Displayed Liquidity Adding Rebate Tier 8 or 9 in the prior month), IEX proposes to change any references in the Fee Schedule to the 15,000,000 Incremental Fee eligible ADV threshold, so that they refer to the new 20,000,000 Incremental Fee eligible ADV threshold.

Specifically, IEX proposes to:

- In the second bullet in the Incremental Fee Tiers section of the Fee Schedule, change the language to read in full:

- A Member qualifies for the Incremental Fee (*i.e.*, Incremental Fee Tier 2) in the current month if its Incremental Fee eligible ADV in the prior month exceeded its Baseline non-displayed ADV by at least 20,000,000 (or by at least 15,000,000 if the Member qualified for Displayed Liquidity Adding Rebate Tier 8 or Tier 9).

- In the “Incremental Fee Tier Calculation Table (used by both Options 1 and 2)” make the following changes:

- Change the “Required Criteria” for Tier 1 to read in full:

- Member’s Incremental non-displayed ADV was less than 20,000,000^a

- Change the “Required Criteria” for Tier 2 to read in full:

- Member’s Incremental non-displayed ADV was greater than or equal to 20,000,000^a

- Change the current references to footnote “a” to instead refer to footnote “b”, and renumber current footnote “a” to be footnote “b”

- Add a new explanatory footnote “a” that reads in full:

- A Member that qualifies for either Displayed Liquidity Adding Rebate Tier 8 or Tier 9 (based on its prior month activity) qualifies for Incremental Fee Tier 2 in the current month if its prior month’s Incremental non-displayed ADV exceeded its Baseline non-displayed ADV by at least 15,000,000. The below examples for Incremental Fee Tier Option 1 and Option 2 assume the Member did not qualify for Displayed Liquidity Adding Rebate Tier 8 or Tier 9, and therefore the Member’s Incremental non-displayed ADV must exceed its Baseline non-displayed ADV by at least 20,000,000 in the prior month to qualify for Incremental Fee Tier 2 in the current month.

IEX also proposes to update the numbers in several examples in the Incremental Fee Tier section of the Fee Schedule, so that the examples accurately reflect the proposed requirement that a Member’s Incremental Fee eligible ADV exceed its Baseline non-displayed ADV by at least 20,000,000 for the Member to qualify for Incremental Fee Tier 2. Specifically, IEX proposes making the following changes

to the examples and explanatory text in the Fee Schedule:

- Revise the last sentence in renumbered footnote “b” to the “Incremental Fee Tier Calculation Table (used by both Options 1 and 2)” by adding 5,000,000 to the Baseline non-displayed ADV and 20,000,000 to the Incremental Fee Eligible ADV. As proposed, the sentence will read as follows:

- For example, if such a Member’s Baseline non-displayed ADV is 20,000,000 and its Incremental Fee eligible ADV is 70,000,000 (*i.e.*, its Incremental non-displayed ADV is 50,000,000), 20,000,000 is assessed the \$0.0010 fee, 40,000,000 is assessed the \$0.0001 fee, and 10,000,000 is assessed the \$0.0004 fee.

- Revise the numbers in the Incremental Fee Tier Option 1 example table by adding 5,000,000 to each cell (except for the Baseline non-displayed ADV, which will remain 20,000,000). Additionally, IEX proposes to apply the revised numbers to the blended rate calculations for the Month 1 and Month 2 Fees, and to update the numbers in those columns to reflect the changed blended rates that result from the higher threshold volume requirement to qualify for Incremental Fee Tier 2.

- As proposed, the example table, and footnotes will read as follows:

Ex.	Baseline non-displayed ADV	Prior month ADV*	Month 1 ADV*	Month 2 ADV*	Month 1 fees	Month 2 fees
1	20mm	40mm	40mm	30mm	\$0.00055/share**	\$0.00055/share.***
2	20mm	45mm	30mm	40mm	0.0006/share	0.0010/share.
3	20mm	45mm	55mm	15mm	0.0006/share	0.00067/share.

* Incremental Fee eligible ADV

** A Member with a Baseline non-displayed ADV of 20,000,000 that has Incremental Fee eligible ADV of 40,000,000 in the Prior Month will pay \$0.00055 for all Incremental Fee eligible ADV in Month 1, because that is the blended average of the Member’s Prior Month trading fees (\$0.0010/share fee for 20,000,000 and \$0.0001/share fee for 20,000,000).

*** Since the prior month’s blended rate is used, the fact that the Member’s Month 2 Incremental Fee eligible ADV did not exceed the Baseline non-displayed ADV by at least 20,000,000 would not be taken into account until Month 3 billing.

- Revise the numbers in the Incremental Fee Tier Option 2 example table by adding 5,000,000 multiplied by the number of trading days in the month, to each cell listing an ADV value (except for the Baseline non-displayed

ADV, which will remain 20,000,000), and any cell listing a TAV value (except for the Baseline non-displayed TAV¹⁹ columns, which will remain unchanged). Additionally, IEX proposes to update the Incremental Fee eligible

TAV,²⁰ Incremental non-displayed TAV,²¹ and Month 1 and 2 Fees values in the example table.

- As proposed, the example table, and footnotes will read as follows:

¹⁹ “Baseline non-displayed TAV” is calculated by multiplying the Baseline non-displayed ADV times the number of trading days in the current month. See Fee Schedule, *supra*, note 7.

²⁰ “Incremental Fee eligible TAV” is calculated by multiplying the current month’s Incremental Fee eligible ADV times the number of trading days in the current month. See Fee Schedule, *supra*, note 7.

²¹ Incremental non-displayed TAV is the amount by which the current month’s Incremental Fee eligible TAV exceeds the Baseline non-displayed TAV. If the Baseline non-displayed TAV is greater than the Incremental Fee eligible TAV, this value is 0. If this value exceeds the Baseline non-displayed TAV, the number of shares eligible for the reduced Incremental Fee is capped at the Baseline non-displayed TAV for Members that have not qualified for Incremental Fee Tier 2 in each of

the three immediately preceding months. For Members that have qualified for Incremental Fee Tier 2 for at least the three immediately preceding months, the number of shares eligible for the \$0.0001 fee is capped at two times the Baseline non-displayed ADV, and any volume greater than three times the Baseline non-displayed ADV is eligible for the \$0.0004 fee. See Fee Schedule, *supra*, note 7.

	Baseline non-displayed ADV	Prior month ADV *	Month 1 (19 trading days)				Month 1 fees
			ADV *	Total volume **	Baseline volume ***	Incremental volume ****	
1	20mm	40mm	40mm	760mm	380mm	380mm	• \$0.0010/share on first 380mm shares. • \$0.0001/share on remaining 380mm shares.
2	20mm	45mm	30mm	570mm	380mm	190mm	• \$0.0010/share on first 380mm shares. • \$0.0001/share on remaining 190mm shares.
3	20mm	45mm	55mm	1,045mm	380mm	665mm (only 380mm eligible for \$0.0001 fee).	• \$0.0010/share on first 380mm shares. • \$0.0001/share on next 380mm shares. • \$0.0010/share on remaining 285mm shares.

* Incremental Fee eligible ADV.
 ** Incremental Fee eligible TAV.
 *** Baseline non-displayed TAV.
 **** Incremental non-displayed TAV.

	Baseline non-displayed ADV	Month 1 ADV *	Month 2 (22 trading days)				Month 2 fees
			ADV *	Total volume **	Baseline volume ***	Incremental volume ****	
1	20mm	40mm	30mm	660mm	440mm	220mm	• \$0.0010/share on first 440mm shares. • \$0.0001/share on remaining 220mm shares.
2	20mm	30mm	40mm	880mm	N/A (Month 1 ADV did not exceed Baseline Vol. by at least 20mm).	N/A	• 0.0010/share on all 880mm shares.
3	20mm	55mm	15mm	330mm	440mm	0 (Baseline Vol. > Total Vol.).	• \$0.0010/share on all 330mm shares.

* Incremental Fee eligible ADV.
 ** Incremental Fee eligible TAV.
 *** Baseline non-displayed TAV.
 **** Incremental non-displayed TAV.

Additionally, IEX proposes to remove the word “proposed” from the first bullet in the “Incremental Fee Tier Option 2” section of the Fee Schedule. This word is a holdover from the filing that proposed the introduction of Option 1 and Option 2 and is no longer accurate or relevant.

As noted above, the Exchange is not proposing to change the fees applicable to executions of and with orders with an execution price below \$1.00 per share.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b) ²² of the Act in general and furthers the objectives of Sections 6(b)(4) ²³ of the Act, in particular, in that it is designed to not be unfairly discriminatory and to provide for the equitable allocation of reasonable dues, fees and other charges among its

Members and other persons using its facilities.

First, IEX believes that this proposal provides for the reasonable and equitable allocation of reasonable fees among its Members and is not designed to be unfairly discriminatory because its proposal to increase the threshold volume Members must satisfy to qualify for Incremental Fee Tier 2 reflects a reasonable pricing structure, made for business and competitive reasons in response to market volumes and activity on IEX. The Exchange further believes the proposed increase to the threshold volume requirement to qualify for Incremental Fee Tier 2 (for Members that did not qualify for Displayed Liquidity Adding Rebate Tiers 8 or 9 in the prior month) will continue to incentivize Members to grow their non-displayed volume on the Exchange. And increased volume on the Exchange contributes to a deeper and more liquid market, which benefits all market participants and provides greater

execution opportunities on the Exchange.

Additionally, IEX believes that the proposed lower threshold to qualify for Incremental Fee Tier 2 for Members that add a substantial amount of displayed liquidity to the Exchange is consistent with the purposes of the Act. This part of the proposal, which IEX makes for business and competitive reasons, is designed to further incentivize Members to add more displayed liquidity to the Exchange, thereby contributing to a deeper and more liquid market, to the benefit of all market participants.

Further, IEX notes that this fee proposal is reasonable, equitable, and not designed to permit unfair discrimination because all similarly situated Members will be treated the same. And IEX does not believe that any aspect of this proposal raises new or novel issues not already considered by the Commission.

Additionally, IEX believes that the proposed updates to the examples in the Fee Schedule described in the Purpose section further the purposes of the Act

²² 15 U.S.C. 78f.

²³ 15 U.S.C. 78f(b)(4).

because they provide greater clarity and consistency to the Fee Schedule, thereby reducing the potential for confusion of any market participants. The Exchange believes that the proposed updated examples will provide greater clarity to Members and the public regarding the Exchange's Fee Schedule and are therefore consistent with the protection of investors and the public interest.

Finally, the Exchange believes that the proposed change to remove the word "proposed" from the description of Option 2 in the Fee Schedule is consistent with the protection of investors and the public interest because it removes an outdated and no longer relevant term from the Fee Schedule, thereby making it more accurate and complete, which is consistent with the protection of investors and the public interest.

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. Within that context, the proposed changes to the Incremental Fee Tier structure are designed to keep IEX's non-displayed trading prices competitive with those of other exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that 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. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if fee schedules at other venues are viewed as more favorable. Consequently, the Exchange believes that the degree to which IEX fees could impose any burden on competition is extremely limited and does not believe that such fees would burden competition between Members or competing venues. Moreover, as noted in the Statutory Basis section, the Exchange does not believe that the proposed changes raise any new or novel issues not already considered by the Commission.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act

because, while different fees are assessed on Members, these fees are not based on the type of Member entering the orders that match, but rather on the Member's own trading activity. Further, the proposed fee change is intended to encourage market participants to bring increased order flow to the Exchange, which benefits all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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)²⁴ of the Act.

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 shall institute proceedings under Section 19(b)(2)(B)²⁵ of the Act 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-IEX-2026-40 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-IEX-2026-40. 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-IEX-2026-40 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-20710 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-106604; File No. SR-CboeEDGX-2026-064]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.15 (Clearly Erroneous Executions)

October 6, 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 September 24, 2026, Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4 (f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

²⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

²⁴ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁵ 15 U.S.C. 78s(b)(2)(B).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") proposes to amend Rule 11.15 ("Clearly Erroneous Executions") in light of the Commission's approval of Overnight Protected Bands for 23/5 Trading. 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/edgx/), 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

Cboe EDGX Exchange, Inc. ("EDGX" or the "Exchange") proposes to amend Rule 11.15 ("Clearly Erroneous Executions") in light of the Commission's approval of Overnight Protected Bands under the LULD Plan for 23/5 Trading.

