

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

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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Would you like a 75% discount?

How about saving \$400K?

FY 2023 MDUFA Fees



Application Type	Standard Fee	Small Business Fee	Fee Reduction
PMA, PDP, PMR, BLA	\$441,547	\$110,387	75%
BLA Efficacy Supplement	\$441,547	\$110,387	75%
Panel-Track Supplement	\$353,238	\$88,309	75%
De Novo Classification Request	\$132,464	\$33,116	75%
180-Day Supplement	\$66,232	\$16,558	75%
Real-Time Supplement	\$30,908	\$7,727	75%
510(k)	\$19,870	\$4,967	75%
Annual Fee for Periodic Reporting on a Class III Device (PMAs, PDPs, and PMRs)	\$15,454	\$3,864	75%
30-Day Notice	\$7,065	\$3,532	50%
513(g)	\$5,961	\$2,980	50%

Learning Objectives

- Describe Qualification Requirements
- Define Critical Concepts
- Walk Through the Submission Process
- Provide Tips for Avoiding Common Mistakes
- Review Common Challenges

SBD Qualification Requirements

Gross Receipts (Includes all Affiliates)

- \leq \$100 Million USD
 - Up to 75% discount
- \leq \$30 Million USD **AND** no prior PMA, BLA, PDP, PMR
 - Fee waived for **first** PMA (including Modular PMA), BLA, PDP, or PMR received by the FDA from a business entity or any of its affiliates

Limitations

- No discount or waiver for Registration Fees
- No Refunds
 - Must obtain SBD **BEFORE** paying for a submission
- Not transferable
 - User Fee System “ORG ID Number” used for SBD request and Pre-Market Submission must be identical

Timeline

- Submit **at least 60 calendar days** prior to your planned Pre-Market Submission
- SBD is good for indicated Fiscal Year
 - October 1, 2023 through September 30, 2024 for FY24
- Doors open on August 1, 2023 for FY24
- SBD determinations for FY24 begin issuing October 1, 2023

❖ **All referenced timeline days are calendar days**

Critical Concepts

Documentation in English

- All documentation provided must be in English
- May be in the local language with an independently certified English translation

What is an Affiliate?

An affiliate means a business entity that has a relationship with a second business entity whether, 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

Proof of Income

- What documents must a business provide?
 - Federal Tax Return (USA)
 - National Tax Authority Seal (Foreign)

Gross Receipts

- Represents business' total sales from all sources
- Does not consider:
 - costs or expenses
 - inter-company transfers
 - refunds
 - net income

National Taxing Authority (NTA)

Governing tax authority for foreign businesses

- Business MUST provide:
 - Country Seal
 - Exchange Rate for currency to USD
 - Date that the applicable Fiscal Year ended

Submission Process

Submission Process

- Read the Guidance
 - Where to Submit
- Download Current Forms
- Confirm Your Account in the User Fee System
 - Must be the same account that will be used for the premarket submission
 - Taxpayer Identification Number:
 - Organization ID Number (Org ID# in your User Fee System Account)

Form 3602 or 3602A*

Depends on where the firm requesting ownership of the SBD is located:

- US firm - Form 3602
- Foreign Firm - Form 3602A
 - If foreign firm is under a US Tax Return, use 3602A and omit NTA certification of Page 2

[* FDA Forms Page](#)

Complete Forms

Make sure your contact information is accurate

- Note: Due to security purposes we will only interact with:
 - individual named on SBD submission
 - additional individuals listed in cover sheet
 - those included by submitter in additional follow up communications

CDRH Learn Modules:

- [How to Complete Form FDA 3602: MDUFA Small Business Qualification and Certification for a Business Headquartered in the United States](#)
- [How to Complete Form FDA 3602A: MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States](#)

Acknowledgement Letters

- Sent by email
 - Check your SPAM/Junk filters
- Received within 10 business days
- Identifies the date application arrived at FDA
 - Arrival date starts the 60-day review target

