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Medical Device User Fee Small Business Qualification and Determination

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Guidance for Industry, Food and Drug Administration Staff and Foreign Governments

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This document supersedes "FY 2018 Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments" dated August 1, 2018.

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 industry.biologics@fda.hhs.gov or at 1-800-835-4709 or 240-402-8010.

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See additional PRA statement in Section VIII of this guidance.

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration 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 20852-1740. Identify all comments with the docket number FDA-2018-D-1873. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry, Food and Drug Administration Staff and Foreign Governments

This guidance represents 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

The Medical Device User Fee Amendments (MDUFA) require the payment of a user fee for most types of medical device applications and reports, as well as for establishment registration. Small businesses, however, may be eligible for application fee reductions or waivers, and for an establishment registration fee waiver, depending on whether they fall below the applicable gross receipts or sales maximums specified in statute, and meet other requirements. A business that is qualified and determined by FDA to be a MDUFA "small business" is eligible for a substantial reduction in these application user fees. Application types eligible for reduced small business fees are: Premarket Notifications (510(k)), De Novo requests, Premarket Applications (Premarket Approval Applications [PMA], Biologics License Applications [BLA], Product Development Protocols [PDP]), Premarket Reports (PMR), PMA/PDP/BLA Supplements and PMA Annual Reports, and 513(g) requests for classification information. See the full list of eligible application types at the MDUFA User Fees website. In addition, a business that is qualified and determined to be a "small business" under a different provision may be eligible for a waiver of the fee for its first premarket application or report, and a business that is qualified and determined to be a "small business" and meets additional requirements under yet another provision may receive a waiver of an establishment registration fee. This guidance describes the process for how a business may request a determination that it qualifies as a small business for the purposes of each of these three provisions, which define "small business" with reference to different gross receipts or sales maximums – $100 million for reduced fees; $30 million for the first premarket application/report fee waiver; $1 million for the registration fee waiver.

FDA's guidance documents, including this 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. Overview

Information about the process to demonstrate qualification and obtain a determination that your business is a small business is described in the following sections of this guidance:

- **for a U.S. Business:**
  - see Section II(B) and Section IV
  - use the MDUFA Small Business Request ("MDUFA SBR") in the Customer Collaboration Portal ("CDRH Portal"), for a business headquartered in the United States
  - if you have foreign affiliates, complete a MDUFA Foreign Small Business Request for a business headquartered outside the United States ("MDUFA Foreign SBR") **for each foreign affiliate.**
- **for a Foreign Business:**
  - see Section II.C and Section V
  - a MDUFA Foreign SBR includes the same information as a MDUFA SBR, with the addition of a completed National Taxing Authority Certification.
  - use the MDUFA SBR in the CDRH Portal.
- **for a National Taxing Authority:**
  - see Section II.D and Section VI
  - work with your Foreign Business/Affiliate to complete a MDUFA Foreign SBR.

The instructions in this guidance are intended to help in understanding and providing the information that is required or recommended for your business.

For additional information about medical device user fees, see FDA's Medical Device User Fees website. This site provides an overview of the laws establishing medical device user fees, links to additional guidance documents, answers to frequently asked questions, and more.

A. Eligibilities

To be eligible for a:

- Reduced application or report fee, FDA must determine that you qualify as a "small business." For the purposes of the reduced small business fee, a small business is one that has gross receipts or sales of no more than $100 million for the most recent tax year, inclusive of its affiliates. If you have any affiliates, you must add their gross receipts or sales to yours, and the total must be no more than $100 million to be able to qualify as a small business.[1] More information about the general applicability of the reduced fee provisions may be found in **Section III** (Small Business Fees and Waivers) and **Section**

[1] See Sections 738(d)(2)(A) and 738(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

VII (Frequently Asked Questions) of this guidance.

- "First Premarket Application/Report Fee Waiver," you must qualify as a small business and neither you nor your affiliates have previously received a "First Premarket Application/Report Fee Waiver." For the purposes of the first premarket application/report fee waiver, a small business is defined as having gross receipts or sales of no more than $30 million for the most recent tax year, inclusive of gross receipts or sales of its affiliates.[2]

- Registration Fee Waiver, a business (owner or operator) must qualify as a small business, have registered and paid the fee in a prior year, and establish to FDA's satisfaction that paying the fee for the year at issue represents a financial hardship. For the purposes of the registration fee waiver, a small business is defined as having gross receipts or sales of no more than $1 million for the most recent tax year, inclusive of gross receipts or sales of its affiliates.[3] More information about these conditions may be found in **Sections IV** (for domestic businesses) and **V** (for foreign businesses). There are no reduced fees for registration.

