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: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As directed by Section 569C of the Federal Food, Drug, and Cosmetic Act, as amended by Section 3001 of the 21st Century Cures Act (Pub. L. 114–255), FDA has developed and implemented strategies to obtain patient input to inform drug development and regulatory decision-making. FDA-led PFDD and externally led-PFDD (EL–PFDD) meetings provide a structured opportunity to hear directly from patients, caregivers, family members, and patient advocates. These meetings center on the aspects of a disease or condition and its treatment that are most meaningful to patients, including symptoms, effects on daily life, and experiences with available therapies.

Patient input from these meetings can inform medical product development, research priorities, and regulatory oversight. In response to stakeholder requests to better understand the outcomes of these meetings, FDA is seeking to collect information about their subsequent impacts. The Agency recognizes that many significant outcomes such as interactions within patient communities, between patient groups and medical product developers, or among clinicians occur in forums to which FDA is not typically a party. Similarly, changes made by medical product developers in response to patient input may not be communicated to FDA outside of a formal regulatory submission.

II. Issues for Consideration and Request for Information

FDA is issuing this request for information to gain a better understanding of how patient input from FDA-led PFDD and EL–PFDD meetings has informed stakeholder activities including research, product development, and patient care, outside of specific regulatory decisions. FDA invites input from all interested parties, including patient organizations, medical product developers, healthcare providers, and academic researchers.

FDA is seeking information that addresses the following:

1. How have PFDD meetings informed patient communities and stakeholder engagement activities?
2. What scientific questions, research initiatives, or identified gaps in the understanding of a disease or condition have resulted from PFDD meetings?
3. In what ways has patient input from PFDD meetings informed medical product development programs or strategies (*e.g.,* endpoint development, clinical trial design, identification of unmet needs, industry partnerships)?
4. How has patient input gathered during PFDD meetings been integrated into or otherwise affected clinical practice?
5. Please describe any other outcomes or effects resulting from PFDD meetings, with examples, that were not addressed in the questions above.

FDA encourages respondents to provide specific examples in their answers where possible.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08524 Filed 4–30–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4268]

Medical Devices; Exemptions From Premarket Notification: Certain Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to exempt from premarket notification requirements certain class II clinical toxicology test system devices. FDA is publishing this notice and requesting public comment in accordance with procedures established by the 21st Century Cures Act. This notice does not represent FDA's final determination with respect to the devices included in this document. FDA will review any comments submitted within the 60-day comment period and will further consider whether the exemption described in this notice should be modified prior to publication of its final determination in the **Federal Register**.

DATES: Either electronic or written comments on the notice must be submitted by June 30, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2026–N–4268 for ''Medical Devices; Exemptions from Premarket Notification: Certain Class II Devices; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday Eastern Time, 240–402–7500.

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

Docket: For access to the docket to read background documents 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:

Joseph Kotarek, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3528, Silver Spring, MD 20993, 301–796–2718, *Joseph.Kotarek@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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

Under section 510(k) of the FD&C Act and FDA's implementing regulations in part 807 of Title 21 of the Code of Federal Regulations (CFR), subpart E (21 CFR part 807, subpart E), persons who are required to register and who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a premarket notification (510(k)) to FDA. The device may not be marketed until FDA finds it ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval. A premarket notification is not required for devices in certain situations, such as when they have been exempted from that requirement under section 510(m) of the FD&C Act.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. After providing at least a 60-day public comment period, FDA must then publish in the **Federal Register** a list representing the final determination with respect to the devices contained in the list under section 510(m)(1)(B). Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon FDA's own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. FDA must publish in the **Federal Register** a notice of its intent to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice.

Exemptions from premarket notification for certain clinical toxicology test systems falling within the regulations identified in the instant notice,[1] in addition to exemptions for other device types, were proposed and finalized in 2017. FDA published its initial notice for these clinical toxicology test systems under section 510(m)(1)(A) of the FD&C Act in the **Federal Register** of March 14, 2017 (82 FR 13609), and issued its final determination of exemption of the devices in a notice in accordance with section 510(m)(1)(B) of the FD&C Act in the **Federal Register** of July 11, 2017 (82 FR 31976). In the **Federal Register** of December 30, 2019 (84 FR 71794), FDA amended the relevant sections of the CFR to reflect the exemptions finalized in July 2017.

