Reduced Medical Device User Fees: Small Business Determination (SBD) Program

Update: October 3, 2024

Beginning October 1, 2024, the FDA will accept Small Business Determination (SBD) requests electronically. All documents to support a request may be submitted through the Customer Collaboration Portal (CDRH Portal (/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal)).

Beginning November 1, 2024, all SBD requests **must** be submitted electronically. See section, "**How do I submit a Small Business Determination (SBD) request using the CDRH Portal?**"

We will continue processing all mailed-in submissions received prior to November 1, 2024. SBD requests received by mail after November 1, 2024, will be returned for your re-submission via the CDRH Portal.

This SBD program update is a step forward to enhance efficiency in submitting and tracking these SBD requests.

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What is CDRH's Small Business Program?

CDRH's Small Business program determines whether a business is qualified and certified as a "small business."

A “small business” is defined as a business, including its affiliates, whose gross receipts and sales are less than **$100 million** for the most recent tax year.

Certified small businesses are eligible for a reduced fee for some types of CDRH submissions that require a user fee.

To learn more about Medical Device User Fees for Small Businesses, check out, Medical Device User Fee Small Business Qualification and Certification - Guidance for Industry, Food and Drug Administration Staff and Foreign Governments (/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification).

The application types eligible for a reduced small business fee are:

- Premarket Notification (510(k)) (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k)
- De Novo request (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request)
- Premarket Applications, including:
    - Premarket Approval Application (PMA) (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma)
    - Biologics License Application (BLA) (/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber)
    - Product Development Protocol (PDP) (https://www.fda.gov/medical-devices/premarket-approval-pma/pma-application-methods#pdp)
- Premarket Report (PMR)
- PMA/BLA supplements and PMA annual reports
- 30-day-Notices
- 513(g) Requests for Information (/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic)

In addition, a small business is eligible for a "first premarket application/report" fee waiver, if the business/affiliate gross receipts or sales are no more than **$30 million.** The "first premarket application/report" is defined as the first PMA (including Modular PMA), BLA, PDP, or PMR received by the FDA from a business entity or any of its affiliates.

The establishment registration fee is **not** eligible for a reduced small business fee.

How do I submit a Small Business Determination (SBD) request using the CDRH Portal?

IMPORTANT: Beginning November 1, 2024, all Small Business Determination requests must be submitted electronically.

To submit and track an SBD request, follow these 6 steps:

Step 1. Gather necessary documents and information

- **Tax documentation:** Refer to the small business guidance document (/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification) for specific details.

Note: You should provide the completed, signed, and dated U.S. Federal income tax returns for the most recent tax year for your U.S. business and any business affiliates, as well as a certified Section III of Form 3602A (https://www.fda.gov/about-fda/forms/mdufa-foreign-small-business-qualification-and-certification-business-headquartered-outside-united) for foreign businesses.

- **Organization ID number (Org ID):** An FDA system-generated number is given to a new organization when they create a User Fee System account. The Org ID is not the same as the Federal Employer Identification Number, Registration Number, or Taxpayer Identification Number.
    - For instructions on how to create or find your Org ID, please review the FDA User Fee System Account Creation Desk Guide (https://userfees.fda.gov/OA_HTML/mdufa_account_creation.pdf).
- **Download the appropriate form** (/about-fda/reports-manuals-forms/forms) **and save it as a PDF:**
    - For U.S. Small Business Qualification and Certification, search and select form: FDA 3602

- For Foreign Small Business Qualification and Certification, search and select form: FDA 3602A

The person to fill out these forms should be the official correspondent, as identified in Section I, Boxes 4 and through 7 of Form FDA 3602 and 3602A.

Step 2. Fill out the form you downloaded for small business qualification and certification (Form 3602 for U.S. businesses and/or 3602A for foreign businesses) using your computer.

