4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA-2018-D-1873

Medical Device User Fee Small Business Qualification and Determination Guidance Final Guidance for Industry and Food and Drug Administration Staff and Foreign Governments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Medical Device User Fee Small Business Qualification and Determination Guidance." This guidance updates the previous version of the guidance, titled "Medical Device User Fee Small Business Qualification and Certification Guidance", issued on August 1, 2018. The guidance includes updates which describe how FDA plans to determine if a small business is experiencing "financial hardship" which makes them eligible for a waiver of their registration fee. The guidance details what information FDA intends to review and consider in making this determination.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA-2018-D-1873 for "Medical Device User Fee Small Business Qualification and Determination Guidance." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Medical Device User Fee Small Business Qualification and Determination Guidance" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Medical Device User Fee Small Business Qualification and Determination Guidance". On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 was signed into law as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328. Section 3309 of the Omnibus -- "Small Business Fee Waiver" -- amended section 738(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding clause (ii) "Small business fee waiver". The amended language gave FDA the discretion, beginning in fiscal year 2025, to waive the annual registration fee for device establishments that are small businesses if FDA determines that paying the fee for such year represents a financial hardship. Additionally, the amended statute acknowledges that device establishments may be located in countries without a National Taxing Authority. As a result of this amended statutory language, FDA is issuing this guidance to update the guidance "Medical Device User Fee Small Business Qualification and Certification" to describe how FDA plans to determine if a small business is experiencing "financial hardship", which makes them eligible for a waiver of their registration fee. The guidance details what information FDA intends to review and consider in making this determination. The guidance further clarifies the various fee waivers and reductions available to small businesses, and describes under what circumstances a small business may avail itself of them.

A notice of availability of the guidance appeared in the *Federal Register* of February 22, 2024 (89 FR 13349). FDA considered comments received and revised the guidance as appropriate in response to the comments, including describing the applicability of the waiver to

previous years, how often a waiver may be used, and clarifying the conditions under which FDA may grant the waiver.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Medical Device User Fee Small Business Qualification and Determination Guidance. 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. FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be deregulatory in nature.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Medical Device User Fee Small Business Qualification and Determination Guidance" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00018007 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

The guidance refers to previously approved FDA collections of information. The collections of information related to Medical Device User Fee Small Business Qualification and Determination have been approved under OMB control number 0910-0508.

Dated: July 28, 2025.

Grace R. Graham

Deputy Commissioner for Policy, Legislation, and International Affairs.
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