Background

In conjunction with the industry's plans for the introduction of trading 23 hours a day, 5 days a week ("23/5 Trading"), the Operating Committee of the Plan to Address Extraordinary Market Volatility ("LULD Plan") filed proposed Amendment 27 to the LULD Plan, which proposed to establish price band protections during overnight trading hours ("Overnight Price Bands").⁵ The Operating Committee proposed that the Overnight Price Bands would initially be temporary static bands 20% above and below two

reference points, and that after implementation, the Operating Committee would evaluate the performance of such Overnight Price Bands and propose appropriate changes in a new plan amendment.⁶ On August 5, 2026, the Commission approved the proposal.⁷

In light of the Commission's approval of these changes to the LULD Plan, the Exchange now proposes several amendments to Rule 11.15 regarding Clearly Erroneous Executions. In general, the rule describes the process a market participant may use to request cancellation of a transaction that was "clearly erroneous." The current rule's central premise is that if LULD Price Bands under the LULD Plan were available and correct at the time the transaction was executed, the transaction is not eligible for clearly erroneous review. Specifically, Rule 11.15(c)(1) currently provides that "[i]f the execution time of the transaction(s) under review is during Regular Trading Hours, the transaction will not be reviewable as clearly erroneous" except in certain limited circumstances, including when (A) the transaction is in an NMS stock that is not subject to the LULD Plan (e.g., rights and warrants), (B) the transaction was executed at a time with LULD Price Bands were unavailable or trading should have been prevented due to a regulatory halt or other halt, or (C) several other limited circumstances.⁸ In approving the existing version of the rule, the Commission noted that restricting clearly erroneous review in this way during times when LULD Price Bands were in effect was "consistent with the Act and will further the goal of providing greater certainty to market participants that trades executed within the Price Bands will stand and not be broken. . . . Thus, the proposal is designed to limit the potential discordance between the LULD mechanism and CEE review process."⁹

Currently, LULD Price Bands are available only during Regular Trading Hours, meaning that the restrictions on clearly erroneous review described

above apply only during Regular Trading Hours. With the introduction of Overnight Price Bands, the Exchange now proposes to extend the existing restrictions on clearly erroneous review to the period when Overnight Price Bands are in place. This proposed change would be consistent with the Commission's rationale in approving the current version of the rule because it would limit any potential discordance between the LULD mechanism and CEE review in the overnight trading session, providing greater certainty to market participants that trades executed with the Overnight Price Bands will stand and not be broken.

Proposed Changes to Rule 11.15(c)(1)

To implement this change, the Exchange proposes to add several definitions to Rule 11.15(c)(1). First, the Exchange would add that the term "LULD Protected Hours" includes Regular Trading Hours and "Overnight Protected Hours" defined in Section VIII of the LULD Plan. Second, the Exchange would define "LULD Price Bands" or "Price Bands" to mean the Price Bands defined in Section V of the LULD Plan (i.e., the Price Bands that apply during Regular Trading Hours) and "Overnight Price Bands" as defined in Section VIII of the LULD Plan (i.e., the Price Bands that apply to the Overnight Protected Hours from 9:00 p.m. ET through 4:00 a.m. ET).

The Exchange proposes to amend the current first sentence of Rule 11.15(c)(1) to replace the phrase "Regular Trading Hours" with "LULD Protected Hours," to provide that "[i]f the execution time of the transaction(s) under review is during LULD Protected Hours, the transaction will not be reviewable as clearly erroneous" This change would extend the LULD-based restrictions on clearly erroneous review currently in place during Regular Trading Hours to the Overnight Protected Hours.

The Exchange also proposes to amend Rule 11.15(c)(1)(B)'s reference to "Percentage Parameter" to incorporate the Percentage Parameter that applies to Overnight Protected Hours. The amended provision would provide for the applicability of clearly erroneous review if the price of the transaction to buy (sell) that is the subject of the clearly erroneous complaint is greater than (less than) the Reference Price by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan (with respect to the Price Bands that apply during Regular Trading Hours) or the "Overnight Percentage Parameter defined in Section VIII of the LULD

⁶ *Id.*

⁷ See Securities Exchange Act Release No. 106042 (August 5, 2026), 91 FR 51515 (August 10, 2026) (File No. 4-631) (Order Granting Approval of the 27th Amendment to the National Market System Plan to Address Extraordinary Market Volatility to Establish Temporary Price Band Protections in Overnight Trading).

⁸ See Rule 11.15(c)(1)(A), (B), and (C).

⁹ See Securities Exchange Act Release No. 95658 (September 1, 2022), 87 FR 55060 at 55063 (September 8, 2022) (SR-CboeBZX-2022-037) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, to Amend BZX Rule 11.17, Clearly Erroneous Executions).

⁵ See Securities Exchange Act Release No. 105596 (June 1, 2026), 91 FR 33774 (June 4, 2026) (File No. 4-631) (Notice of Filing of 27th Amendment to the National Market System Plan).

Plan” (with respect to Overnight Protected Hours).

In addition to these changes, the Exchange also proposes to make a non-substantive change to Rule 11.15(c)(1)(A), substituting the term “LULD Plan” for the current text “the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ‘Limit Up-Limit Down Plan’ or ‘LULD Plan,’)” as the “LULD Plan” would be defined in the proposed revision to Rule 11.15(c)(1).

Proposed Changes to Rule 11.15(c)(2), (d)(3), and (f)

As noted above, current Rule 11.15(c)(1)(A) permits clearly erroneous review even during Regular Trading Hours when the transaction in question is in an NMS Stock that is not subject to the LULD Plan, *i.e.*, rights and warrants. Such transactions are reviewed for clearly erroneous status using the procedures set out in Rule 11.15(c)(2), including the Numerical Guidelines set out in the table accompanying Rule 11.15(c)(2)(A). The Exchange now proposes to introduce a similar provision regarding transactions in NMS Stocks not subject to the LULD Plan that are executed during the Overnight Protected Hours; such transactions would be subject to the same Numerical Guidelines as transactions occurring in the Early Trading, Pre-Opening, and Post-Closing Sessions.

The heading of Rule 11.15(c)(2) addresses “[r]eview of transactions occurring during Early Trading, Pre-Opening, Post-Closing Session, or eligible for review pursuant to paragraph (c)(1)(A).” The Exchange proposes to replace the phrase “eligible for review pursuant to paragraph (c)(1)(A)” (which, in the current rule, means transactions executed during Regular Trading Hours in NMS Stocks not subject to the LULD Plan) with “during LULD Protected Hours in NMS Stocks not subject to the LULD Plan.” This proposed language would cover transactions in NMS Stocks not subject to the LULD Plan in Regular Trading Hours and expand the same treatment to transactions executed in NMS Stocks not subject to the LULD Plan during Overnight Protected Hours. As such, the proposed change is not novel.

The Exchange proposes to make the same change everywhere else such language appears in the rule—namely, in the text of paragraphs (c)(2)(A), (c)(2)(B), (c)(2)(C), (c)(2)(D), (d)(3), and

(f).¹⁰ In each case, the Exchange proposes to replace the phrase “transactions occurring during the Early Trading, Pre-Opening, or Post-Closing Session or eligible for review pursuant to paragraph (c)(1)(A)” with “transactions occurring during the Early Trading, Pre-Opening, or Post-Closing Session or during LULD Protected Hours in NMS Stocks not subject to the LULD Plan.”

The Exchange also proposes to make corresponding changes to the headings of the table accompanying Rule 11.15(c)(2)(A). The Exchange proposes to change the heading of the second column from “Regular Trading Hours Numerical Guidelines for transactions eligible for review pursuant to paragraph (c)(1)(A)” to “Numerical Guidelines for Transactions Executed During Regular Trading Hours in NMS Stocks Not Subject to the LULD Plan.” This change would simply replace the shorthand “eligible for review pursuant to paragraph (c)(1)(A)” with the fuller description that such transactions are “executed during Regular Trading Hours in NMS Stocks not subject to the LULD Plan,” and is not a substantive change.

Similarly, the Exchange proposes to change the heading of the third column from “Early Trading, Pre-Opening and Post-Closing Session Numerical Guidelines” to “Numerical Guidelines for Transactions Executed During the Early Trading, Pre-Opening and Post-Closing Session or During Overnight Protected Hours in NMS Stocks Not Subject to the LULD Plan.” The proposed change addresses the fact that transactions executed during Overnight Protected Hours in NMS Stocks not subject to the LULD Plan are eligible for clearly erroneous review—just as are transactions in NMS Stocks not subject to the LULD Plan executed during Regular Trading Hours—but at the Numerical Guidelines that apply outside of Regular Trading Hours.

Together, these proposed changes would extend the eligibility of clearly erroneous review for transactions in NMS Stocks not subject to the LULD Plan that is currently in place during Regular Trading Hours to the Overnight

Protected Hours, and would apply the Commission’s recent approval of Overnight Price Bands to the clearly erroneous executions rule.

Implementation

The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals,¹¹ the substance of which are identical to this proposal. The Exchange proposes that this rule change would become operative at the commencement of 23/5 Trading, which is scheduled to commence industry-wide on December 6, 2026.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.¹² Specifically, the proposal is consistent with Section 6(b)(5) of the Act¹³ because it would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, protect investors and the public interest.

The Exchange believes that the proposed change is consistent with just and equitable principles of trade because it extends the basic premise of the current rule that clearly erroneous review should be generally unavailable any time a transaction is executed within LULD Price Bands at a time the Price Bands were available and correct. Currently, LULD Price Bands are available only during Regular Trading Hours, meaning that the restrictions on clearly erroneous review described above apply only during Regular Trading Hours. With the introduction of Overnight Price Bands, the Exchange believes that extending such restrictions on clearly erroneous review to the period when Overnight Price Bands are in place would remove impediments to and perfect the mechanism of a free and open market and a national market system by enhancing the transparency and consistency of the rule.

The resulting rule would thus extend the LULD-related limits on clearly erroneous review that are applicable in Regular Trading Hours to the overnight

¹⁰ Rule 11.15(c)(2)(A)–(D) specifies general rules for applying clearly erroneous review to transactions where such review is not precluded by paragraph (c)(1). Rule 11.15(d)(3) specifies conditions where the Exchange may use a revised Reference Price for the purpose of clearly erroneous review in certain transactions where such review is not precluded by paragraph (c)(1). Rule 11.15(f) specifies that for transactions where clearly erroneous review is not precluded by paragraph (c)(1), an Officer of the Exchange or senior level employee designee may initiate clearly erroneous review on his or her own motion.

¹¹ See, e.g., Securities Exchange Act Release No. 106315 (September 9, 2026), 91 FR 58201 (September 14, 2026), SR–NYSEAMER–2026–080 (September 2, 2026) (“NYSE American CEE Filing”).

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

period. The proposed change would also be consistent with the Commission's rationale in approving the current version of the rule because it would limit any potential discordance between the LULD mechanism and CEE review in the overnight trading session, providing greater certainty to market participants that trades executed with the Overnight Price Bands will stand and not be broken.¹⁴

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposal is consistent with Section 6(b)(8) of the Act¹⁵ in that it does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather than impacting competition, the proposed change would simply extend the basic premise of the current rule that clearly erroneous review should be generally unavailable any time a transaction is executed within LULD Price Bands at a time the Price Bands were available and correct. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals, the substance of which are identical to this proposal. Thus, the proposed rule change will help to ensure consistency across SROs without implicating any competitive issues.

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

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest; impose any significant burden on competition; and become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁶ and Rule 19b-4(f)(6)¹⁷ 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-CboeEDGX-2026-064 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-CboeEDGX-2026-064. 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-CboeEDGX-2026-064 and should be submitted on or before October 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-20709 Filed 10-8-26; 8:45 am]

BILLING CODE 8011-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. MCF 21154]

First Student, Inc.—Acquisition of Control—Autumn Transportation Inc. and Ambassador Wheelchair Services, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving and authorizing finance transaction.