A Small Business Determination is granted for a single fiscal year (FY) and expires at the end of that FY. A FY runs from October 1 through September 30, inclusive of the following calendar year. A sponsor who wishes to apply any applicable reduction in user fee for a submission must apply and be granted the Small Business Determination for each FY in which they plan to submit a medical device application that requires a user fee.[4] The first premarket application/report fee waiver, per MDUFA, is a one-time benefit. FDA intends to grant the registration fee waiver to an entity once in relation to the circumstances that gave rise to the waiver.

Applicants seeking any of the three types of small business determinations must submit evidence of qualification at least 60 days before the fee at issue is due.[5] The periods for submitting evidence are described in the following paragraph.

For the purposes of the reduced small business fee and the first premarket application/report fee waiver, FDA accepts Small Business Requests ("SBR") beginning August 1, prior to next FY starting on October 1. For example, requests for FY 2026 status (which runs from October 1, 2025, through September 30, 2026) will be accepted from August 1, 2025, through July 31, 2026. SBRs for the next FY received before August 1 will not be accepted. Please plan your request strategy accordingly.

For purposes of the registration fee waiver, for actively registered firms, the FDA accepts SBRs through October 31. For example, requests for FY 2026 status (which runs from October 1, 2025, through September 30, 2026) will be accepted from August 1, 2025, through October 31, 2025.

[2] See Section 738(d)(1) of the FD&C Act.
[3] See Section 738(a)(3)(B)(ii)(I).
[4] See Section 738(a)(2)(C) of the FD&C Act.
[5] See Sections 738(a)(3)(B)(ii)(V),738(d)(2)(D) and 738(e)(2)(D).

B. U.S. Businesses

If your business is headquartered in the United States, you should follow the guidance in **Section IV** (Guidance for U.S. Businesses). To qualify as a small business, please complete a MDUFA SBR, and submit to FDA in the CDRH Portal. Detailed instructions on this process can be found at the website titled "Reduced Medical Device User Fees: Small Business Determination (SBD) Program."

If you have any foreign affiliates, please complete a MDUFA Foreign SBR for each foreign affiliate and review the SBD Program website for necessary information to complete a MDUFA Foreign SBR.

C. Foreign Businesses

If your business is a foreign business headquartered outside the United States and your business does not file a Federal (U.S.) income tax return, you should follow the guidance in **Section V** (Guidance for Foreign Businesses). To qualify as a small business, please follow these sequential steps:

1. Visit the website "Reduced Medical Device User Fees: Small Business Determination (SBD) Program" for detailed instructions on accessing and completing a MDUFA Foreign SBR.

2. Complete the sections entitled "Information about the Business Requesting Small Business Status" and "Information about You and Your Affiliates" on the MDUFA Foreign SBR.

3. Submit the MDUFA Foreign SBR to your National Taxing Authority (the equivalent of the U.S. Internal Revenue Service), to complete Section III of that form (National Taxing Authority Certification).

4. Request that the National Taxing Authority return the completed MDUFA Foreign SBR to you.

5. Submit the fully completed MDUFA Foreign SBR to FDA in the CDRH Portal for review. In addition, if your business has any foreign affiliates, you must send a separate, certified National Taxing Authority Certification for each foreign affiliate. If your business has any U.S. affiliates, you must send a Federal U.S. income tax return for each U.S. affiliate.[6]

We recommend that you review **Section VI** (Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification) to understand the responsibility of your National Taxing Authority and, specifically, the National Taxing Authority Certification of the MDUFA Foreign SBR.

D. National Taxing Authority

[6] See Section 738(d)(2)(A) and Section 738(e)(2)(A) of the FD&C Act.

If you are a National Taxing Authority, you should review **Section VI (**Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification) for instructions on your responsibilities. Complete the National Taxing Authority Certification of the MDUFA Foreign SBR submitted to you by a business headquartered in your nation and return the completed form back to the business that sent you the form.