FDA is now publishing this notice to announce its intent to expand the 510(k) exemptions in the classification regulations included in this notice to additional devices within the device types, and to request public comment, in accordance with section 510(m)(2) of the FD&C Act. If finalized, the expansion of these exemptions will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. Specifically, regulated industry will no longer have to invest time and resources in 510(k) submissions for devices exempt from such requirements.

II. Factors FDA Generally Considers for Exemption

There are a number of factors FDA generally considers to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, titled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary or if an exemption would be appropriate for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices from the 510(k) requirements, these devices would still be subject to general limitations of exemptions. FDA's determinations that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness for class II devices are often based on the Agency's knowledge of the devices, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption, as discussed in section III of this notice.

III. Limitations of Exemptions

A. General Limitations of Exemptions

FDA's exemptions from premarket notification requirements for the class II device types listed in table 1 apply only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostics, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality (see § 862.9 (21 CFR 862.9) (titled ''Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act)''). Thus, a manufacturer of a device listed in this document will still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into interstate commerce for commercial distribution when the device exceeds any of the limitations of exemptions described in § 862.9.

B. Partial Limitations of Exemptions

In addition to the general limitations described in section III.A of this notice, partial limitations may limit an exemption from premarket notification requirements to specific devices within a device type.

Currently, the classification regulations included in this notice already include an exemption from 510(k) requirements (subject to the general limitations in § 862.9 as discussed in section III.A of this notice) ''provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing,'' and as long as the device is not intended for use in Federal drug testing programs.[2] In this notice, FDA is announcing its intent to remove the exception to the 510(k) exemption for devices intended for Federal drug testing programs. As such, under the proposal, devices in the device types listed in table 1 would be exempt from 510(k) requirements even if intended for use in Federal drug testing programs as long as they do not exceed any of the general limitations of exemptions in § 862.9, and provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, as described in table 1.

When FDA finalized the partial exemptions from 510(k) requirements that are currently included in the classification regulations listed in table 1, FDA assigned new product codes to ensure that exempt and non-exempt devices within a device type would have separate product codes (82 FR 31976 at 31977). If the proposed expansion of the 510(k) exemptions described in this notice is finalized, FDA will continue to use the previously established product codes; however, the definitions of the product codes for exempt devices will be modified to accurately reflect the scope of the exemption,[3] and devices which are newly exempt will change from a non-exempt product code to the corresponding exempt product code.

IV. List of Class II Devices

FDA has made an initial determination that premarket notification is no longer necessary to provide a reasonable assurance of safety and effectiveness for these devices when they are intended for Federal drug testing programs (see ''Proposed Partial Limitations'' listed in table 1 of this notice). If the proposed expansion of the 510(k) exemptions described in this

[1] See table 1 for the device types.

[2] 21 CFR 862.3100, 862.3150, 862.3170, 862.3250, 862.3270, 862.3580, 862.3610, 862.3620, 862.3630, 862.3640, 862.3650, 862.3700, 862.3870, and 862.3910; 84 FR 71794. Federal drug testing programs include, for example, programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.

[3] For example, the current definition for product code PUX (Test, Amphetamine, Employment and Insurance Testing, Exempt) includes a reference to 82 FR 31976 (the action establishing the exemption). Should the proposal in this notice be finalized, this reference, and corresponding ones for the other exempt product codes, would be replaced with a reference to the **Federal Register** document codifying the expanded scope of the exemption.

notice is finalized, devices in the device types listed in table 1 would not require premarket notification under section 510(k) of the FD&C Act when they are intended for Federal drug testing programs, so long as they do not exceed the proposed partial limitations of exemptions specified in table 1 and the corresponding general limitations of exemptions described in section III.A of this notice.