SUMMARY: On August 4, 2026, First Student, Inc. (First Student), a noncarrier, filed an application seeking Board approval to acquire control of Autumn Transportation Inc. (Autumn) and Ambassador Wheelchair Services, Inc. (Ambassador) (collectively, the Target Carriers), through First Student's acquisition of all of the issued and outstanding capital stock of each entity. On September 23, 2026, EQT Infrastructure V Collect EUR SCSp and EQT Infrastructure V Collect USD SCSp, each a noncarrier acting by its manager EQT Fund Management S.à r.l., (collectively, EQT or the EQT Entities), filed a supplement to join First Student's application (EQT Supplement). First Student and EQT will be collectively referred to as Applicants. Also on September 23, 2026, First Student filed a supplement addressing the competitive conditions in the geographic area served by the Target Carriers (Competition Supplement). The Board is tentatively approving and authorizing the proposed acquisition of control. If no opposing comments are timely filed, this notice will be the final Board action.

DATES: Comments must be filed by November 23, 2026. If any comments are filed, First Student may file a reply by December 8, 2026. If no opposing comments are filed by November 23, 2026, this notice shall be effective on November 24, 2026.

ADDRESSES: Comments, referring to Docket No. MCF 21154, may be filed with the Board either via e-filing on the Board's website or in writing addressed to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423-0001. In addition, send one copy of comments to First Student's representatives: Alan Abes, Dinsmore & Shohl LLP, 255 East Fifth Street, Suite 1900, Cincinnati, OH 45202.

FOR FURTHER INFORMATION CONTACT: Sarah Fancher at (202) 740-5507. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245-0245.

SUPPLEMENTARY INFORMATION: The EQT Entities form part of the investment vehicles collectively known as EQT

¹⁴ See 87 FR 55060 at 55063, *supra* note 9.

¹⁵ 15 U.S.C. 78f(b)(8).

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁸ 17 CFR 200.30-3(a)(12).

Infrastructure V. (EQT Suppl. 2.)¹ The EQT Entities are organized under the laws of Luxembourg and are headquartered in Luxembourg City, Lux. (*Id.*) The EQT Entities are noncarriers but control carrier First Student and its carrier affiliates.²

Applicants state that First Student is a Delaware corporation and is the largest student transportation service provider in North America, providing over 865 million student journeys annually to approximately 1,400 school districts. (Appl. 4.) In addition to its home-to-school student transportation services, First Student provides a range of other transportation services, including special needs transportation, routing and fleet management, vehicle electrification, maintenance services, and charter transportation. (*Id.*) First Student has approximately 66,000 employees and operates a fleet of over 48,000 vehicles. (*Id.*) First Student currently controls and operates multiple passenger transportation affiliates in the United States, as discussed below.³

First Student controls Total Transportation Corp. (Total Transportation), a holding company for a group of affiliated transportation services providers, identified below, that operate primarily in the New York

City tri-state region. Total Transportation and its operating subsidiaries provide student transportation services under contract with the New York City Department of Education, as well as transportation services for the New York City Department of Correction and the New York City Department of Homeless Services. Total Transportation's subsidiaries are as follows:

- L&M Bus Corp. provides home-to-school student transportation services in the New York City tri-state region. This entity performs special education and pre-K routes for NYC Department of Education and pre-K Routes for Nassau County, Long Island. (Competition Suppl., Ex. A.)

- Maggie's Paratransit Corp. provides paratransit transportation services in the New York City tri-state region. This entity performs paratransit routes for the Metropolitan Transit Authority (MTA) via the MTA Access-A-Ride Program. (*Id.*)

- Mat Bus Corp (NY) provides transportation services in the tri-state region. This entity performs home-to-school transportation in the Westchester Area. It has previously operated a small number of routes that enter Connecticut but does not currently operate any such routes. (*Id.*)

- Mat Bus Corp (PA) provides transportation services in Pennsylvania. This entity performs home-to-school transportation in the Philadelphia, Pa. area. (*Id.*)

- MPC Bus Corp (NJ) provides transportation services in New Jersey. This entity performs paratransit routes for Union County and the New Jersey Transit Authority via the Access Link Program. (*Id.*)

- Quality Transportation Corp provides transportation services in the New York City tri-state region. This entity performs general education routes for NYC Department of Education. (*Id.*)

- Total Transit Corp operates a paratransit contract in Philadelphia. This entity performs paratransit routes for the Southeastern Pennsylvania Transportation Authority (SEPTA) via the SEPTA Access Program. (*Id.*)

- TTC Bus Corp has operated bus services in Connecticut. Currently, this entity does not operate any transportation service contracts. The entity owns vehicles registered in the state of Connecticut. (*Id.*)

First Student also controls Cook-Illinois Corp. (Cook-Illinois), a holding company for a group of affiliated transportation services providers that operate throughout Illinois. Cook-Illinois and its operating subsidiaries provide home-to-school student

transportation and related services. (*Id.*) Cook-Illinois' subsidiaries are as follows:

- Kickert School Bus Line, Inc., provides home-to-school student transportation services in the Chicago, Ill. area. (*Id.*)

- Kickert Bus Lines, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Liberty School Bus Company, Inc., provides home-to-school student transportation services in the Chicago metropolitan area. Liberty School Bus is the trade name under which American School Bus Company, LLC, conducts operations. (*Id.*)

- American School Bus Company, LLC, provides home-to-school student transportation services in the Chicago metropolitan area and conducts operations under the trade name Liberty School Bus. (*Id.*)

- North Shore Transit, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Richlee Vans, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Warning Charter Service, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Westway Coach, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Indian Head Transit Company, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Chicago School Transit, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Alpha School Bus Company, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Cook County School Bus, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Crawford Bus Service, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Grand Prairie Transit, Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

- Illinois School Bus Co., Inc., provides home-to-school student transportation services in the Chicago area. (*Id.*)

Finally, First Student controls the following additional subsidiaries:

- Continental Air Transport-Chicago School Transit Joint Venture, LLC, provides airport shuttle transportation services in the Chicago metropolitan area. (*Id.*)

¹ Neither the EQT Supplement nor the Competition Supplement contain page numbers. The pages cited in this decision therefore refer to the pdf page numbers of those filings.

² EQT acquired control of First Student, along with carriers First Transit, Inc. (First Transit), First Mile Square, LLC (First Mile), First Canada ULC (First Canada), and Transit Management of Dutchess County, Inc. (Transit Management), from FirstGroup plc and its subsidiary FirstBus Investments Ltd. through a stock purchase agreement. *EQT Infrastructure V Collect EUR SCSps—Acquis. of Control—First Student, Inc.*, MCF 21093 (STB served May 21, 2021). As discussed in this decision, First Student and First Mile continue to operate in the United States and are still controlled by EQT. In a letter filed on October 5, 2026, Applicants clarified the status of the three other motor carriers acquired by EQT in the transaction approved in MCF 21093. According to the letter, First Transit was sold to Transdev North America, Inc., and is no longer owned or controlled by EQT. (Letter 1); see *Transdev Group, S.A.—Acquis. of Control—First Transit Topco, Inc.*, MCF 21103 (STB served Jan. 5, 2023). Transit Management ceased operations and was dissolved on June 25, 2025. (Letter 1.) First Canada is an affiliate of First Student and operates throughout Canada. (*Id.* at 2.) Although included in the corporate structure chart submitted with the pending application, the Applicants state that First Canada no longer operates in the United States. (*Id.*)

³ Additional information about First Student's affiliated passenger transportation operations within the United States, including USDOT numbers, motor carrier numbers and USDOT safety fitness ratings, can be found in the application and the Competition Supplement. (See Appl. 5; *id.*, Ex. B; Competition Suppl., Ex. A.) Additional information on the entity chart for First Student, its affiliates, and ultimate parent companies is also included in the Competition Supplement. (See Competition Suppl., Ex. B.)

- Apple Bus Company is a transportation services provider of home-to-school student transportation, operating predominantly in Missouri, South Dakota, North Dakota, Nebraska, Alaska, and Louisiana. (*Id.*)
- Penny Transportation, Inc., provides home-to-school student transportation in New York, performing pre-K Routes for the NYC Department of Education. (*Id.*)
- Smart Pick, Inc., provides home-to-school student transportation in New York. This entity performs pre-K Routes for NYC Department of Education. (*Id.*)
- Safety Bus Service, Inc., provides home-to-school student transportation, operating throughout the state of New Jersey. (*Id.*)
- Safety Tours, Inc., provides charter transportation services, operating throughout the state of New Jersey. (*Id.*)
- First Mile provides home-to-school student transportation, operating primarily in Upstate New York, with a concentration in Westchester County. It has previously operated a small number of routes that enter Connecticut but does not currently operate any such routes. (*Id.*)
- Pride Transportation Services, Inc., provides home-to-school student transportation services in the New York City tri-state region. This entity performs special education and general education routes for the NYC Department of Education. It previously operated routes that travel from one of the five boroughs of NYC to Connecticut but does not currently operate any such routes. (*Id.*)
- GVC II, Inc., provides paratransit transportation services in the New York City tri-state region. This entity performs paratransit routes for MTA via the MTA Access-A-Ride Program. (*Id.*)
- Bella Bus Corp. provides adult handicapped and homeless transportation services in the New York City tri-state region. (*Id.*)

Applicants seek Board approval to acquire control of the Target Carriers through First Student's acquisition of all of the issued and outstanding capital stock of Autumn and Ambassador. Applicants state that upon consummation of the proposed transaction, the Target Carriers will become direct subsidiaries of First Student and will each remain a separate legal entity operating under Applicants' control. (Appl. 1.)

Autumn is a Connecticut corporation, headquartered in Rocky Hill, Conn. (*Id.* at 5.) Applicants state that Autumn provides student transportation services for public school districts and educational institutions within Connecticut. (*Id.*) Specifically,

Applicants explain that Autumn provides such services in the Greater Hartford area—the City of Hartford and surrounding towns, including Wethersfield, Newington, Rocky Hill, Glastonbury, and Windsor—with limited additional service extending into the Farmington Valley and Storrs. (Competition Suppl. 4.) According to Applicants, the substantial majority of Autumn's revenues are derived from school transportation services in Connecticut provided pursuant to contracts with school districts. (Appl. 5.) Applicants state that Autumn also performs limited charter and special transportation operations, including occasional regulated interstate passenger transportation and that all interstate transportation originates in Connecticut and is primarily associated with field trips, athletic events, and other school-related activities. (*Id.* at 5–6.) Applicants also provide additional details regarding Autumn's operations, customers, USDOT number, FMCSA docket number, fleet composition, and driver count. (*Id.*; Competition Suppl. 4–5.)

Ambassador is a Connecticut corporation, headquartered in Rocky Hill. (Appl. 6.) Applicants state that Ambassador provides wheelchair accessible and non-emergency passenger transportation services and special education transportation services primarily within Connecticut, (*id.*), with a service territory spanning Hartford, Tolland, Middlesex, and Fairfield counties. (Competition Suppl. 5.) Applicants further state that Ambassador provides interstate passenger transportation on a regular but limited basis based on the needs of its customers, explaining that such interstate transportation originates in Connecticut and includes trips to destinations in neighboring states, including Massachusetts, New York, and Rhode Island. (Appl. 6–7.) Applicants also provide additional details regarding Ambassador's operations, customers, USDOT number, FMCSA docket number, fleet composition, and driver count. (*Id.*; Competition Suppl. 5–6.)

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds is consistent with the public interest, taking into consideration at least (1) the effect of the proposed transaction on the adequacy of transportation to the public, (2) the total fixed charges resulting from the proposed transaction, and (3) the interest of affected carrier employees. Here, Applicants have submitted the information required by 49 CFR 1182.2, including (1) information to

demonstrate that First Student's acquisition of the Target Carriers is consistent with the public interest under 49 U.S.C. 14303(b), *see* 49 CFR 1182.2(a)(7); and (2) a jurisdictional statement under 49 U.S.C. 14303(g) that the aggregate gross operating revenues of the involved carriers exceeded \$2 million during a consecutive 12-month period ending not more than six months before the date of the agreement of the parties, *see* 49 CFR 1182.2(a)(5).