E. Important Note for Submitters of Pre-FY2026 Small Business Requests

The process and principles described in this guidance are substantially similar to the previous version of this guidance. Please be advised that FDA continues to make quality improvements in the program, in areas such as administrative completeness and consistency of documentation. These updates assist the applicant in developing and submitting the SBR and FDA in reviewing the request in a consistent, timely manner.

III. Small Business Fees and Waivers

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

A. MDUFA User Fee Schedule

The standard MDUFA User Fee must be paid for the identified applications in order for FDA to begin its review, unless the applicant is eligible for a reduction, waiver or exemption.[7] A fee must also be paid for establishment registration, unless an establishment is eligible for a waiver and FDA grants the waiver.[8] The current user fees are shown at the FDA MDUFA User Fees website and are set by law.[9]

B. Benefits of Qualifying as a Small Business

(1) Reduced Application Fees

If the FDA determines that you qualify as a small business, you will pay a lower user fee than the standard fee for applicable submissions from the date of FDA's determination of your small business status through the end of that FY (i.e., September 30). Applicable submissions are: PMA, PDP, PMA and PDP Supplements (Panel-Track, 180-day, Real-Time and 30-day Notice), Modular PMA, BLA, BLA Efficacy Supplement, 510(k) (Traditional, Abbreviated, and Special), PMR, PMA Annual Reports, 513(g) and De Novo request.[10] Under Sections 738(d)(2)(D) and 738(e)(2)(D) of the FD&C Act, applicants seeking this fee reduction must submit supporting information at least 60 days before the fee is due. Sections 738(d)(2)(D) and 738(e)(2)(D) additionally state that FDA's decision regarding whether an applicant qualifies for a small business reduced application fee is not reviewable.

[7] Section 738(a)(2)(C) of the FD&C Act.
[8] Section 738(a)(3)(C) of the FD&C Act.
[9] See Sections 738(a)(2) and 738(a)(3) of the FD&C Act.
[10] See Sections 738(d)(1) and (2) and 738(e) of the FD&C Act.

To qualify for the reduced application fees, FDA must determine that you qualify as a small business with gross receipts or sales of no more than $100 million, including the gross receipts or sales of all of your affiliates.[11]

(2) First Premarket Application/Report Fee Waiver

If the FDA determines that you are eligible for a "first premarket application/report fee waiver", this means that you will not have to pay the fee for your first premarket application/report (i.e., PMA, including Modular PMA, BLA, PDP, or PMR).[12] This fee waiver may only be applied once. The first premarket application/report is defined as the first PMA (including Modular PMA), BLA, PDP, or PMR received by FDA from a business entity or any of its affiliates. If a second business entity (or any of its affiliates) acquires another business entity that has previously submitted a premarket application/report, then the second business entity is not eligible for a "first premarket application/report waiver." Under Section 738(d)(2)(D) of the FD&C Act, applicants seeking this waiver must submit supporting information at least 60 days before the fee is due. Section 738(d)(2)(D) additionally states that FDA's decision regarding whether an applicant qualifies for a small business premarket application/report fee waiver or reduction is not reviewable.

To qualify for the "first premarket application/report fee waiver", you must meet **both** criteria:

1. FDA must determine that you qualify as a small business with gross receipts or sales of no more than $30 million, including the gross receipts or sales of all of your affiliates.[13]

   Note: This means that some businesses may qualify as a **small business** for the purpose of reduced application fees because their gross receipts or sales are less than $100 million but would not qualify for the **"first premarket application/report fee waiver"** if their gross receipts or sales are more than $30 million.

2. FDA must determine that this is your first premarket application/report (i.e., PMA, including Modular PMA, BLA, PDP, or PMR). Specifically, if you or any affiliate previously submitted a premarket application/report, then your next application does not qualify for the "first premarket application/report fee waiver", and you must pay the fee that would otherwise apply.[14]

   Examples of situations that do not qualify for the "first premarket application/report fee waiver":

   a. Business A has an approved PMA and is acquired by Business B. Business B has not submitted a PMA, BLA, PDP or a Modular PMA to FDA. Because Business A has submitted a PMA, Business B is not eligible for the first premarket

[11] See Sections 738(d)(2)(A) and 738(e)(2)(A) of the FD&C Act.
[12] See Section 738(d)(1) of the FD&C Act.
[13] See Section 738(d)(1) of the FD&C Act.
[14] See Section 738(d)(1) of the FD&C Act

application/report fee waiver.

b. A business with Name A has submitted a BLA and then changes its name to Name B. Under Name B, the business submits a Modular PMA. This is considered the same business. The business is not eligible for the first premarket application/report fee waiver.

c. A business submits a PMA that is not approved and then submits a Modular PMA for a different product. The business is not eligible for the first premarket application/report fee waiver because it has already submitted a premarket application regardless of whether it was approved.