TABLE 1—PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS AND PARTIAL LIMITATIONS

21 CFR section	Generic device type	Exempt product code	Non-exempt product codes	Current partial limitations	Proposed partial limitations
862.3100	Amphetamine test system.	PUX	DIT, DJL, DJP, DKZ, DNI, DOD, DPJ, NFT, NVI, OIW.	Exemption is limited to test systems intended to measure amphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure amphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3150	Barbiturate test system.	PUY	DIS, DJN, DKN, DKX, DLX, DMF, KZY, PTH.	Exemption is limited to test systems intended to measure barbiturates for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure barbiturates for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3170	Benzodiazepine test system.	PUZ	JXM, KZZ, LAA, LAB, NFV.	Exemption is limited to test systems intended to measure any of the benzodiazepine compounds for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the benzodiazepine compounds for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3250	Cocaine and cocaine metabolite test system.	PVA	DIN, DIO, DIR, DLN, DMN, DNG, DOM, JXO, KLN, LAC, NFY.	Exemption is limited to test systems intended to measure cocaine and a cocaine metabolite (benzoylecgonine) for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure cocaine and a cocaine metabolite (benzoylecgonine) for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3270	Codeine test system.	PVB	DLD, LAD, LAE	Exemption is limited to test systems intended to measure codeine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure codeine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3580	Lysergic acid diethylamide (LSD) test system.	PVC	DLB, DOL	Exemption is limited to test systems intended to measure LSD for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure LSD for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3610	Methamphetamine test system.	PVD	DJC, LAF, LAG, NGG.	Exemption is limited to test systems intended to measure methamphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure methamphetamine for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3620	Methadone test system.	PVE	DIW, DJR, DKR, DMB, DNT, DPP, PTG.	Exemption is limited to test systems intended to measure methadone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure methadone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3630	Methaqualone test system.	PVF	KXS	Exemption is limited to test systems intended to measure methaqualone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure methaqualone for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.

TABLE 1—PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS AND PARTIAL LIMITATIONS—Continued

21 CFR section	Generic device type	Exempt product code	Non-exempt product codes	Current partial limitations	Proposed partial limitations
862.3640	Morphine test system.	PVG	DIQ, DJJ, DLR, DMY, DNA, DNK, DOE, DOK, DPK, NGI.	Exemption is limited to test systems intended to measure morphine and its analogs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure morphine and its analogs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3650	Opiate test system	PVH	DJF, DJG, DKT, DLT, LAH, LAI, NGL.	Exemption is limited to test systems intended to measure any of the addictive narcotic pain-relieving opiate drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the addictive narcotic pain-relieving opiate drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3700	Propoxyphene test system.	PVI	DPN, JXN, LAJ, LAK, QBF.	Exemption is limited to test systems intended to measure propoxyphene for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure propoxyphene for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3870	Cannabinoid test system.	PVJ	DKE, LAT, LDJ, NFW.	Exemption is limited to test systems intended to measure any of the cannabinoids for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the cannabinoids for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.
862.3910	Tricyclic antidepressant drugs test system.	PVK	LFG, LFH, LFI, MLK, QAW.	Exemption is limited to test systems intended to measure any of the tricyclic antidepressant drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing, and does not include devices intended for Federal drug testing programs.	Exemption is limited to test systems intended to measure any of the tricyclic antidepressant drugs for employment and insurance testing and for which the test system labeling includes a statement that the device is intended solely for employment and insurance testing.

V. Paperwork Reduction Act of 1995

While this notice 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 (44 U.S.C. 3501–3521). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

VI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* Although FDA verified the website address in this document, please note that websites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/media/72685/download.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08499 Filed 4–30–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3240]

List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is evaluating substances that have been nominated for inclusion on a list of bulk drug substances (active pharmaceutical ingredients) for which there is a clinical need for outsourcing facilities to use in compounding (the 503B Bulks List). This notice identifies three bulk drug substances that FDA has considered and proposes not to include on the 503B Bulks List: semaglutide, tirzepatide, and liraglutide. Additional bulk drug substances nominated for inclusion on this list are under consideration and may be the subject of future notices.

DATES: Either electronic or written comments on the notice must be submitted by June 30, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 30, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be