Applicants assert that the proposed transaction will not adversely affect the adequacy of transportation services available to the public. (Appl. 10.) Applicants state that the Target Carriers provide passenger transportation services pursuant to contracts with their customers, and the Target Carriers will continue to perform those contractual obligations following consummation of the proposed transaction. (*Id.*) Applicants explain that the transaction does not contemplate any material changes to the Target Carriers' operations, service offerings, facilities, routes, equipment, or management of day-to-day transportation services. (*Id.*) Further, Applicants expect that, as affiliates of First Student, the Target Carriers will benefit from First Student's resources, expertise, and support. (*Id.*) Therefore, Applicants expect that the Target Carriers will maintain, and potentially enhance, the quality and reliability of their transportation services after the proposed transaction. (*Id.*)

Applicants explain that the Target Carriers operate in a fragmented, low-barrier market with no dominant supplier. (Competition Suppl. 3.) According to Applicants, competition is expected to continue to increase as transportation contracts come up for bid and rebid, customers regularly evaluate and reevaluate service providers, and new competitors enter the market. (*Id.*) Applicants state that the competitive bidding environment in Connecticut, the low barriers to entry in the van and special education service segments, the presence of multiple credible alternative carriers in every district and service area served by the Target Carriers, and the demonstrated willingness of school districts to switch providers or self-operate ensure that the proposed transaction will not diminish competition or adversely affect the public interest. (*Id.* at 3, 7.) Applicants also explain that First Student's existing Connecticut operations do not significantly overlap with those of either Target Carrier in any service segment or geographic area.⁴ (*Id.* at 7.)

⁴ The Competition Supplement states that:

Applicants state the proposed transaction is not expected to result in any material increase in the fixed charges associated with the operations of the Target Carriers. (Appl. 10.) The transaction, therefore, is not expected to impose fixed charges that could adversely affect the provision of transportation services or the financial condition of the carriers involved. (*Id.*)

Because the Target Carriers will continue providing transportation services under their existing customer contracts following the transaction, Applicants expect the Target Carriers to continue requiring substantially the same workforce to support those operations. (*Id.* at 11.) Applicants state that they have no current plans to reduce employee staffing levels as a result of the proposed transaction, (*id.*), and anticipate offering employment to substantially all of the Target Carriers' existing employees, (Competition Suppl. 7–8).

Based on Applicants' representations, the Board finds that the proposed transaction, as described in the application as supplemented, is consistent with the public interest. The application will be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. See 49 CFR 1182.6. If no opposing comments are filed by expiration of the comment period, this notice will take effect automatically and will be the final Board action in this proceeding.

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available at www.stb.gov.

It is ordered

1. The transaction is approved and authorized, subject to the filing of opposing comments.

First Student's Connecticut customers consist of school transportation contracts with West Hartford, New Haven, Bethel, Bolton, Easton-Redding-Region 9, Montville/Killingly, Lisbon, Watertown, Weston, Norwich, and Bozrah, many of which are located outside Autumn's primary Greater Hartford service area. First Student and Autumn serve distinct customer bases in Connecticut, with the only overlap among the customers served by each company being [Capital Region Education Council] (CREC) . . . where First Student operates as a direct contractor and Autumn subcontracts to another provider with a contract with CREC, so the parties have not bid directly against each other for CREC work.

(Competition Suppl. 4.) Applicants state that any overlap is limited and they describe the school transportation market in the Connecticut area as highly competitive. (*Id.* at 4–5.)

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective on November 24, 2026, unless opposing comments are filed by November 23, 2026. If any comments are filed, First Student may file a reply by December 8, 2026.

4. *A copy of this notice will be served on:* (1) the U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW, Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE, Washington, DC 20590.

Decided: October 7, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Tammy Lowery,
Clearance Clerk.

[FR Doc. 2026–20783 Filed 10–8–26; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Submission Deadline for Schedule Information for Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, and San Francisco International Airport for the Summer 2027 Scheduling Season

AGENCY: Department of Transportation, Federal Aviation Administration (FAA).

ACTION: Notice of submission deadline.

SUMMARY: Under this notice, FAA announces the submission deadline of October 16, 2026, for Summer 2027 flight schedules at Chicago O'Hare International Airport (ORD), John F. Kennedy International Airport (JFK), Los Angeles International Airport (LAX), Newark Liberty International Airport (EWR), and San Francisco International Airport (SFO).

DATES: Schedules should be submitted by October 16, 2026.

ADDRESSES: Schedules may be submitted to the Slot Administration Office by email to: 7-AWA-slotadmin@faa.gov.

FOR FURTHER INFORMATION CONTACT: Al Meilus, Manager, Slot Administration and Capacity Analysis, AJR–G, Federal Aviation Administration, 800 Independence Avenue SW, Washington,

DC 20591; telephone (202) 267–2822; email Al.Meilus@faa.gov.

SUPPLEMENTARY INFORMATION: This document provides routine notice to carriers serving capacity-constrained airports in the United States, including ORD, JFK, LAX, EWR, and SFO. In particular, this notice announces the deadline for carriers to submit schedules for the Summer 2027 scheduling season.

General Information for All Airports

FAA has designated JFK as an IATA Level 3 airport consistent with the Worldwide Slot Guideline (WSG).¹ FAA currently limits scheduled operations at JFK by Order that expires on October 28, 2028.²

FAA has designated EWR, LAX, ORD, and SFO as IATA Level 2 airports³ subject to a schedule review process premised upon voluntary cooperation. The Summer 2027 scheduling season is from March 28, 2027, through October 30, 2027, in recognition of the IATA Summer scheduling period.

FAA is primarily concerned about scheduled and other regularly conducted commercial operations during designated hours, but carriers may submit schedule plans for the entire day. The designated hours for the Summer 2027 scheduling season are as follows:

- For EWR and JFK, from 0600 to 2300 Eastern Time (1000 to 0300 UTC);
- For LAX and SFO, from 0600 to 2300 Pacific Time (1300 to 0600 UTC); and
- For ORD, from 0600 to 0000 Central Time (1100 to 0500 UTC).

These hours are unchanged from previous scheduling seasons except for ORD.⁴

Carriers should submit schedule information in sufficient detail

¹ FAA generally applies the WSG to the extent there is no conflict with U.S. law or regulation. FAA recognizes the WSG has been replaced by the Worldwide Airports Slot Guidelines (WASG). The currently effective version of the WASG is edition 4, effective August 1, 2025. However, despite several updates to the guidelines, FAA generally applies its predecessor, the WSG, edition 9, to the extent there is no conflict with U.S. law or regulation. The WASG is published jointly by Airports Council International-World, IATA, and the Worldwide Airport Coordinators Group (WWACG). While FAA is considering whether to implement certain changes to the Guidelines in the United States, it will continue to apply WSG edition 9.

² Operating Limitations at John F. Kennedy International Airport, 73 FR 3510 (Jan. 18, 2008), as most recently extended, 91 FR 37769 (June 23, 2026). The slot coordination parameters for JFK are set forth in this Order.

³ These designations remain effective until FAA announces a change in the **Federal Register**.

⁴ Previously, designated hours at ORD were from 0600 to 2100 Central Time (1100 to 0200 UTC).

including, at minimum, the marketing or operating carrier, flight number, scheduled time of operation, frequency, aircraft equipment, and effective dates. IATA standard schedule information format and data elements for communications at Level 2 and Level 3 airports in the IATA Standard Schedules Information Manual (SSIM) Chapter 6 may be used. The WSG provides additional information on schedule submissions at Level 2 and Level 3 airports. Some carriers at JFK manage and track slots through FAA-assigned Slot ID numbers corresponding to an arrival or departure slot in a particular half-hour on a particular day of the week and date. FAA has a similar voluntary process for tracking schedules at EWR with Reference IDs, and certain carriers are managing their schedules accordingly. The primary users of IDs are U.S. and Canadian carriers that have the highest frequencies and considerable schedule changes throughout the season, and can benefit from a simplified exchange of information not dependent on full flight details. Carriers are encouraged to submit schedule requests at those airports using Slot or Reference IDs.

As stated in the WSG schedule facilitation at a Level 2 airport is based on the following: (1) Schedule adjustments are mutually agreed upon between the carriers and the facilitator; (2) the intent is to avoid exceeding the airport's coordination parameters; (3) the concepts of historic precedence and series of slots do not apply at Level 2 airports, although WSG recommends giving priority to approved services that plan to operate unchanged from the previous equivalent season at Level 2 airports; and (4) the facilitator should adjust the smallest number of flights by the least amount of time necessary to avoid exceeding the airport's coordination parameters. Consistent with the WSG, the success of Level 2 in the United States depends on the voluntary cooperation of carriers.

FAA considers several factors and priorities that are consistent with the WSG as it reviews schedule and slot requests at Level 2 and Level 3 airports, including (1) historic slots or services from the previous equivalent season over new demand for the same timings; (2) services that are unchanged over services that plan to change time or other capacity relevant parameters; (3) introduction of year-round services; (4) effective period of operation; (5) regularly planned operations over *ad hoc* operations; and (6) other operational factors that may limit a carrier's timing flexibility.

FAA seeks to maintain close communications with carriers and terminal schedule facilitators on potential runway schedule issues or terminal and gate issues that may affect the runway times. In addition to applying these priorities from the WSG, the U.S. Government has adopted a number of measures and procedures to promote competition and new entry at U.S. slot-controlled and schedule-facilitated airports.

Slot management in the United States differs in some respects from procedures in other countries. In the United States, FAA is responsible for facilitation and coordination of runway access for takeoffs and landings at Level 2 and Level 3 airports; however, the airport authority or its designee is responsible for facilitation and coordination of terminal/gate/airport facility access. The process with the individual airports for terminal access and other airport services is separate from, and in addition to, FAA schedule review based on runway capacity.

Generally, FAA uses average hourly runway capacity throughput for airports and performance metrics in conducting its schedule review at Level 2 airports and determining the scheduling limits at Level 3 airports included in FAA rules or orders.⁵ FAA also considers other factors that can affect operations, such as capacity changes due to runway, taxiway, or other airport construction, air traffic control procedural changes, airport surface operations, and historical or projected flight delays and congestion.

Finally, FAA notes that the schedule information submitted by carriers to FAA may be subject to disclosure under the Freedom of Information Act (FOIA). The WSG also provides for release of information at certain stages of slot coordination and schedule facilitation. In general, once it acts on a schedule submission or slot request, FAA may release information on slot allocation or similar slot transactions, or schedule information reviewed as part of the schedule facilitation process. FAA does not expect that practice to change, and most slot and schedule information

⁵ FAA typically determines an airport's average adjusted runway capacity or typical throughput for Level 2 airports by reviewing hourly data on the arrival and departure rates that air traffic control indicates could be accepted for that hour, commonly known as "called" rates. FAA also reviews the actual number of arrivals and departures that operated in the same hour. Generally, FAA uses the higher of the two numbers, called or actual, for identifying trends and schedule review purposes. Some dates are excluded from analysis, such as during periods when extended airport closures or construction could affect capacity.

would not be exempt from release under FOIA. FAA recognizes that some carriers may submit information on schedule plans that are both customarily and actually treated as private. Carriers that submit such confidential schedule information should clearly mark the information, or any relevant portions thereof, as proprietary information ("PROPIN"). FAA will take the necessary steps to protect properly designated information to the extent allowable by law.

EWR General Information

FAA issued a Final Order (June 2025 Order) on June 10, 2025, limiting operations at EWR due to elevated delays and operational disruptions caused by air traffic controller staffing challenges, construction, congestion, and telecommunication issues.

On September 29, 2025, FAA issued an extension of the June 2025 Order through the end of the Summer 2026 scheduling season and increased the hourly operating limitations from 68 to 72.⁶ The staffing challenges persisted throughout the summer and could not be resolved prior to the start of the Winter 2025/2026 scheduling season or by the close of the Summer 2026 scheduling season.

On June 23, 2026, FAA extended the existing operating limitations at EWR through the end of the Summer 2027 scheduling season, October 30, 2027.⁷ This determination was made as staffing levels for Area C of the Philadelphia TRACON (PHL), which manages EWR, remain level and will not increase significantly prior to the start of the Summer 2027 scheduling season. Carriers are reminded that FAA approval for runway access is separate from the approval process for gates or other airport infrastructure and both are essential for success at EWR. FAA expects that all carriers operating at EWR will respect the scheduling limits and work cooperatively with FAA in order to avoid unacceptable delays and other adverse operational impacts at the airport.

ORD General Information

FAA issued a Final Order (April 2026 Order) on April 20, 2026, limiting operations at ORD due to elevated delays and operational disruptions caused by factors such as airport construction and competitive

⁶ www.federalregister.gov/documents/2025/09/29/2025-18871/operating-limitations-at-newark-liberty-international-airport.