(3) Registration Fee Waiver

If you:

- reported $1,000,000 or less in gross receipts or sales in your most recent Federal (U.S.) income tax return (including the returns of your affiliates[15]), and
- provided evidence that paying the annual registration fee represents a financial hardship[16], as described below and FDA determines this to be the case, and
- provided proof of prior paid registration,

then you may be eligible to receive a waiver of the establishment registration fee for the fiscal year identified in the approval letter. If you are granted this registration fee waiver, you are still obligated to comply with the applicable registration and listing requirements found in 21 CFR Part 807.

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 supporting information at least 60 days before the fee is due, which, for actively registered firms, is December 31. Accordingly, applicants must submit supporting information for this waiver between August 1 and October 31. Section 738(a)(3)(B)(ii)(V) additionally states that FDA's decision regarding whether an applicant may receive a small business registration fee waiver is not reviewable.

IV. Guidance for U.S. Businesses

A U.S. business is a business headquartered in the United States. If you are a U.S. business, you should follow the guidance provided in this section. If your business is headquartered in a foreign country, you should follow the guidance in **Section V** (Guidance for Foreign Businesses).

[15] See Section 738(a)(3)(B)(ii)(I).
[16] See Section 738(a)(3)(B)(ii)(II).

If you believe you qualify as a small business and want to pay reduced fees or have certain fees waived, you should submit the following documents to FDA:

- a completed MDUFA SBR
  - include your Organization ID Number (Org ID). Org ID is a system-generated number assigned to a new organization during the User Fee account creation process that uniquely identifies your business in the FDA User Fee System. Your Org ID is separate and distinct from any other number that may be associated with your company. See **Section VII** (Frequently Asked Questions) of this guidance for instructions on obtaining your Org ID.
- Documentation demonstrating that the total gross sales and receipts for you and your affiliates are under the relevant amount for each benefit, which are $100 million for reduced application fees, $30 million for a first premarket application/report fee waiver, and $1 million for the registration fee waiver (hereinafter "Applicable Thresholds"). This documentation must include:
  - a complete, signed copy of your original Federal (U.S.) income tax return for the most recent tax year;
  - a separate Federal (U.S.) income tax return for each U.S. affiliate; and
  - a certified National Taxing Authority Certification on the MDUFA Foreign SBR for each foreign affiliate.
    - This can be completed by submitting the National Taxing Authority Certification to your National Taxing Authority (the equivalent of the U.S. Internal Revenue Service), who then completes the Certification and returns the updated form to you.

FDA will review your submission and supporting materials within 60 calendar days of receipt. Upon completion of our review, we will send you a letter that indicates whether or not your business has been determined to be a small business under MDUFA and for what purposes. A small business is then eligible for a reduced or waived fee for submissions made during the FY and may be eligible for a registration fee waiver. If your business qualifies as a small business, FDA's decision letter will assign you a Small Business Decision number and specify which fee reduction or waiver(s) FDA has determined you are eligible for. You should provide this number to FDA each time you want to receive a small business fee discount for any of your eligible applications or, if you qualify, when you want to obtain a fee waiver for your first premarket application/report or a registration fee waiver.

What is an affiliate?

The term "affiliate" is defined in Section 737(13) of the FD&C Act. An affiliate means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly:

(a) one business entity controls, or has the power to control, the other business entity; or
(b) a third party controls, or has power to control, both of the business entities.

You must include the gross receipts or sales of all your affiliates with your own gross receipts or

sales when you prepare your MDUFA SBR.[17]

Why does FDA require me to submit a Federal (U.S.) income tax return?
Regarding the reduced application fee and the first premarket application/report fee waiver, Sections 738(d)(2)(B)(i) and 738(e)(2)(B)(i) of the FD&C Act require an applicant to pay the standard fees for its submissions *unless* it demonstrates it is a small business by submitting a copy of its most recent Federal (U.S.) income tax return (and returns of all affiliates). Regarding the registration fee waiver, Section 738(a)(3)(B)(ii)(III) requires a small business to submit its most recent Federal income tax return to support its eligibility for the registration fee waiver. A consequence of this requirement is that you cannot qualify as a small business under MDUFA if you have not submitted a Federal (U.S.) income tax return. FDA cannot accept a foreign tax return or state tax return in place of a Federal (U.S.) income tax return.

