Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–348–1967, *Brooke.DalSanto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''E22 General Considerations for Patient Preference Studies.'' The draft guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In November 2025, the ICH Assembly endorsed the draft guideline entitled ''E22 General Considerations for Patient Preference Studies'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance outlines general harmonized considerations about the use, design, conduct, analysis, and submission of PPS aimed at informing drug development, regulatory submission and evaluation, drug approvals and maintenance of such approvals.

While the information provided by PPS does not replace the information provided by efficacy and safety studies, the PPS information may be useful across the different phases of drug development, pre- and post-marketing, and may be considered together with the efficacy and safety information in the benefit-risk assessment of drugs and related regulatory decisions.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''E22 General Considerations for Patient Preference Studies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02324 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0232]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) has identified a list of class II devices that, when finalized, will be exempt from premarket notification requirements, subject to certain limitations. 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 consider whether the list of class II devices should be modified prior to publication of its final determination in the **Federal Register**.

DATES: Submit either electronic or written comments on the notice by April 7, 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 April 7, 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–0232 for ''Medical Devices; Exemptions from Premarket Notification: 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, 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, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1528, Silver Spring, MD 20993, 301–796–6424, *Jismi.Johnson@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, post-market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions FDA (the Agency or we) deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

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

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, persons 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 (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

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. Additionally, FDA must provide at least a 60-day comment period for any such notice published under section 510(m)(1)(A) of the FD&C Act. FDA published its initial notice 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 such 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).

FDA is now publishing this notice and requesting public comment in accordance with section 510(m)(1)(A) of the FD&C Act. In a future action, and after considering comments, FDA intends to amend the codified language for each listed regulation to reflect FDA's final determination with respect to each exempt class II device type. Such final action will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulation. 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 May Consider for Exemption

There are a number of factors FDA may consider 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, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (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 the limitations of exemptions. FDA's determination that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness for class II devices is based, in part, 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 proposal to exempt the class II devices listed in table 1 and table 2 from premarket notification requirements applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type. After the 60-day comment period and FDA's issuance of a notice announcing FDA's final determination, 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 meets any of the limitations of exemptions described in 21 CFR parts 862–892 in the section of each part entitled ''Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).'' [1]

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 devices that satisfy certain conditions within a device type when the Agency determines that the factors described in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices within a generic type of device. Where a partial limitation of exemption has been identified in this notice (see table 2), FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for devices that fall outside of the limitations.

In table 2, for example, FDA is listing a proposed exemption from 510(k) requirements for uterine tenaculum (21 CFR 884.4530, product code HDC [2]) but is limiting the proposed exemption to manual mechanical devices. The proposed exemption thus excludes devices that are powered. Whereas the characteristics of a manual mechanical uterine tenaculum necessary for the safe and effective performance of the device are well-established, a powered uterine tenaculum has a relatively complex design that carries additional risks beyond those of a manual mechanical device, and FDA therefore considers premarket notification requirements for a powered device, such as a vacuum-based device, to be necessary to provide a reasonable assurance of safety and effectiveness. If this proposed exemption is finalized, a uterine tenaculum that meets the partial limitation of exemptions and the general limitations of exemptions in 21 CFR 884.9 would be exempt from the 510(k) requirements and would be identified under a new product code. However, a uterine tenaculum that does not meet the limitations of exemptions would remain subject to 510(k) requirements and would remain under the product code HDC.

IV. List of Class II Devices

FDA has determined that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness for the class II devices listed in table 1 and table 2 of this notice.

In table 1, FDA is identifying the following list of class II devices that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations of exemptions described in section III.A of this notice:

[1] See 21 CFR 862.9, 864.9, 866.9, 868.9. 870.9, 872.9, 874.9, 876.9, 878.9, 880.9, 882.9, 884.9, 886.9, 888.9, 890.9, and 892.9.

[2] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to help categorize and ensure consistent regulation of medical devices. A product code consists of three characters that are assigned at the time a product code is generated and is unique to a product type. The three characters carry no other significance and are not an abbreviation.

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

21 CFR section	Device type	Product code
870.1120	Blood pressure cuff	DXQ
872.3920	Teeth, porcelain	ELL
872.6660	Powder, porcelain	EIH
876.1500	Image, illumination, fiberoptic, for endoscope	FFS
876.1500	Jelly, lubricating, for transurethral surgical instrument	FHX
876.4300	System, alarm, electrosurgical	FFI
876.5360	Laparoscopic accessories, esophageal sizing	QJN
878.4370	Dental barriers and sleeves	PEM
884.4530	Forceps, surgical, gynecological	HCZ
886.1640	Preamplifier, AC-powered, ophthalmic	HLT
886.1640	Preamplifier, battery-powered, ophthalmic	HLW
888.4515	Manual instruments designed for use with total disc replacement devices	QLQ
888.4520	Manual instruments designed for use with non-fusion spinous process spacer devices	QLR

In table 2, FDA is identifying the following list of class II devices that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the proposed partial limitations of exemptions as well as the general limitations of exemptions found in §§ 862.9 to 892.9. If this list is finalized, devices listed in table 2 would be exempt only if they meet the proposed partial limitations of exemptions specified in table 2 and the corresponding general limitations of exemptions described in section III.A of this notice.