⁷ <https://www.federalregister.gov/documents/2026/06/23/2026-12589/operating-limitations-at-newark-liberty-international-airport>.

scheduling dynamics occurring between the two largest carriers at the airport.⁸

On July 14, 2026, FAA extended the April 2026 Order through the end of the Summer 2027 scheduling season, October 30, 2027.⁹ This determination was made as airport construction and adjustments on the airfield would continue through the Summer 2027 scheduling season. Carriers are reminded that FAA approval for runway access is separate from the approval process for gates or other airport infrastructure and both are essential for success at ORD. FAA expects that all carriers operating at ORD will respect the scheduling limits and work cooperatively with FAA in order to avoid unacceptable delays and other adverse operational impacts at the airport.

Issued in Washington, DC, on October 6, 2026.

Gianfranco Burdhamo II,

Acting Deputy Vice President, System Operations Services.

[FR Doc. 2026-20784 Filed 10-7-26; 4:15 pm]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2026-1090]

Agency Information Collection Activities: Notice of Request for an Extension of Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for an extension of an existing information collection that is summarized below under

SUPPLEMENTARY INFORMATION. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by December 8, 2026.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 1090 by any of the following methods:

Website: For access to the docket to read background documents or

comments received go to the Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Fax: 1-202-493-2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

WANG, Shuqing, Office of Administration, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 7 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Travel Monitoring Analysis System (TMAS).

OMB Control: 1225-0587.

Background: 23 U.S. Code § 150 National Goals and Performance Management Measures requires the U.S. D.O.T. to establish a performance management system for its Federal-aid highway program. The Federal Highway Administration, U.S. D.O.T. promulgated the performance management via 23 CFR 490: National Performance Management Measures. Traffic data, including volume (of vehicles and travelers), classification (types of vehicles), weight (weight of vehicles), and travel time (speed), are parameters the performance management program relies upon.

The FHWA is planning to continue collecting these traffic data under the TMAS process. The information will continue to be used by the FHWA and other D.O.T. agencies to manage its Federal-aid highway program through the performance management mechanism, evaluate changes in vehicular and nonmotorized travel in order to assess impacts on highway safety, analyze the role of travel in economic development and productivity, assess impacts and demands from truck travel, and maintain and improve our Nation's mobility while protecting the human and natural environment. To carry out the data collection, the FHWA will be requesting that State Departments of Transportations (SDOTs) continue to provide traffic volume, vehicle classification, vehicle speed, vehicle

weight data, and nonmotorized data, which SDOTs collect as part of states' traffic monitoring programs.

States and local governments collect nonmotorized volume data and motorized traffic volume, vehicle classification, vehicle speed, and vehicle weight data throughout the year using various detection devices. These data allow transportation professionals at the Federal, State, and local levels to make informed decisions on projects, programs, plans, and policies.

Respondents: 52 D.O.T.s, including all States, the District of Columbia and Puerto Rico.

Frequency: Monthly.

Estimated Average Burden per Response: Under the Intermodal Surface Transportation Efficiency Act, the Transportation Equity Act for the 21st Century, and the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, all SDOTs have established their statewide traffic monitoring system (T.M.S.). This T.M.S. system enables the collection of traffic data in a continuous manner. The burden for the data to be submitted to the TMAS rests with data transmission and data quality checks. The estimated average monthly burden for the States and the District of Columbia and Puerto Rico is 4.16 hours for an annual burden of 50 hours per agency. In addition, to further reduce the burden for data submittal to TMAS due to data file size issues and transmission issues, the TMAS system can accept data submitted in a weekly or biweekly manner (reduced file size) at each SDOT's choice. To further reduce the reporting burden, there is no size limit to the monthly data submittals in TMAS.

Estimated Total Annual Burden Hours: 2,600.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

⁸ Operating Limitations at Chicago O'Hare International Airport, Order Establishing Scheduling Limits, 91 FR 21071 (April 20, 2026), as amended on April 27, 2026, 91 FR 22573.

⁹ 91 FR 43144 (July 14, 2026).

Issued on: October 6, 2026.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2026–20718 Filed 10–8–26; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2026–0958]

Parts and Accessories Necessary for Safe Operation; Application for Exemption From Aurora Operations, Inc (USDOT #341156)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), U.S. Department of Transportation (DOT).

ACTION: Notice of final disposition; grant of application for exemption.

SUMMARY: FMCSA announces its decision to grant a limited five-year exemption to Aurora Operations, Inc. (Aurora) and other motor carriers operating Level 4 automated driving system (ADS)-equipped commercial motor vehicles (CMVs), with prior notice to FMCSA, from compliance with the warning device placement requirements, the steady-burning lamp requirements, and the requirements for the types and number of warning devices. This exemption permits motor carriers to use cab-mounted warning beacons in lieu of traditional warning devices on Level 4 ADS-equipped CMVs. The Agency has determined that granting the exemption would likely achieve a level of safety equivalent to or greater than the level of safety provided by the regulation.

DATES: The exemption is effective October 7, 2026 and expires October 7, 2031.

FOR FURTHER INFORMATION CONTACT: Mr. Vinay Nagabhushana, Vehicle and Roadside Operations Division, Office of Carrier, Driver and Vehicle Safety Standards; MCPSV@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2026-0958/document> and choose the document to review. To view comments, click this notice, then click “Document Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in the DOT West Building, 1200 New Jersey Avenue SE,

W58–213, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSR). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the exempted party will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulatory Requirements

Aurora requests an exemption from certain FMCSR related to requirements for placing warning devices around a stopped CMV, requirements that exterior lamps be steady burning, and requirements that specific types of warning devices be used. Section 392.22(b) of the FMCSR requires the driver of a CMV stopped on the traveled portion or shoulder of a road for any cause other than a necessary traffic stop to activate hazard warning signal flashers and place required warning devices as soon as possible, but within ten minutes, at specified locations behind and in front of the stopped CMV. Section 392.22(b) also specifies placement of warning devices in certain circumstances, such as during daylight hours, or where devices may be obstructed from view (e.g., when stopped within 500 feet of a curve or the crest of a hill).

Section 393.25(e) of the FMCSR requires that all exterior lamps be steady burning, with exceptions not relevant here.

Section 393.95(f) of the FMCSR specifies the types and number of warning devices to be used for stopped vehicles, namely three bidirectional emergency reflective triangles or at least six fuseses. The reference to three liquid-burning flares was removed by a final rule published on February 19, 2026 (91 FR 7867). Other warning devices may be used in addition to required devices, as long as they do not reduce the effectiveness of required devices.

Applicant’s Request

Aurora’s application for exemption was described in detail in a **Federal Register** notice published on April 15, 2026 (91 FR 20252) and will not be repeated as the facts have not changed.

IV. Public Comments

FMCSA received a total of 402 comments in response to Aurora’s application. Commenters who support the exemption include the Montana Trucking Association; the Nevada Trucking Association; the Texas Trucking Association; the Autonomous Vehicle Industry Association (AVIA); the Association of Uncrewed Vehicle Systems International (AUVSI); the National Association of Manufacturers; the American Trucking Associations (ATA); the Intelligent Transportation Society of America (ITS America); Stack AV; Hirschbach Motor Lines LLC; Kodiak AI; International Motors and PlusAI; Gatik AI; Uber Technologies Inc.; Waymo LLC; Torc Robotics; Amazon; TechNet; Volvo Group North America (Volvo); the Consumer Technology Association (CTA); C.R. England Trucking; the Allegheny Conference on Community Development; the Bay Area Council; the Chamber of Progress; the Arizona Technology Council; Safety21, the U.S. Department of Transportation National University Transportation Center for Safety led by Carnegie Mellon University; DriveOhio; and the National Fraternal Order of Police.

Comments in support of the exemption cite the need for continued development of automated technologies and highlight the safety benefits of eliminating the requirement for a human to exit the vehicle to place warning devices under potentially hazardous roadway and traffic conditions. AUVSI supports granting the exemption to all Level 4 ADS-equipped CMV operators, conditioned on prior FMCSA notification, to allow the industry to innovate. AUVSI asserts that granting the exemption would acknowledge the reality that it is impossible for a driverless truck to place warning triangles on the roadway.

TECHNET states that “the elevated and actively illuminated warning beacons enhance vehicle conspicuity, enabling earlier detection and safer responses from approaching motorists,” as well as eliminate the need for a human to enter an active roadway. Commenters including TECHNET and CTA note that the current requirements for warning devices were developed decades ago. Several commenters, including AVIA and Volvo, not only support cab-mounted warning beacons for ADS-equipped CMVs, but also support warning beacons for traditional CMVs to eliminate the risk for drivers to exit the vehicle into potentially unsafe road conditions. Volvo highlights that ADS-equipped vehicles are designed with redundancies across critical systems, and cab-mounted beacons should have the same standards of reliability and automation as other critical systems.

Cassandra Burke Robertson, a professor from Case Western Reserve University School of Law, submitted comments in an individual capacity expressing support for the exemption. Professor Robertson notes in part that beacons are more reliable than warning triangles, which are vulnerable to displacement by wind, passing traffic, and terrain. Professor Robertson cites some concerns with longer vehicle combinations and suggests requiring supplementary rear-mounted beacons or reflectors on such vehicles. The ATA comments that FMCSA should grant the exemption based on the data from Aurora’s operation under the waiver and the research studies submitted by Aurora. The ATA asks FMCSA to consider how data from multiple exemptions related to lighting solutions can be analyzed to improve conspicuity and safety for all CMVs.

Commenters who oppose the exemption include the Truck Safety Coalition (TSC), Citizens for Reliable and Safe Highways (CRASH), and Parents Against Tired Truckers (P.A.T.T.); the Federation of Professional Truckers (FOPT); the Small Business in Transportation Coalition (SBTC); AWM Associates; REAL Women in Trucking; Advocates for Highway and Auto Safety (Advocates); the Owner-Operator Independent Drivers Association (OOIDA); Mission Ready Transport; and DD-214 Transport LLC. Most commenters who oppose the exemption are individuals, including many truck drivers. Many individual commenters who oppose the exemption express concerns regarding blind corners blocking sight lines, the risk of single point electrical failures, the lack of performance standards for the proposed beacons, and the possible

articulation of trailers blocking warning beacons.

OOIDA expresses concern that the two studies submitted with Aurora’s application do not account for the varying weather, road, lighting, and traffic conditions that CMVs encounter. OOIDA also notes that Aurora did not provide specific information on the road conditions, time of day, and location where its cab-mounted beacons activated during the period in which Aurora operated under a waiver. OOIDA states that FMCSA should not grant any exemptions until it completes its ongoing research study on warning devices.¹ Several commenters, including OOIDA, Shon’s Equipment, and an anonymous individual, commented that the existing regulations already require the use of flashing lights, and that the warning triangles provide an additional layer of safety not present with the warning beacons. REAL Women in Trucking also commented that warning triangles create a progressive warning zone to give motorists time to identify hazards. REAL Women in Trucking also cites concerns that the beacons could be obstructed by a trailer, roadway curvatures, hills, or other conditions.

Advocates commented that FMCSA denied Aurora’s previous exemption request due to insufficient data and that the current application fails to address the previously identified deficiencies. Advocates believes that Aurora’s use of the beacons for a total of ten hours during expected stops does not provide a sufficient basis to grant a five-year exemption and that testing the beacons during expected stops does not provide data on the performance of the beacons in an emergency. Advocates also states that the public should have the opportunity to review the waiver term reports that Aurora submitted to FMCSA. AWM Associates questions the effectiveness of the beacons in real-world scenarios where a truck breaks down at an angle, noting that an out-of-line trailer would physically block the cab-mounted lights. Further, AWM Associates suggests if the exemption were approved, it should be restricted to Aurora only for a one-year period. Joint comments submitted by TSC, CRASH, and P.A.T.T. note that cab-mounted beacons require the cab to be aligned with the trailer but in many emergencies a slight or severe jackknife may occur.

FOPT highlights the distance-spaced warning devices as necessary for blind curves, hills, entrance ramps, exit ramps, shoulders and low-visibility

weather. SBTC asserts, among other things, that granting the exemption “would open a can of worms” in holding ADS-equipped CMVs to more lenient standards than CMVs driven by humans. Mission Ready Transport comments that the exemption would create a self-certification mechanism with no independent safety review of the equipment used by motor carriers operating under the exemption.