What is an acceptable copy of a Federal (U.S.) income tax return?
An acceptable copy of a Federal (U.S.) income tax return is an identical signed copy of the entire original Federal (U.S.) income tax return submitted to the United States Internal Revenue Service (IRS). Please do not include your state tax return. Only the Federal (U.S) income tax return is needed.

The copy of the Federal (U.S.) income tax return must include the signature and the date of the signature of an officer, partner, or member of the company. Alternatively, you may submit a copy of the e-file form submitted to the IRS, if your documentation includes a dated signature of an officer, partner or member.

What is the most recent tax year?
You should submit your most recent tax return. If you submit your SBR prior to the current year's due date for your taxes, you may submit your previous year's tax return.

If you obtained an extension to file your taxes, then you may use your most recent return filed prior to the extension. In this scenario, you should also include your IRS Form 7004: Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns in your SBR.

My organization filed a Form 990, Return of Organization Exempt from Income Tax. Do I still need to qualify as a Small Business?
Yes. The FD&C Act does not exempt you from medical device user fees or grant you automatic small business status simply because you are exempt from Federal (U.S.) income tax. You are subject to the same "gross receipts or sales" thresholds as other applicants. You should report your Total Revenue (line 12 of Form 990) as your "gross receipts or sales." In addition, include a signed copy of your Form 990.

How do I access and complete a MDUFA SBR?
You may access and complete a MDUFA SBR in the CDRH Portal. Detailed instructions on this process can be found at the website titled "Reduced Medical Device User Fees: Small Business Determination (SBD) Program."

[17] See Sections 738(a)(3)(B)(ii)(III), 738(d)(2)(A), and 738(e)(2)(A) of the FD&C Act.

What do I provide if I have a foreign affiliate?
If you have a foreign affiliate, you should submit a MDUFA Foreign SBR (which includes a National Taxing Authority Certification) for that affiliate. A National Taxing Authority is the government agency that collects the national income tax in the country where your affiliate is located. Please contact that national government to identify the appropriate point of contact for the National Taxing Authority where your affiliate is located.

What if the National Taxing Authority does not provide the certification for my foreign affiliate?
A certification from a National Taxing Authority, if extant, is required to authenticate the gross sales and receipts for a foreign business or affiliate.[18]

How can I demonstrate "financial hardship" and receive a 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.[19] 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 registration fee waiver, we recommend you provide all of 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 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), and
- evidence that the establishments for which you are seeking a waiver have, under your owner/operator ID with FDA, previously registered and paid the associated registration fees.

V. Guidance for Foreign Businesses

A foreign business is a business headquartered outside the United States. If you are a foreign business, you should follow the guidance provided in this section. If your business is headquartered in the United States, you should follow the guidance in **Section IV** (Guidance for U.S. Businesses).

If you are a foreign business and wish to qualify as a small business, please follow these sequential steps:

[18] See Sections 738(a)(3)(B)(ii)(IV), 738(d)(2)(B)(iii), and 738(e)(2)(B)(iii) of the FD&C Act.
[19] See Section 738(a)(3)(B)(ii).

Access the form needed to complete a MDUFA Foreign SBR in the CDRH Portal

1. Detailed instructions on this process can be found at the website titled "Reduced Medical Device User Fees: Small Business Determination (SBD) Program" describing how to access the form.
2. Complete the "Information about the Business Requesting Small Business Status" and "Information about you and your Affiliates" sections of the MDUFA Foreign SBR. Note you need to generate your Organization ID Number (Org ID) and include this in the MDUFA Foreign SBR. Your Org ID is separate and distinct from any other number that may be associated with your company. See **Section VII** (Frequently Asked Questions) of this guidance for instructions on generating the Org ID.
3. Submit the MDUFA Foreign SBR to your National Taxing Authority (the equivalent of the U.S. Internal Revenue Service), who then completes the National Taxing Authority Certification. Please ensure all appropriate boxes and lines are filled in.
4. The National Taxing Authority returns the updated form to you.
5. Submit a fully completed MDUFA Foreign SBR to FDA for review, including a completed National Taxing Authority Certification. In addition, if your business has any foreign affiliates, you must send a separate certified National Taxing Authority Certification for each foreign affiliate. If your business has any U.S. affiliates, you must send a Federal (U.S.) income tax return for each U.S. affiliate. Note that the website titled "Reduced Medical Device User Fees: Small Business Determination (SBD) Program" provides detailed information on accessing and completing a MDUFA Foreign SBR.