If additional help is needed:

- Review Appendix 2 and 3 in the small business guidance document (/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification) for instructions.
- View the training modules for How to Complete the U.S. Small Business Qualification and Certification Form (https://www.accessdata.fda.gov/cdrh_docs/presentations/how-to-complete-form-fda-3602/story.html) (FDA 3602) or How to Complete the Foreign Small Business Qualification and Certification Form (https://www.accessdata.fda.gov/cdrh_docs/presentations/how-to-complete-form-fda-3602a/story.html) (FDA 3602A).

You may also download and print out the appropriate form and either use a typewriter or complete by hand. Any method is acceptable as long as it is legible. Then, scan the completed form and upload it to your computer.

Step 3. Log into the CDRH Portal.

- Log into the CDRH Portal (https://fda-cdrh.okta.com/app/fda-cdrh_customercollaborationportal_1/exk5t7i49upPRHASh4h6/sso/saml) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Enter your login information, if you have an active account.
- If you do not have an account, register for an account through the CDRH Portal (https://fda-cdrh.okta.com/signin/register) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). CDRH uses Okta for identity verification and single sign-

on purposes when users register for a CDRH Portal account. Account registration and password reset requests will come from an email ending in **@okta.com**.

Step 4. Create a new request.

- Select “Create a Request” in the left navigation panel.
- Select the “Start” button next to “Small Business Determination request” to begin.
- Complete the required fields and upload all documents.
- Submit your SBD request.

Step 5. Check your email for an automated notification from the FDA.

- The first email will confirm that your request has been received.
- You will receive additional emails, if there are issues with your request and upon completion of FDA’s review.

Step 6. Check the status of your submission by logging into the CDRH portal.

The portal provides the status of your SBD and other requests in near real-time.

Statuses are generally defined below:

- Processing: When a request is submitted, and a virus scan is in progress.
- Reviewing: When the FDA is reviewing a request.
- On hold: When reviewers have flagged issues and need additional information from the applicant.
- Finished: When an application is either Approved or Denied by the reviewer.
- Withdrawn: When an application is withdrawn by the applicant.

What is the review timeline for a Small Business Determination request, and how can I view the status of my submission?

The FDA will typically complete its review of the Small Business Determination request within 60 calendar days of receipt. Upon completion of our review, we will send the business a letter that indicates whether or not the business has been qualified as a small business.

In the CDRH Portal, you can view the status of your submission at any time.

What is the fee for a Small Business Determination request?

There is **no** fee associated with the submission of a Small Business Determination request.

Frequently Asked Questions:

Q. When can I submit my MDUFA Small Business Determination request?

The FDA accepts Small Business Determination requests beginning August 1 prior to the next Fiscal Year (which starts on October 1). For example, requests for Fiscal Year 2025 status will be accepted from August 1, 2024 through September 30, 2025.

Q. As a small business, am I eligible for a waiver of the annual registration fee?

No, the FDA is not currently able to grant an annual registration fee waiver.

Q. May I use my Small Business Determination to pay the reduced fee for a submission where the applicant is a different firm?

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.

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 certification. 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.

The firm that will be paying for and listed as the applicant of any submission requiring a user fee will need to submit their own Small Business Determination request and obtain certification to be eligible for the reduced user fee. The firm's information and Organization ID (Org ID) within their certification letter must match that of the submission requiring the user fee.

Q. What is an Organization ID number (Org ID)?

The Organization ID Number (Org ID) uniquely identifies a business in the FDA User Fee System. The Org ID is a system-generated number assigned to a new organization during the account creation process. It is not the same as the Federal Employer Identification Number, Registration Number, or Taxpayer Identification Number.

Q. How to locate a business Organization ID number (Org ID)?

What if my business has a user fee account?

If your business has a user fee account, you will have an Org ID associated with it. Do not create a new one. Please use the current Org ID.

A business's Org ID may be found in the "Profile" section, under "Business Information" on the User Fee System MDUFA screen. Follow these instructions to locate the Org ID:

1. Login to the User Fee System MDUFA screen (https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp) and enter a valid username 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. The number listed there is the businesses' organization ID number.