Jonathan Judge, an owner-operator, strongly opposes the exemption and states that the docket was flooded with comments that reflect a coordinated campaign to inflate Aurora’s safety claims artificially. In addition, Mr. Judge observes that comments were submitted by individuals and organizations with undisclosed affiliations with Aurora. Mr. Judge further notes that a cab-mounted beacon does not provide depth perception. He explains that the National Transportation Safety Board has defined the concept of “perceptual looming,” which causes the driver to realize that an object is stationary and not moving. He states that the Manual on Uniform Traffic Control Devices and Traffic Incident Management protocols provide that first responders should establish an “Advance Warning Area” to initiate the perceptual looming response. He notes that law enforcement also deploys cone tapers and “Lane + 1 blocking” in recognition that emergency lights are insufficient.

Many individual commenters commented generally on their opposition to driverless CMVs. Those comments are out of scope because the exemption request relates specifically to Aurora’s exemption request from the warning device placement requirements in 49 CFR 392.22(b), the steady-burning lamp requirement in 49 CFR 393.25(e), and the requirements for the types and number of warning devices is 49 CFR 393.95(f).

V. FMCSA Decision

FMCSA has evaluated Aurora’s exemption application, supporting materials, and the comments received. The Agency has determined that granting an exemption to allow Aurora to install cab-mounted warning beacons for Level 4 ADS-equipped CMVs, in lieu of placing warning triangles at specified locations in front of and behind the stopped CMVs, would likely achieve a level of safety equivalent to, or greater than, the level of safety that would be achieved without exemption. Other motor carriers operating Level 4 ADS-equipped CMVs may operate under the exemption only with prior notice to

¹ See <https://www.fmcsa.dot.gov/research-and-analysis/research/warning-devices-stopped-cmv>.

FMCSA as described in the terms and conditions below.

As noted in Aurora's exemption application, Aurora initially applied for an exemption from the warning device placement requirements in 2023. FMCSA denied that exemption request, finding that the request to "exempt a class of unspecified carriers using unspecified equipment on unspecified vehicles only further undermines the claimed likely equivalent level of safety" (89 FR 105675, 105679, Dec. 27, 2024). The Agency subsequently granted a temporary, narrow waiver to Aurora, which Aurora attached to its present exemption application, and which is available in the docket. Aurora's present exemption application requests similar limitations to those included in the waiver. FMCSA finds that those limitations reasonably address the reasons for the 2024 denial and has incorporated those limitations into the terms and conditions of this exemption, providing the specificity and monitoring controls necessary to ensure highway safety. For example, the 2024 exemption request sought industry-wide regulatory relief whereby any motor carrier operating Level 4 ADS-equipped CMVs could operate under the exemption without any prior notice to FMCSA and made no mention of annual reports to the Agency, lacking monitoring controls. In contrast, this exemption requires any motor carrier, other than Aurora, to provide written notification to FMCSA prior to commencing operations covered by the exemption. Furthermore, to enable FMCSA's effective oversight, motor carriers must submit an annual report detailing any malfunctions, power issues, or other instances where the beacons did not operate in accordance with the exemption. In addition, the previous exemption request did not suggest prohibiting higher risk operations. This exemption prohibits operations that would otherwise require an "H," "X," "P," or "S" commercial driver's license endorsement if a human driver were present, explicitly barring the transportation of passengers or of hazardous materials as defined in 49 CFR 383.5.

The 2024 denial also noted a lack of sufficient details about the proposed alternative devices. This exemption resolves that ambiguity by including technical specifications that mandate SAE J595 photometric performance standards, dictate specific mounting locations, and require a redundant source of power for the cab-mounted beacons to prevent single-point power failures of the beacons. Based on the above-mentioned limitations and terms

and conditions, the Agency determined that the waiver would likely achieve a level of safety equivalent to, or greater than, the level of safety that would be achieved in the absence of the waiver. FMCSA has incorporated these precise waiver limitations into the terms and conditions of this exemption to distinguish it directly from the 2024 denial, providing the necessary specificity and monitoring controls.

Aurora states that it successfully used cab-mounted warning beacons under the waiver from October 10, 2025 through January 9, 2026 on 34 CMVs that traveled over 500,000 miles. This real-world mileage represents new performance data that was gathered after the December 2024 denial and, as such, was not contemplated by the Agency when it issued that prior decision. During that period, the beacons activated for a total duration of nearly 10 hours. Aurora reports that, to the company's knowledge, the beacons were reliable and operated as expected without any faults, malfunctions, or power issues. Aurora's CMVs that operated under the waiver were not involved in, nor contributed to, any roadway collisions while stopped on the roadway and using the beacons. Therefore, all data collected under the waiver indicated that Aurora's operations with the cab-mounted beacons did not degrade highway safety. Moreover, FMCSA did not receive any comments providing additional data or information, and is not aware of any additional data or information, indicating that the waiver negatively impacted safety. In response to Advocates' request to review the term reports that Aurora submitted to FMCSA under the waiver, FMCSA notes that Aurora submitted this information as confidential business information, per the terms of the waiver. Aurora's exemption application, however, summarizes the aggregate data reported during its operations under the waiver from October 10, 2025 through January 9, 2026 and is available in the docket.

In response to comments questioning the sufficiency of the studies submitted by Aurora, and the performance of the cab-mounted warning beacons in all roadway and weather conditions, FMCSA has reconsidered the two studies that Aurora submitted with its 2023 exemption application and again with its present application. The first is the "Naturalistic Study of Warning Device Equivalency," prepared by Aurora in October 2022 (App. D to Aurora's application). The second is the "Stopped Automated Commercial Motor Vehicle Warning Device Surrogates" study, prepared by the Virginia Tech

Transportation Institute (VTTI) for Waymo LLC on August 1, 2022 (App. E to Aurora's application). In the 2024 denial, FMCSA expressed concern that the Aurora naturalistic study showed a slightly lower percentage of drivers responding to beacons than warning triangles in five of eight scenarios. However, further analysis of the comprehensive data within these studies overcomes this concern and supports granting the exemption. Although the overall proportion of respondents may have been nominally lower in certain scenarios, the Aurora study revealed that the quality and timing of the responses were greater with the beacons. Specifically, in six of the eight tested scenarios, motorists initiated their first evasive response (such as a lane change or slowing down) further back from the trailer when exposed to the beacons compared to the triangles. Overall, the average Distance at Response (DAR) was 135.71 meters for the beacons versus 133.24 meters for the triangles, demonstrating that the beacons effectively gave drivers a greater distance to react. The study concluded that the beacons performed equivalently to the deployment of the triangles. The VTTI study corroborated these findings in a controlled environment, concluding that drivers demonstrated equivalent detection, recognition, and performance metrics across both daytime and nighttime conditions. Crucially, the VTTI study highlighted specific areas where beacons outperformed triangles, noting that nighttime beacon exposure elicited earlier braking and slower, safer passing speeds. VTTI researchers also observed that drivers exposed to the triangles were associated with an overcorrection of lateral distance during certain scenarios when compared to the beacons. The study also surveyed participants for their subjective opinions of the beacons compared to triangles. The results of the survey indicated 78.26 percent of daytime participants and 83.33 percent of nighttime participants reported that the beacons were more noticeable and easier to see than the traditional triangles. When considered together, these studies further support a determination that the beacons are likely to achieve a level of safety equivalent to, or greater than, the level of safety that would be achieved absent the exemption.

Although there may be some edge case circumstances in which a cab-mounted warning beacon may not perform as expected, "such as a CMV on its side" (89 FR at 105679), warning

triangles are also susceptible to being knocked over or not placed correctly or not placed at all due to human error or incapacitation following a crash. FMCSA has no data suggesting that the edge case circumstances where beacons fail to perform as expected occur more frequently than those where warning triangles are compromised. In addition, current regulations permit a 10-minute window before a driver is required to place warning triangles under 49 CFR 392.22(b). In the 2024 denial, FMCSA noted that while the applicants claimed their beacons would activate immediately, providing an advantage over the “up to ten minutes” allowed for triangles, they failed to demonstrate “the timing with which they would do so, and how that timing compares to timing required under the FMCSR” (89 FR at 105679). To cure this, FMCSA explicitly requires in the terms and conditions below that cab-mounted warning beacons must activate within five minutes, ensuring they activate much more quickly and minimize the hazardous period where a stopped vehicle sits without extended warning signals. By requiring a shortened five-minute activation window, this exemption enforces a clear, verifiable safety improvement over both the prior denied request and the existing regulatory allowance.

Although this exemption is limited in scope to CMVs equipped with a Level 4 ADS, cab-mounted warning beacons also present a practical safety benefit for traditional trucking operations. By eliminating the need for a driver to exit the cab physically, walk along an active highway or shoulder, and manually place warning devices, the beacons prevent drivers from being exposed to the risk of being struck by oncoming traffic. Given this likely benefit for human operators, FMCSA recognizes that updating the underlying warning device requirements for all CMVs, not just ADS-equipped CMVs, may be ripe for future regulatory action.

In response to Mr. Judge’s comment about law enforcement procedures for traffic incident management, FMCSA does not have any data showing that warning triangle placement has the same effect on approaching motorists as lane +1 blocking or more extensive cone tapering methods used by law enforcement. In response to REAL Women in Trucking, FMCSA similarly lacks data showing that warning triangles significantly improve driver reaction time. As FMCSA observed in its letter granting the waiver (App. C to Aurora’s application), there are historically unresolved questions of whether the use of such warning

devices improves traffic safety and, if so, how and to what extent. Without information on the level of safety the current regulatory requirements provide, the two studies submitted in support of Aurora’s application reasonably support a determination that motorists detect and respond to the beacons at a similar rate as existing warning devices under the terms and conditions imposed by this exemption.

FMCSA acknowledges Professor Robertson’s concerns about the rear visibility of longer combination vehicles. The Agency is limiting the use of the exemption for longer combination vehicles to combinations using two, 28-foot trailers. As Aurora notes, a combination of two, 28-foot trailers adds approximately only 9.5 feet to a standard CMV’s length. Although this configuration creates a minimally extended occlusion zone directly behind the trailer, the warning beacons’ visibility is not materially impacted by this setup. The combination of the high mounting location on the cab, the brightness of the flashing amber beacons, the requirement for standard hazard warning signal flashers to activate, and the existing requirement for rear reflective markings in 49 CFR 393.11, ensures that approaching motorists will likely still observe the warning before nearing or entering this narrow area of occlusion. Furthermore, because motorists generally do not drive perfectly in line with the direct center of the rear of a trailer, and roadways are rarely perfectly straight, any potential occlusion of the cab-mounted beacons would likely be fleeting. Even during such brief moments, the vehicle’s standard rear hazard warning signal flashers will remain activated per the terms of the exemption to provide continuous conspicuity to approaching traffic. FMCSA also allows use of the exemption for tankers. A tanker’s cylindrical shape and lower overall profile is reasonably likely to provide greater awareness and visibility of the cab-mounted beacons compared to that of a traditional 53-foot box trailer. Transportation of passengers or hazardous materials that would otherwise require a commercial driver’s license endorsement if a human driver were present are prohibited under the exemptions. FMCSA will monitor the use of the exemption as to LCVs and tankers through the annual reporting requirement in the terms and conditions in Section VI.C.7 of the exemption.

In response to comments expressing concern that the submitted studies and waiver operations do not account for every varying weather, road, lighting, and traffic condition encountered across

the entire country, the terms of this exemption proactively address this limitation. Aurora’s operations under the waiver were conducted primarily on the U.S. Interstate Highway System and under environmental conditions that were specific to its validated Operational Design Domain (ODD), and similarly, this exemption does not grant unrestricted nationwide deployment. Instead, the terms and conditions limit operations to roadways that are part of the validated ODD for the specific ADS-equipped CMV. Because a Level 4 ADS is constrained to operate only within its specific ODD, the vehicle—and its associated warning systems—will only be deployed in the specific geographic, roadway, and environmental conditions for which it has been engineered and validated to operate. By linking the use of the exemption directly to the vehicle’s validated ODD, the Agency effectively bounds the operational risk and mitigates concerns associated with untested environments.