We recommend that you review **Section VI** (Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification) to understand the responsibility of your National Taxing Authority.

FDA will complete its review of your SBR, which includes your completed MDUFA Foreign SBR and supporting evidence, within 60 calendar days of receipt. Upon completion of our review, we will send you a letter that indicates whether your business has been determined to be a small business under MDUFA and for what purposes. A small business meeting the Applicable Threshold(s) is then eligible for a reduced or waived fee for submissions made during that FY, and may be eligible for a registration fee waiver. If your business is qualified as a small business, FDA's decision letter will assign you a Small Business Decision number. You should provide this number to FDA each time during the applicable FY that you want to receive a small business fee discount for any of your eligible applications or, if you qualify, when you want to obtain a fee waiver for your first premarket application/report or a registration fee waiver.

What is an affiliate?
The term "affiliate" is defined by Section 737(13) of the FD&C Act. An affiliate means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly:

(a) one business entity controls, or has the power to control, the other business entity; or

(b) a third-party controls, or has power to control, both of the business entities.

You must include the gross receipts or sales of all of your affiliates with your own gross receipts or sales when you prepare your MDUFA Foreign SBR.[20]

Who is my National Taxing Authority?
Your National Taxing Authority is the government agency that collects your national income tax. Please contact your national government to identify the appropriate point of contact for your National Taxing Authority.

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 Applicable Threshold to qualify for a small business fee waiver or reduction. FDA plans to review evidence on a case-by-case basis to determine whether you qualify for a small business fee waiver or reduction.

What if the National Taxing Authority does not provide the required certification for my business or my foreign affiliate?
A certification from a National Taxing Authority, if extant, is required to authenticate the gross sales and receipts for a foreign business or affiliate.[21]

May a foreign applicant file a Federal (U.S.) income tax return in order to qualify as a small business under MDUFA?
Although the law does not prohibit a foreign business from submitting a Federal (U.S.) income tax return, filing a Federal (U.S.) income tax return may have significant tax and other legal consequences beyond simply making you eligible as a small business under MDUFA. FDA cannot provide advice regarding whether you should or should not file a Federal (U.S.) income tax return. If you are in doubt as to whether it is advisable for you to file a Federal (U.S.) income tax return, you should consider consulting with qualified legal and tax professionals. Additional information on Federal (U.S.) income taxation is available from the United States Internal Revenue Service (https://www.irs.gov).

How do I access and complete a MDUFA Foreign SBR?
You may access and complete a MDUFA Foreign SBR in the CDRH Portal. Detailed instructions on this process can be found at the website titled "Reduced Medical Device User Fees: Small Business Determination (SBD) Program."

How can I demonstrate "financial hardship" and receive a waiver of the registration fee 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.[22] FDA intends to grant waivers only where financial hardship is shown by a clear and

[20] See Sections 738(a)(3)(B)(ii)(IV), 738(d)(2)(B)(iii), and 738(e)(2)(B)(iii) of the FD&C Act.
[21] See Sections 738(a)(3)(B)(ii)(IV), 738(d)(2)(B)(iii), and 738(e)(2)(B)(iii) of the FD&C Act.
[22] See Section 738(a)(3)(B)(ii).

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 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 you have filed your jurisdiction's equivalent of a United States bankruptcy action, including evidence that the applicant has initiated the action (i.e., a document analogous to a United States bankruptcy petition) and evidence that the bankruptcy action is active, and
- evidence that each establishment for which you are seeking a waiver has previously registered and paid the registration fee, under your owner/operator ID with FDA.

VI. Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification

Qualification as a MDUFA small business may allow the business to pay reduced medical device user fees and/or be eligible for certain fee waivers. If a foreign business has not previously submitted a Federal (U.S.) income tax return, it may obtain a certification from its National Taxing Authority" showing that its gross receipts or sales do not exceed the Applicable Thresholds. The law[23] requires that this certification, referred to as the "National Taxing Authority Certification":

- be in English;
- be from the National Taxing Authority of the country in which the business (or affiliate) is headquartered;
- provide the business's gross receipts or sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in converting local currency to U.S. dollars;
- provide the dates during which the reported receipts or sales were collected; and
- bear the official seal of the National Taxing Authority.