What if my business has never paid a user fee?

Your business should create a new User Fee System account (https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp). See the FDA User Fee System (UFS) Account Creation Desk Guide (https://userfees.fda.gov/OA_HTML/mdufa_account_creation.pdf) for detailed instructions.

Q. How is the Org ID used?

The Org ID is used by the FDA as a unique identifier when interacting with an organization to ensure proper payment of its medical device applications that require the payment of a user fee.

Q. Can I obtain a MDUFA Small Business Certification if I have not filed a Federal (U.S) income tax return?

Sections 738(d)(2)(B) and 738(e)(2)(B) 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 returns (and returns or National Taxing Authority Certification of all affiliates). 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.

If you have been in business for less than a year, you can provide the FDA with a copy of your (U.S.) income tax return that includes less than 1 year. The dates that the (U.S.) income tax return encompasses should be identified on the tax return. In addition, please provide documentation identifying the businesses formation to justify the lack of a full year's tax return.

You may submit your personal (U.S.) income tax return. Your (U.S.) income tax return must identify your business and their gross receipts or sales, under Schedule C, within your personal 1040 U.S. Federal Tax Return.

Q. What do I provide if I am headquartered in the United States, and I have a foreign affiliate?

If you have a foreign affiliate, you should submit a separate Form FDA 3602A MDUFA Foreign Small Business Determination request, for a Business Headquartered Outside the United States, including Section III that has been completed by the affiliate's National Taxing Authority.

Q. My National Taxing Authority won't provide the certification on Section III of Form FDA 3602A. What can I do?

Form FDA 3602A contains a field for certification from a National Taxing Authority for a foreign business or affiliate, which serves as authentication of the gross sales and receipts for that business/affiliate. The FDA expects you to obtain this official certification.

If the National Taxing Authority does not provide the certification, you may provide a written explanation of impossibility for why you were unable to obtain this certification, along with Form FDA 3602A. All explanations should include documentation from the National Taxing Authority, in English, of their refusal to provide the certification. All explanations are reviewed on a case-by-case basis.

Q. What if I pay the MDUFA user fee prior to submitting an application to the FDA that requires a user fee?

If you submit an application before the FDA has qualified you as a small business, you will be required to pay the standard (full) amount of any fee that applies. The 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 the FDA.

Q. Does a Small Business Determination status expire?

Yes, the small business status expires on September 30 of the fiscal year in which it is granted. A new MDUFA Small Business Determination request must be submitted and approved each fiscal year in order to qualify as a small business. For example, a business that obtains small business status on October 7, 2024 will have this status through September 30, 2025.

Contact

If you have any questions about the program or would like to refer prospective small businesses to the program, please direct them to the Division of Industry and Consumer Education via email at DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov).

Resources

- The Medical Device User Fee Small Business Qualification and Certification: Guidance for Industry, Food and Drug Administration Staff and Foreign Governments (/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-certification)
- FDA Form 3602 (/about-fda/reports-manuals-forms/forms)
- FDA Form 3602A (/about-fda/reports-manuals-forms/forms)
- CDRH Portal (/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal)
- MDUFA User Fees (/industry/medical-device-user-fee-amendments-mdufa/fy-2019-mdufa-user-fees)
- MDUFA User Fee Cover Sheet (/industry/medical-device-user-fee-amendments-mdufa/mdufa-cover-sheets)
- CDRH Learn Module: How to Complete Form FDA 3602: MDUFA Small Business Qualification and Certification for a Business Headquartered in the United States (http://www.accessdata.fda.gov/cdrh_docs/presentations/how-to-complete-form-fda-3602/story.html)
- CDRH Learn Module: How to Complete Form FDA 3602A: MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States (https://www.accessdata.fda.gov/cdrh_docs/presentations/how-to-complete-form-fda-3602a/story.html)