In conclusion, the totality of the evidence—comprising over 500,000 miles of real-world operation under the waiver without a negative safety impact, nearly 10 hours of successful beacon deployment, and empirical data from the VTTI and Aurora studies—demonstrates that cab-mounted beacons likely perform as effectively in alerting approaching motorists as triangles. By pairing this performance data with operational guardrails, including mandatory five-minute activation, redundant power requirements, ODD limitations, annual reporting requirements, and other specific terms similar to the waiver, FMCSA finds that this exemption cures the deficiencies identified in its prior denial (89 FR 105675). Therefore, the Agency determines that granting this exemption will likely achieve a level of safety equivalent to, or greater than, the level of safety that would be achieved absent such exemption.

VI. Exemption

A. Grant of Exemption

FMCSA grants an exemption from the warning device placement requirements in 49 CFR 392.22(b), the steady-burning lamp requirement in 49 CFR 393.25(e), and the requirements for the types and number of warning devices is 49 CFR 393.95(f). This exemption allows motor carriers operating under the exemption to use cab-mounted warning beacons, subject to the terms and conditions of the exemption, in lieu of the warning devices specified in 49 CFR 393.95(f).

B. Applicability of Exemption

This exemption applies to Aurora for its operation of commercial motor vehicles (CMVs), as defined in 49 CFR 390.5T, equipped with a Level 4 ADS, as defined by SAE International in Table 1 of SAE J3016 (Apr. 2021). This exemption also applies to any other motor carrier operating CMVs equipped with a Level 4 ADS, provided such motor carrier provides written notification to FMCSA that includes the notification specified in Section VI.C. During the exemption period, motor carriers operating Level 4 ADS-equipped CMVs may install and use cab-mounted warning beacons at locations specified in VI.C.

C. Terms and Conditions

1. *Notification.* Any motor carrier, other than Aurora, that intends to operate CMVs under this exemption must notify FMCSA in writing prior to commencing operations covered by this exemption. The notification must be sent to FMCSA via email to MCPSV@dot.gov with the following information:

a. The motor carrier's legal name, USDOT number, and principal place of business, and point of contact of the motor carrier.

b. A statement that adequately demonstrates the motor carrier currently has cab-mounted warning beacons and the ability to comply with all terms and conditions of this exemption.

c. A statement affirming the motor carrier will comply with all terms and conditions of this exemption.

d. In accordance with 28 U.S.C. 1746, the notification must include the following language: "I, [Name], certify under penalty of perjury that the foregoing is true and correct. Executed on [Date], [Signature]."

2. Operations.

a. Operations under this exemption shall occur only on roadways that are part of the validated Operational Design Domain for the specific ADS-equipped CMV.

b. Operations under this exemption are prohibited if operations would otherwise require an "H," "X," "P," or "S" endorsement under 49 CFR 383.93—if a human driver were present.

c. Operations under this exemption of longer combination vehicles (LCV), as defined in 49 CFR 380.105, are limited to LCV doubles with two, 28-foot trailers. This exemption must not be used for operations with LCV triples.

d. Each motor carrier operating under this exemption is prohibited from operating as a for-hire passenger carrier or private passenger carrier, or transporting hazardous materials as

defined in 49 CFR 383.5, while using this exemption.

3. *Cab-Mounted Warning Beacon Specifications.* The cab-mounted warning beacons, a safety device, used under this exemption must consist of forward- and rearward-facing flashing lights.

a. *Mounting.* At least one rearward-facing light must be mounted on each side of the cab, and at least one forward-facing light mounted on the front of the cab. The mountings must provide stable support for the beacons. The total width of the vehicle, inclusive of mountings and lights, may not exceed 122 inches.

b. *Location.* All lights must be mounted at least 100 inches from the ground and located at or above the upper edge of the sideview mirrors but below the top edge of the cab.

c. *Performance.* The cab-mounted warning beacons must be amber in color and meet the Class 1 photometric performance requirements of SAE J595.

d. *Flash Pattern.* The activation of the warning system must cause the beacons to flash at a rate different from the vehicle's standard hazard warning signal flashers required under 49 CFR 392.22(a).

e. *Power.* The beacons must be designed and installed with redundant power sources to prevent failure due to a single-point power failure.

4. Activation and Operation:

a. The beacons must activate as soon as possible, but in any event within five minutes, whenever the CMV is stopped on the traveled portion or the shoulder of a highway for any cause other than necessary traffic stops (*i.e.*, whenever 49 CFR 392.22(b) would otherwise apply).

b. The beacons must remain flashing for the entire duration of the stop, from the initial stop until the vehicle reinitiates movement or the vehicle is recovered.

c. Standard hazard warning signal flashers must also activate as required by 49 CFR 392.22(a) and must continue flashing for the entire duration of the stop.

5. Other.

a. Each motor carrier operating under this exemption must comply with all other applicable Federal Motor Carrier Safety Regulations (49 CFR parts 350–399).

b. Each motor carrier operating under this exemption shall, at FMCSA's request, meet with FMCSA to answer questions regarding data and information required to be provided under this exemption.

6. *Crash Reporting.* Each motor carrier operating under this exemption must notify FMCSA via email to MCPSV@dot.gov not later than five calendar days

of any crash involving a CMV while the cab-mounted warning beacons are activated or should have been activated per the conditions of this exemption. For the purposes of this exemption, the term "crash" shall have the same meaning as defined in the National Highway Traffic Safety Administration's (NHTSA) Third Amended Standing General Order (SGO) 2021–01.² Notification must include all available information regarding the circumstances of the crash, including the following information:

1. Identifier of the Exemption ("Exemption of Warning Device Requirements").

2. Date and time of the crash.

3. City or town, and State, in which the crash occurred, or closest to the crash scene, and geolocation information.

4. Vehicle Identification Number (VIN).

5. Description of any property damage.

6. Number of individuals suffering physical injury.

7. Number of fatalities.

8. The police-reported narrative of the crash (if available at the time of the report or provided upon its completion).

7. Annual Report

Each motor carrier operating under this exemption, must submit a report to FMCSA via email to MCPSV@dot.gov upon request, and annually by November 1 each year the motor carrier operates under the exemption (or not later than 30 calendar days of ceasing operations under this exemption). This report must include the following information covering the entire period of operation under this exemption:

a. Total number of its CMVs that operated under the exemption.

b. Total vehicle miles traveled by its CMVs under the exemption.

c. Data on the frequency, duration, date, location (including road type: interstate, State highway, local road, etc.), vehicle configuration (including tanker, double trailer, single trailer, straight truck), and reason for each malfunction, power issue, or other instance where the beacons did not

² Under NHTSA's Third Amended SGO 2021–01, "Crash" means any physical impact between a vehicle and another road user (vehicle, pedestrian, cyclist, etc.) or property that results or allegedly results in any property damage, injury, or fatality. A subject vehicle is involved in a crash if it physically impacts another road user or if it contributes or is alleged to contribute (by steering, braking, acceleration, or other operational performance) to another vehicle's physical impact with another road user or property involved in that crash." The SGO is available at: https://www.nhtsa.gov/sites/nhtsa.gov/files/2025-04/third-amended-SGO-2021-01_2025.pdf.

operate in accordance with the terms of the exemption.

d. The specific mounting locations of all cab-mounted warning beacons used on its CMVs.

e. Whether any variations in cab-mounted warning beacon types, mounting, or flash patterns were used across its fleet when operating under the exemption. If variations were used, any performance differences among the beacons.

8. *Request To Treat Information as Confidential Business Information (CBI)*. Nonpublic information submitted by a motor carrier under Section VI.C.6 or 7 above will be treated as CBI, which is defined as commercial or financial information that is both customarily and actually treated as private by its owner,³ if designated as such by the submitting motor carrier. FMCSA will withhold CBI from public disclosure to the greatest extent possible consistent with the Freedom of Information Act (5 U.S.C. 552), and DOT's implementing regulations at 49 CFR part 7.

9. *Safety Notification*. Each motor carrier operating under this exemption, must notify FMCSA via email to MCPSV@dot.gov not later than five calendar days after it becomes aware, or otherwise determines, that the continued use of cab-mounted beacons covered by this exemption is no longer likely to maintain a level of safety that is at least equivalent to the level that would be achieved absent this exemption.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

VII. Termination

FMCSA does not expect the motor carriers covered by this exemption will experience any deterioration of their safety record. However, the exemption will be revoked as to all motor carriers or an individual motor carrier if: (1) the motor carrier or motor carriers operating under the exemption fail to comply with the terms and conditions of the exemption; (2) the exemption results in a lower level of safety than was

maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of Title 49, chapter 313 or section 31136.

Derek D. Barrs,

Administrator.

[FR Doc. 2026–20734 Filed 10–8–26; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–1684]

Request for Comments on the Renewal of a Previously Approved Information Collection: Application and Reporting Elements for Participation in the Tanker Security Program

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget (OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0554 (Application and Reporting Elements for Participation in the Tanker Security Program) is used to evaluate the eligibility of applicants for participation in the Tanker Security Program (TSP). Since the last renewal, the application form for this collection is being updated to include minor clerical amendments regarding the authorizing statute and procedures for electronic submission. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

ADDRESSES: Written comments and recommendations for the proposed information collections 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: Richard Wanerman, 202–366–2306, Office of Sealift Support, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–103, Mail Stop 2, Washington, DC 20590, Richard.Wanerman@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: Application and Reporting Elements for Participation in the Tanker Security Program.

OMB Control Number: 2133–0554.

Type of Request: Extension with change of a currently approved collection.

Abstract: 46 U.S.C. chapter 534 established the Tanker Security Program (TSP) as a fleet of active, commercially viable, militarily useful, privately owned product tank vessels to meet national defense and other security requirements and maintain a United States presence in international commercial shipping. TSP provides for enrollment of eligible tank vessels in the program for FY 2022 through FY 2040. Applications and amendments will be used to select vessels for the fleet. Periodic reporting will be used to monitor adherence of participants to program parameters.

Respondents: Operators of United States-registered product tank vessels.

Affected Public: Business or other for profit.

Estimated Number of Respondents: 10.

Estimated Number of Responses: 160.

Estimated Hours per Response: 1–6.

Annual Estimated Total Annual

Burden Hours: 280.

Frequency of Response: Monthly/Annually.

A 60-day **Federal Register** Notice soliciting comments on this information collection was published on July 30, 2026 (FR 48216, Vol.91, No. 145). No comments were received.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2026–20760 Filed 10–8–26; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2026–1685]

Request for Comments on the Renewal of a Previously Approved Information Collection: War Risk Insurance, Applications, and Related Information

AGENCY: Maritime Administration (MARAD), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: MARAD invites public comments on its intention to request Office of Management and Budget

³ *Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 440 (2019).

(OMB) approval to renew an information collection in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 2133–0011 (War Risk Insurance, Applications, and Related Information) is used to obtain war risk insurance from the U.S. Government, when such insurance is unavailable on reasonable terms from the commercial market. The program is mutually beneficial to the U.S. and the ship owner, in that it assures continued flow of essential U.S. trade and provides protection for the ship owner from loss by risks of war. MARAD is required to publish this notice in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments must be submitted on or before December 8, 2026.

ADDRESSES: You may submit comments identified by Docket No. MARAD–2026–1685 through one of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Search using the above DOT docket number and follow the online instructions for submitting comments.

- **Mail or Hand Delivery:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Instructions: All submissions must include the agency name and docket number for this rulemaking.

Note: All comments received will be posted without change to www.regulations.gov including any personal information provided.

Comments are invited on: (a) whether the proposed collection of information is reasonable for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be lessened without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Cameryn L. Miller, 202–641–5352, Office of Financial Approvals and Marine Insurance, U.S. Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590, cameryn.miller@dot.gov.

SUPPLEMENTARY INFORMATION:

Title: War Risk Insurance, Applications, and Related Information.

OMB Control Number: 2133–0011.

Type of Request: Extension without change of a currently approved collection.

Abstract: The information collected on the forms associated with OMB 2133–0011 (War Risk Insurance, Applications and Related Information) are used to determine the eligibility of the applicant and their vessel(s) for participation in the War Risk Insurance program. The applicant submits the forms for the following purposes: to declare to MARAD that both the property and persons to be insured are eligible for insurance; to identify the perils for which the insurance is requested; to confirm that the applicant is an eligible U.S. citizen owning or controlling the vessel; and also to assert that the applicant intends to operate the insured property in the U.S. waterborne commerce in compliance with MARAD warranties. Such warranties assure continued waterborne service in the interests of national defense or economic prosperity of the United States.