In addition, the applicant must submit a statement signed by its head or CFO that it has submitted certifications for all of its affiliates, or that it has no affiliates.

What are "gross receipts or sales"?
If you are unsure how "gross receipts or sales" relate to your national income taxation system, please contact the United States Internal Revenue Service through the United States Embassy.

[23] See Sections 738(a)(3)(B)(ii)(IV), 738(d)(2)(B)(iii), and 738(e)(2)(B)(iii) of the FD&C Act.

What information should the business submit to the National Taxing Authority?
The business should send the National Taxing Authority a MDUFA Foreign SBR, with the information other than the National Taxing Authority Certification fully completed.

Each National Taxing Authority may require the business to provide additional information and evidence needed by the National Taxing Authority to determine the gross receipts or sales it will report in the National Taxing Authority Certification for the business.

What exchange rate should be used to convert local currency to U.S. dollars?
You should use the exchange rate in effect as of the ending date of the period during which the reported receipts or sales were collected; this is the date provided as the ending date in which reported receipts or sales were collected in the National Taxing Authority Certification. FDA cannot provide this information to you; each National Taxing Authority is responsible for determining the appropriate exchange rate to use.

Why does FDA require the National Taxing Authority Certification to bear the official seal of the National Taxing Authority?
This is a statutory requirement. Sections 738(a)(3)(B)(ii)(IV), 738(d)(2)(B)(iii) and 738(e)(2)(B)(iii) of the FD&C Act require the National Taxing Authority Certification to bear the official seal of the National Taxing Authority.

VII. Frequently Asked Questions

What is the purpose of a Small Business Decision number?
The Small Business Decision number is used by FDA to confirm that you have qualified as a small business and may receive the appropriate user fee reduction or waiver when you make a submission that requires a user fee (as described at the FDA MDUFA User Fees website). You should use your Small Business Decision number to document that you have qualified as a small business. You should include your Small Business Decision number when you submit a Medical Device User Fee Cover Sheet, which is available from the FDA User Fee System.

When will my status as a small business begin?
Your status as a small business will begin on the date of FDA's decision letter, which determined that you qualified as a small business.

When will my status as a small business expire?
Your status as a small business will expire at the end of the FY for which the small business status was granted (September 30). You should submit a new MDUFA SBR each year to qualify as a small business for the purpose of reduced fees. This is because:

- Your gross sales and receipts will vary from one year to another.
- We will always need a copy of your most recent Federal (U.S.) income tax return (if you are a U.S. business) or your most recent certification of income from your National Taxing Authority (if you are a foreign business).

What is an Organization ID Number (Org ID)?
Org ID is a system-generated number assigned to a new organization during the User Fee account creation process that uniquely identifies your business in the FDA User Fee System. It is not the same as the Federal Employer Identification Number, Registration Number, or Taxpayer Identification Number. It is important that this number is correct, because FDA uses the Org ID to interact with an organization to ensure proper payment of its medical device applications that require the payment of a user fee. If this number is incorrect there could be a delay in processing your Small Business Determination reduced user fee or waiver.

If you are a registered company, you should already have an organization ID number. You should use this one – do not create a new one.

Your Org ID may be found in the Profile section, under Business Information on the User Fee System MDUFA screen. Follow these instructions to obtain your organization number:

1. Login to the User Fee System MDUFA screen and enter a valid user name and password to sign into the Medical Device User Fee Website.
2. Click the "Go" button for the Medical Device User Fee (MDUFA Cover Sheets (e.g., PMA, De Novo, 510(k), etc.)) option, under the Cover Sheets section.
3. Click the Profile icon located on the top of the page.
4. You will see Business Information under the Details tab. The organization ID number is listed below the organization name.

If your company has never paid a user fee, you should create a new User Fee System account. See the FDA User Fee System (UFS) Account Creation Desk Guide for detailed instructions.

If you forgot your user name and/or password or a message displays "Invalid username and/or password" while attempting to login, you may retrieve your user name and/or password online by returning to the User Fee System website and clicking on the "Forgot User Name/Password?" link. You will need to enter your username and/or email address and then click on the "email My Password" button. If the email address or username is valid, a temporary password will be sent to the user with the requested information. If the message "We're sorry, but we haven't been able to locate your account information" is displayed, you should create a new User Fee account.

