U.S. FOOD & DRUG ADMINISTRATION

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)

- ≤ $100 Million USD
  - Up to 75% discount
- ≤ $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

Section 737(12) of the FD&C Act

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

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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

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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

- Described Qualification Requirements
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Questions