Respondents: Vessel Owners and their representatives.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 20.

Estimated Number of Responses: 20.

Estimated Hours per Response: 12.8.

Annual Estimated Total Annual

Burden Hours: 258.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.49.)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026–20761 Filed 10–8–26; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Consent To Extend the Time To Assess Tax Under Section 367—Gain Recognition Agreement

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 December 8, 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. 1545–1395” in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this collection should be directed to Marcus W. McCrary, 470–769–2001.

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: Consent To Extend the Time To Assess Tax Under Section 367—Gain Recognition Agreement.

OMB Control Number: 1545–1395.

Form Number: 8838.

Abstract: Form 8838 is used to extend the statute of limitations for U.S. persons who transfer stock or securities to a foreign corporation. The form is filed when the transferor makes a gain recognition agreement. This agreement allows the transferor to defer the payment of tax on the transfer. The IRS uses Form 8838 so that it may assess tax against the transferor after the

expiration of the original statute of limitations.

Current Actions: There is no change to the existing collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business for other for-profit organizations.

Estimated Number of Responses: 200.

Estimated Time per Response: 8 hours and 13 minutes.

Estimated Total Annual Burden Hours: 1,644.

Dated: October 7, 2026.

Marcus W. McCrary,
Tax Analyst.

[FR Doc. 2026–20743 Filed 10–8–26; 8:45 am]

BILLING CODE 4831–GV–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Information-Sharing Initiative: Digital Assets Criteria Form

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

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 comment on the proposed information collection listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before December 8, 2026.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to U.S. Department of the Treasury, Attention: Treasury PRA Clearance Officer, 1500 Suite #8100, JBAB, 250 Murray Lane SW, Bldg. 410/Door 123, Washington, DC 20222, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927–5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Title: Information-Sharing Initiative: Digital Assets Criteria Form.

OMB Control Number: 1505–0286.

Type of Review: Extension without change of a currently approved collection.

Description: The collection is necessary for Treasury to fulfill its

responsibilities as the Sector Risk Management Agency for the Financial Services Sector under 6 U.S.C. § 665d. To fulfill these responsibilities, Treasury must verify that a requesting entity is eligible to receive Treasury's non-public cyber threat information before granting access. The Intake Form for Digital Asset Firms collects the minimum information required to confirm the applicant's identity, U.S. legal status, organizational category, digital asset function, regulatory status, cybersecurity maturity, ability to protect non-public information, and cybersecurity purpose for requesting access. Without this information, Treasury would lack a consistent, documented basis to determine whether an entity meets Treasury's criteria, whether the entity has a legitimate cybersecurity need-to-know, or whether the entity can comply with Treasury's Traffic Light Protocol (TLP) markings and dissemination restrictions. There are no changes from the previous approval.

Form: Intake Form for Digital Assets Firms.

Affected Public: Businesses or other for-profits, Not-for-profit Institutions.

Estimated Number of Respondents: 300.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 100.

Estimated Time per Response: 3 hours.

Estimated Total Annual Burden Hours: 300 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. 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 technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 44 U.S.C. 3501 *et seq.*

Juliana L. Pearson,

Treasury PRA Clearance Officer.

[FR Doc. 2026–20737 Filed 10–8–26; 8:45 am]

BILLING CODE 4810–25–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: October 15, 2026, 12:00 p.m. to 3:00 p.m., Eastern Time.

PLACE: The meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 996 4822 6740, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is <https://kellen.zoom.us/join/99648226740>.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Finance Subcommittee (the “Subcommittee”) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Finance Subcommittee Chair

The UCR Finance Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Finance Subcommittee Chair

For Discussion and Possible Subcommittee Action

The agenda will be reviewed, and the Subcommittee will consider adopting the agenda.

Ground Rules

Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Subcommittee Minutes From the July 9, 2026, Meeting—UCR Finance Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from July 9, 2026, Subcommittee meeting will be reviewed. The Subcommittee will consider taking action to approve.

V. 2027 and 2028 Registration Fees Update—UCR Finance Subcommittee Chair

The UCR Finance Subcommittee Chair will provide an update on the 2027 and 2028 registration fees.

VI. Revenues From 2025 and 2026 Registration Fees—UCR Depository Manager

The UCR Depository Manager will review the revenues received from the 2025 and 2026 plan year registration fees.

VII. 2025 Financial Audit Update—UCR Finance Subcommittee Chair and UCR Depository Manager

The UCR Finance Subcommittee Chair and UCR Depository Manager will provide an update on UCR's 2025 Financial Audit.

VIII. 2027 Administrative Fund Budget—UCR Finance Subcommittee Chair and UCR Depository Manager

For Discussion and Possible Subcommittee Action

The UCR Finance Subcommittee Chair and UCR Depository Manager will discuss a proposed administrative fund budget for 2027. The Subcommittee may take action to recommend to the UCR Board a 2027 administrative fund budget.

IX. Discussion About RFP for the 2026 Audit—UCR Finance Subcommittee Chair and UCR Depository Manager

For Discussion and Possible Subcommittee Action

The UCR Finance Subcommittee Chair and UCR Depository Manager will discuss an RFP for the 2026 UCR audit. The Subcommittee may take action to recommend to the UCR Board an RFP be issued for the 2026 UCR audit.

X. Other Business—UCR Finance Subcommittee Chair

The UCR Finance Subcommittee Chair will call for any other items

Subcommittee members would like to discuss.

XI. Adjourn—UCR Finance Subcommittee Chair

The UCR Finance Subcommittee Chair will adjourn the meeting. The agenda will be available no later than 5:00 p.m. Eastern time, October 7, 2026 at: <https://plan.ucr.gov>.

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305-3783, eleaman@board.ucr.gov.

Alex B. Leath,
Chief Legal Officer, Unified Carrier
Registration Plan.

[FR Doc. 2026-20759 Filed 10-7-26; 4:15 pm]

BILLING CODE 4910-YL-P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: October 14, 2026, 12:00 p.m. to 3:00 p.m., Eastern time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1-929-205-6099 (US Toll) or 1-669-900-6833 (US Toll), Meeting ID: 940 8146 1004, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is <https://kellen.zoom.us/join/94081461004>.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Education and Training Subcommittee (the "Subcommittee") will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Education and Training Subcommittee Chair

The Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and

distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Education and Training Subcommittee Chair

For Discussion and Possible Subcommittee Action

The Subcommittee Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➤ Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Subcommittee Minutes From the October 1, 2025, Subcommittee Meeting—UCR Education and Training Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the October 1, 2025, Subcommittee meeting will be reviewed. The Subcommittee will consider action to approve.

V. Project Development—UCR Education and Training Subcommittee Chair

The Subcommittee Chair will discuss the development of key projects. The projects that will be discussed include the development of educational and volunteer resources.

VI. Other Business—UCR Education and Training Subcommittee Chair

The Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

VII. Adjournment—UCR Education and Training Subcommittee Chair

The Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, October 6, 2026 at: <https://plan.ucr.gov>.

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305-3783, eleaman@board.ucr.gov.

Alex B. Leath,
Chief Legal Officer, Unified Carrier
Registration Plan.

[FR Doc. 2026-20756 Filed 10-7-26; 4:15 pm]

BILLING CODE 4910-YL-P



FEDERAL REGISTER

Vol. 91

Friday,

No. 195

October 9, 2026

Part II

The President

Executive Order 14435—Emergency Tax Relief on Diesel Fuel

Presidential Documents

Title 3—

Executive Order 14435 of October 5, 2026

The President

Emergency Tax Relief on Diesel Fuel

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Purpose and Policy.* Farmers and truckers are essential to the American way of life. Restricted global diesel supply has led to rising prices, and these key industries have been particularly hard hit. While my Administration has already undertaken historic efforts to ensure fuel affordability for our citizens, it is clear that further temporary relief is necessary.

To that end, today I am directing the Secretary of the Treasury (Secretary) to use his authority to defer certain diesel fuel tax payment obligations and to provide penalty relief to the extent permitted by law. I am also directing the Secretary of Agriculture and the Secretary of Transportation to facilitate implementation of this policy. This targeted action will put money directly in the pocket of American farmers, truckers, and workers, to support their vital service to our Nation.

Sec. 2. *Deferring Certain Payments of Excise Tax Liability and Providing Penalty Relief.* (a) Within 5 days of the date of this order, the Secretary, in consultation with the Secretary of War, as appropriate, shall determine whether relief is authorized under 26 U.S.C. 7508A, including whether a qualifying event has occurred and which taxpayers have been affected by that event. If the Secretary makes those determinations, the Secretary shall, to the extent authorized by law, defer payment by those taxpayers of the taxes imposed by 26 U.S.C. 4041(a)(1)(A) or by 26 U.S.C. 4041(b)(1)(B) and that are incurred during the period of October 5, 2026, through December 31, 2026.

(b) Amounts deferred pursuant to the Secretary's exercise of authority described in subsection (a) of this section shall, to the extent authorized by law, be deferred without any penalties, interest, additional amount, or addition to the tax.

(c) Within 5 days of the date of this order, the Secretary shall direct the Internal Revenue Service to announce that it will not impose a penalty under 26 U.S.C. 6715 (a)(1) or 26 U.S.C. 6715 (a)(2), when dyed diesel fuel is sold for use or used on the highway during the period of October 5, 2026, through December 31, 2026. The announcement shall also address relief from penalties for failure to make semimonthly deposits of that tax.

Sec. 3. *Implementing Guidance.* The Secretary shall issue guidance implementing this order. The guidance shall identify the specific relief being granted and any conditions on such relief; the legal basis for relief, covered taxpayers, persons, locations, acts, liabilities, and deadlines; the beginning and ending dates of each applicable period; the date by which postponed taxes must be paid.

Sec. 4. *Tax Forgiveness.* The Secretary shall explore avenues, including legislation, to eliminate the obligation to pay the amounts deferred pursuant to the Secretary's exercise of authority described in section 2 of this order.

Sec. 5. *Prioritizing Fuel Compliance Resources.* The Secretary shall assess how the Internal Revenue Service should allocate resources to inspections of vehicle fuel tanks and fuel sampling during the period of any relief

provided under section 2 of this order, and shall publicly announce that determination.

Sec. 6. *Maintaining Safety and Efficiency on America's Highways.* The Secretary of Transportation, acting through the Administrator of the Federal Motor Carrier Safety Administration (Administrator), shall:

(a) engage with State governments, relevant industry leadership as determined by the Administrator, and relevant labor organizations as determined by the Administrator to encourage safe and expedient coordination between the Federal Government and these various stakeholders in furtherance of the policies of this order; and

(b) continue all compliance enforcement measures, including audits, inspections, and monitoring programs, as provided for by law.

Sec. 7. *Promoting Diesel Access for Farmers.* The Secretary of Agriculture shall further the priorities of this order, including by:

(a) coordinating with agricultural cooperatives, rural fuel distributors, farm supply organizations, and other agricultural stakeholders, as determined by the Secretary of Agriculture, to ensure adequate distribution of dyed diesel for their use in high-demand areas; and

(b) encouraging corresponding State action to further the policies of this order.

Sec. 8. *Engaging State Governments.* The Director of the White House Office of Intergovernmental Affairs shall engage with States to further the policies of this order, taking appropriate action to encourage States to adopt policies that correspond to the Secretary's exercise of authority described in section 2 of this order, in accordance with applicable law.

Sec. 9. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

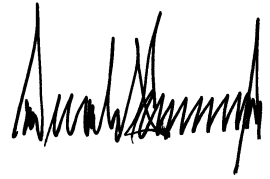
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The costs for publication of this order shall be borne by the Department of Agriculture.

A handwritten signature in black ink, appearing to be "Donald Trump", located in the upper right quadrant of the page.

THE WHITE HOUSE,
October 5, 2026.

[FR Doc. 2026-20855
Filed 10-8-26; 11:15 am]
Billing code 3410-18-P

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Federal Register

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in “slip law” (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202-512-1808). The text is available at <https://www.govinfo.gov/app/collection/plaw>. Some laws may not yet be available.

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