Please contact the User Fee Helpdesk at userfees@fda.gov or (301) 796-7200 if you need assistance obtaining your Organization ID Number (Org ID) or there are any issues with your account. Be prepared to provide your organization name and address.

What fee should I pay if I submit an application before FDA determines that I qualify as a small business?
If you submit an application before FDA has qualified you as a small business, you must pay the standard (full) amount of any fee that applies. FDA will **not** refund the difference between the standard (full) fee and the small business fee if you later qualify as a small business. If you want to pay the small business fee for an application, you should not submit your application until you obtain your Small Business Decision number from FDA.

May a company request a small business determination for a prior FY?
No. All of the fee reduction and waiver provisions require an applicant seeking a fee reduction or waiver to submit supporting information to FDA at least 60 days before payment of the fee is required. See Section 738(a)(3)(B)(ii)(V), Section 738(d)(2)(D), and Section 738(e)(2)(D). We have no provision for an applicant to retroactively request a small business status for a prior FY.

What may happen if I submit a false SBR concerning my business?
When you make your SBR you are explicitly certifying:

> ". . . to the best of my knowledge, the information I have provided in this Request is complete and accurate. I understand that submission of a false request may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes."

This statement appears immediately above your signature.

A false certification is one where you report information that is *not true* (for example, your gross receipts or sales are actually higher than you state) or if you *fail to disclose* required information (for example, you fail to disclose the existence of a parent, partner, or affiliate).

If FDA determines that you submitted a false certification, we may suspend your status as a small business, we may suspend the review of any application you submitted until you pay the full fee that applies to that type of application, we may seek payment of the unpaid portion of fees that should have been paid, we may take other legal actions that are appropriate under the circumstances, and you may be subject to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Who is the contact for the SBR?
The primary contact for the SBR is the person making the certification that the information provided in the SBR is complete and accurate. If you would like to identify additional contacts, please identify any additional contacts on the cover letter of your SBR. To protect your confidential information, we will only communicate with individuals you have identified as contacts.

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 of the fee or the lower fee rate.[24] 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."[25]

The statute does not contain a transferability provision pursuant to which a small business

[24] See Sections 738(d)(2)(B)(i) and 738(e)(2)(B)(i) of the FD&C Act.
[25] See Section 738(a)(3)(B)(ii)(II) of the FD&C Act.

determination and qualification for the fee waiver or reduction could be transferred to another entity. For example, if the owner/operator of a device establishment, determined 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.[26] 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.[27] If you have previously registered with FDA a facility under your owner/operator ID, and the gross receipts or sales for you and all of your affiliates combined are $1 million or less, and you can show that paying the fee would be a financial hardship, FDA may grant the waiver. If you have been granted a 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 registration fee waiver, it does not intend to grant this waiver more than once to the same entity in relation to the circumstances that gave rise to the waiver. This means FDA intends to grant a small business registration fee waiver for an active bankruptcy for one year only, even if the bankruptcy lasts for several years.

Am I eligible for a refund for previous years where I paid the full fee, if I currently qualify for a fee waiver or reduction or would have qualified for a fee waiver or reduction in that previous year where I paid the full fee?

No, the statute requires any establishment seeking a fee waiver or reduction to submit their supporting information at least 60 days before the fee is due for that year. The statute does not provide a mechanism to retroactively apply the waiver or reduction to previous years.

If I have a question, whom may I ask?

If you need additional information about becoming a MDUFA small business, contact FDA's Division of Industry and Consumer Education by email at DICE@fda.hhs.gov or by phone at 800-638-2041 or 301-796-7100.

[26] See Section 738(d)(2)(B)(i) of the FD&C Act.
[27] For more information see FDA's website, "Who Must Register, List, and Pay the Fee."

VIII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to be 1 hour per response. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0508 (to find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).

Guidance History[*]	Date	Description
Level 1 Final Guidance	July 2025	See Notice of Availability for more information.** This guidance supersedes the final guidance titled "FY 2018 Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments" and published August 2018.
Level 1 Draft Guidance	February 2024	Select Updates, See Notice of Availability for more information.**

*This table was implemented, beginning April 2025 and previous guidance history may not be captured in totality.
**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.