Contains Nonbinding Recommendations

Draft – Not for Implementation

Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on February 22, 2024.

You should submit comments and suggestions regarding this draft document within 60 days (standard), days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact CDRH's Division of Industry and Consumer Education at 800-638-2041 or DICE@fda.hhs.gov.
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) by email at ocod@fda.hhs.gov or at 1-800-835-4709 or 240-402-8010.

When final, this guidance will update and supersede the applicable sections of "Medical Device User Fee Small Business Qualification and Certification", issued on August 1, 2018.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

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Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00018007 and complete title of the guidance in the request.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance, as listed on the title page.

I. Introduction

FDA has developed this draft guidance to propose select updates to the FDA guidance document, "Medical Device User Fee Small Business Qualification and Certification"[1] ("Small Business Guidance"). The existing Small Business Guidance remains, in its current form, the Agency's current thinking on the topic until this draft guidance is finalized. FDA intends to incorporate this draft guidance into one final guidance document, after obtaining and considering public comment on these select updates. The proposed sections referenced below are intended to enhance applicable sections of the existing Small Business Guidance. The sections of the existing Small Business Guidance that are not affected by this select update will not be substantively changed and will remain the Agency's current thinking on the topic.

On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 ("FDORA") 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" amends section 738(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to give FDA discretion, beginning in fiscal

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification

year (FY) 2025, to waive the establishment registration fee for device establishments that are small businesses, if FDA determines that paying such fee represents a financial hardship.

Based on this amendment, FDA is proposing updates to the guidance that describe how small businesses can show financial hardship to qualify for a small business registration fee waiver. For purposes of this new fee waiver provision, small business is defined as those that reported $1,000,000 or less of gross receipts or sales in their most recent Federal income tax return.[2] Additionally, FDA is proposing updating the guidance to reflect how applicants based in jurisdictions without a National Taxing Authority (NTA) need not submit a certification from an NTA to be eligible for fee waivers or reductions.[3]

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic, and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Policy

FDA is proposing to modify the language in the second paragraph in Section II.A of the Small Business Guidance to read:

"The establishment registration fee ("registration fee") may be waived if a business (owner or operator) meets the conditions described in Sections III (for domestic businesses) and IV (for foreign businesses) below to receive a small business registration fee waiver. There are no reduced fees for registration."

FDA is proposing to change the title of Section III to "Small Business Fees and Waivers." and to modify the introductory paragraph to Section III of the Small Business Guidance and add language to Section III.D:

"This section identifies the MDUFA User Fee schedule, explains the benefits of qualifying as a small business, defines the "first premarket application/report" fee waiver, and defines the "small business registration fee waiver."

D. Small Business Registration Fee Waiver

[2] See Section 738(a)(3)(B)(ii)(I) of the FD&C Act.

[3] See Section 738(a)(3)(B)(ii)(IV) of the FD&C Act, as amended by section 3309(a) of FDORA/FY23 Omnibus, which allows a firm to qualify as a small business by providing a "certification, in English, from the national taxing authority, **if extant**, of the country in which the establishment or, if applicable, affiliate is headquartered" (emphasis added). See also, sections 738(d)(2)(B)(iii) and 738(e)(2)(B)(iii) of the FD&C Act, as amended by sections 3309(b) and 3625(d) of FDORA/FY23 Omnibus, respectively.

Applicants that report $1,000,000 or less in gross receipts or sales in their most recent Federal (U.S.) income tax return (including the returns of its affiliates) may be eligible to receive a waiver of the fee required for their annual registration (excluding the initial registration) if FDA determines that paying the annual registration fee represents a financial hardship to the applicant. FDA intends to combine and update the forms FDA-3602 and FDA-3602A to request both minimal information needed to evaluate an SBD hardship determination and evidence of prior paid registration fees. Under section 738(a)(3)(B)(ii)(V) of the FD&C Act, applicants seeking a small business registration fee waiver must submit any supporting information at least 60 days before the fee is due. Section 738(a)(3)(B)(ii)(V) additionally states FDA's decision regarding whether an applicant may receive a registration fee waiver is not reviewable.

FDA is proposing to add the following language at the end of Section IV "Guidance for U.S. Businesses".