TABLE 2—PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS AND PARTIAL LIMITATIONS

21 CFR section	Device type	Product code	Partial limitations
870.1875	Stethoscope, electronic	DQD	Exemption is limited to devices that meet the following conditions: 1. Stethoscopes without algorithms; 2. Stethoscopes without diagnostic outputs, such as murmur detection, arrhythmias, or heart failure; and 3. Stethoscopes solely intended for sound amplification, filtering, and transferring sounds.
870.5800	Sleeve, limb, compressible	JOW	Exemption is limited to devices that meet the following conditions: 1. Device is intended for prescription use in adults with intact skin; 2. Device is indicated only for deep vein thrombosis (DVT) prophylaxis and for the treatment of lymphedema, venous stasis ulcers, venous insufficiency, and/or peripheral edema; 3. Device is a garment only and intended for single patient use on thigh, calf, ankle and/or foot; 4. Device is pneumatic with operating pressures between 20mmHg and 120mmHG and inflation time between 5s to 30s and deflation time between 30s to 120s; and 5. Device is not intended to heat or cool a patient.
878.4810	Light based over the counter wrinkle reduction.	OHS	Exemption is limited to devices that meet the following conditions: 1. Device emitters have a maximum output that cannot produce intensities at the skin surface that exceed 150 mW/cm^2 and 180 J/cm^2 per treatment; and 2. Device uses only yellow, red, or amber, or a combination of yellow, red, or amber with infrared color (from 800nm to 900nm) of light.
878.4810	Light based over-the-counter hair removal.	OHT	Exemption is limited to devices that meet the following conditions: 1. Device emitters have a pulse width ≥0.5 milliseconds, spot size ≤7 cm^2, and fluence ≤10 J/cm^2; 2. Device uses Intense Pulsed Light (IPL) with a wavelength range of 470nm–1200nm; and 3. Device is intended for use on the legs, arms, back, chest, upper lip, and/or armpit.
880.5570	Container, sharps	MMK	Exemption is limited to devices that meet the following conditions: 1. Device is intended for single use; 2. Device is intended to be used in a healthcare setting; 3. Device is intended to contain only sharps for disposal; 4. Device does not include software or electronic components; and 5. Appropriate analysis and non-clinical testing (such as that outlined in the currently FDA-recognized editions of ISO 23908, ''Sharps injury protection—Requirements and test methods—Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling,'' and ISO 23907–1, ''Sharps injury protection—Requirements and test methods—Part 1: Single-use sharps containers'') must validate specifications and performance of the device.

TABLE 2—PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS AND PARTIAL LIMITATIONS—Continued

21 CFR section	Device type	Product code	Partial limitations
884.4530	Tenaculum, uterine	HDC	Exemption is limited to manual mechanical devices.
884.5160	Pump, breast, powered	HGX	Exemption is limited to devices that meet the following conditions: 1. Device is a tabletop breast pump that has a vacuum pressure <250 mmHg, uses AC/DC power only, and does not include a battery; and 2. Device does not utilize internet, wireless connection, communication ports (*e.g.,* USB) capable of updating software or transmitting information, or a mobile application.
884.5300	Lubricant, personal	NUC	Exemption is limited to devices that meet the following conditions: 1. Device is made entirely of silicone (*i.e.,* dimethicone, dimethiconol, cyclopentasiloxane) with no additional ingredients; 2. Water activity is <0.3 Aw per USP<1112> (Application of Water Activity Determination to Nonsterile Pharmaceutical Products); and 3. Device is not intended for treatment of medical conditions or specific patient populations.
884.6170	System, water, reproduction, assisted, and purification.	MTW	Exemption is limited to assisted reproduction water and does not include water purification systems.
890.5500	Laser, comb, hair	OAP	Exemption is limited to devices that meet the following conditions: 1. Device emitters have a maximum output that cannot produce intensities at the scalp surface that exceed 68 J/cm^2; and 2. Device only uses red light.
890.5650	Massager, powered inflatable tube.	IRP	Exemption is limited to devices that meet the following conditions: 1. Device is pneumatic with operating pressures between 0 mmHg and 200 mmHg positive pressures; 2. Device is indicated for adults in good health, for the temporary relief of minor muscle aches and/or pains, for temporary increase in circulation to the treated areas, and/or to simulate kneading and stroking of tissues; 3. Device is not intended for use on neck and/or head; 4. If device compresses thoracic (chest, back) and/or abdominal areas, the device does not exceed pressure of 120 mmHg; 5. Device is not intended to heat or cool a patient; and 6. Device is not intended to be used for direct skin contact.

If the proposed exemptions for the device types listed in table 2 are finalized, FDA will assign new product codes to the device types that will be exempt subject to the corresponding partial limitations of exemptions in order to ensure that these devices can be identified distinctly from devices that do not fall within the partial limitations of exemptions (which will continue to be assigned to the existing product code). Exempt and non-exempt devices within a device type will therefore have different product codes.

V. 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.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02377 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1655]

Paul Zachary Lamberty: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Paul Zachary Lamberty for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Lamberty was convicted of two felonies under Federal law; one felony count for conspiracy and one felony count for introduction of misbranded drugs with intent to defraud and mislead. The factual basis supporting Mr. Lamberty's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Lamberty was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of September 8, 2025 (30 days after receipt of the notice), Mr. Lamberty had not responded. Mr. Lamberty's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable February 6, 2026.

ADDRESSES: Any application by Mr. Lamberty for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the