Respond to Any Deficiencies

- Deficiencies sent by email from SBD reviewer
 - Will identify required update(s)
 - Will identify requested documentation
 - Most deficiencies are resolvable in less than 30 days

Receive Final Determination

- Decision Letter sent by email from SBD reviewer
 - Has instruction next steps
- Pay your MDUFA User Fee using your SBD Approval Number
- Submit your premarket medical device package with the Cover Sheet for review

Avoiding Common Mistakes

Review the Guidance

- Provides information and instructions how to develop and submit SBD Certification Requests
- Common errors
 - Wrong version of the forms
 - Wrong mailing address

[Guidance: Medical Device User Fee Small Business Qualification and Certification](#)
[Device Advice: Reduced Medical Device User Fees: Small Business Determination](#)
[\(SBD\) Program](#)

Adobe PDF Reader

- The SBD forms are fillable PDF form templates
- Save the file to your computer
- Open and edit in the stand alone Adobe PDF reader
 - Do not open and edit in your web browser

Missing / Incorrect Information

- Fill in all blanks
 - Common omissions:
 - Wrong Fiscal Year
 - Missing or incorrect “ORG ID”
 - Missing Country
 - Missing Affiliates
 - Gross Receipts not listed on Line 17 (3602) or Line 7 (3602A)

Accurate and Consistent Information

- Some fields on forms must be identical
 - Name of Firm must be consistent on all pages
 - Signature must be that of the individual named in Line 4

NTA Certification

- Form 3602A
 - Must be completed by
 - the NTA or
 - their legally delegated representative

Common Challenges

Business Recently Incorporated

ALL Businesses Must file a Tax Return

- If no taxes filed with IRS; business will not qualify as a Small Business
- May qualify after filing an annual tax return
- Some firms elect to make an early annual tax return (less than a 365 day fiscal year)

NTA Refuses Complete 3602A

If NTA refuses, business **MUST** provide ALL of the following:

- A sworn affidavit/statement, translated in English, and notarized
 - Attest that someone from the firm directly interacted with the NTA
- An explanation as to why section III of form 3602A was not certified
- Confirmation of signature of person who dealt with NTA representative
- A copy of the tax return submitted to NTA

Pop Quiz

Knowledge Check



In how many days does the FDA try to review an SBD application?

- A. 30 days
- B. 60 days
- C. 90 days
- D. 1 year

Knowledge Check

What is the maximum Gross Receipt threshold for approval as a Medical Device Small Business?

- A. \$1 Million
- B. \$30 Million
- C. \$50 Million
- D. \$100 Million

Knowledge Check

What is the first thing to do before filling out a request for Small Business Determination?

- A. Read the current SBD guidance
- B. Pay for my premarket submission coversheet

Knowledge Check

You must pay for your MDUFA User Fee, then get your SBD rebate.

- A. True
- B. False

Knowledge Check

There are SBD reduced fees for Registration.

- A. True
- B. False
- C. It depends

Resources



Slide Number	Cited Resource	URL
3	FY2023 MDUFA Fee Setting Notification	www.federalregister.gov/documents/2022/10/07/2022-21967/medical-device-user-fee-rates-for-fiscal-year-2023
11	Section 737(12) of the FD&C Act	uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section379i&num=0&edition=prelim
16 & 17	FDA Forms	www.fda.gov/about-fda/reports-manuals-forms/forms

Resources



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19	CDRH Learn: How to Complete Form FDA 3602: MDUFA Small Business Qualification and Certification for a Business Headquartered in the United States	www.fda.gov/training-and-continuing-education/cdrh-learn
19	CDRH Learn: How to Complete Form FDA 3602A: MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	www.fda.gov/training-and-continuing-education/cdrh-learn

Resources



Slide Number	Cited Resource	URL
23	Device Advice: Reduced Medical Device User Fees: Small Business Determination (SBD) Program:	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-medical-device-user-fees-small-business-determination-sbd-program
23	Guidance: Medical Device User Fee Small Business Qualification and Certification	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-medical-device-user-fees-small-business-determination-sbd-program

Summary

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Questions