How can I demonstrate "financial hardship" and receive a small business registration fee waiver?

FDA may, but is not required to, grant a waiver of the fee for annual registration to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such year represents a financial hardship to the establishment as determined by FDA. FDA intends to grant waivers only where financial hardship is shown by a clear and objective standard, the meeting of which is publicly transparent. The only situation we are currently aware of that meets this is where the small business is in active bankruptcy. FDA believes that active bankruptcy represents financial hardship that is shown by a clear, objective standard, the meeting of which is a matter of public record. Thus, if you are seeking the small business registration fee waiver, we recommend you provide the following:

- your most recent Federal (U.S.) income tax return(s) showing $1,000,000 or less in gross receipts or sales (including affiliates);
- evidence that the establishments for which you are seeking a waiver have, under your owner/operator ID with FDA, previously registered and that the associated registration fees have been paid; and
- evidence that you have filed a petition for bankruptcy in United States Bankruptcy Court and that the bankruptcy is currently active (debts have yet to be discharged or a reorganization plan has not been confirmed.)

FDA is proposing to add the following language at the end of Section V. "Guidance for Foreign Businesses":

How can I demonstrate "financial hardship" and receive a small business registration fee waiver if I am located outside of the United States?

FDA may, but is not required to, grant a waiver of the fee for annual registration to applicants that qualify as a small business if FDA finds that the establishment is a small business and paying the fee for such year represents a financial hardship to the establishment as determined by FDA. FDA intends to grant waivers only where financial hardship is shown by a clear and objective standard that is publicly transparent. The only situation we are currently aware of that meets this is where the small business is in active bankruptcy. FDA believes that active bankruptcy represents financial hardship that is shown by a clear, objective standard, the meeting of which is a matter of public record. Thus, if you are applying for the small business registration fee waiver, we recommend you provide the following:

- The most recent income tax return(s) submitted to your National Taxing Authority showing $1,000,000 or less in gross receipts or sales (including affiliates);
- evidence that each establishment for which you are seeking a waiver have previously registered and paid the registration fee under your owner/operator ID with FDA; and
- evidence that you have filed your jurisdiction's equivalent of a United States bankruptcy action, including evidence the applicant has initiated the action (i.e., evidence analogous to a United States bankruptcy petition) and evidence that the bankruptcy action is active.

What if I live in a jurisdiction without a National Taxing Authority?

You may submit evidence of your gross sales and receipts (e.g., end of fiscal year financial statements or shareholder reports) to show that you fall below the relevant threshold to qualify for a small business fee waiver or reduction. FDA plans to review evidence on a case-by-case basis to determine if it is sufficient to show that you qualify for a small business fee waiver or reduction.

FDA is proposing to add the following language to the end of Section VII. Frequently Asked Questions

If my firm qualifies as a "small business," may I take advantage of the reduced fees or fee waivers on behalf of another entity?

No. For purposes of application fee waivers or reductions, the law provides that "an applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies" for a waiver or the lower fee rate. See sections 738(d)(2)(B) and 738(e)(2)(B) of the FD&C Act. Similarly, for purposes of the registration fee waiver, FDA may grant a waiver of the registration fee for an establishment for a year if FDA "finds that the establishment is a small business and paying the fee for such year represents a financial hardship to the establishment." See section 738(a)(3)(B)(ii)(II).

The statute does not contain a transferability provision pursuant to which a small business finding and qualification for the fee waiver or reduction could be transferred to another entity. For example, if the owner/operator of a device establishment found to be a small business is acquired by another entity, and that acquiring entity submits an application, the applicant must pay the full fee unless it obtains its own small business determination. Additionally, a third-party consultant who submits an application on behalf of its client is not the applicant and may not qualify for a reduction or waiver.

As a small business that can show financial hardship, will I be liable for the annual registration fee?

Under 21 CFR Part 807, establishments must register annually with FDA.[4] If you have registered a facility under your owner/operator ID with FDA previously and you have been granted a small business registration fee waiver, you will not be required to pay the annual registration fee for that year.

How often will FDA grant the small business registration fee waiver?

If FDA grants the small business fee waiver, it does not intend to grant this waiver to the same entity in relation to the circumstances that gave rise to the waiver.

[4] For more information see https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee