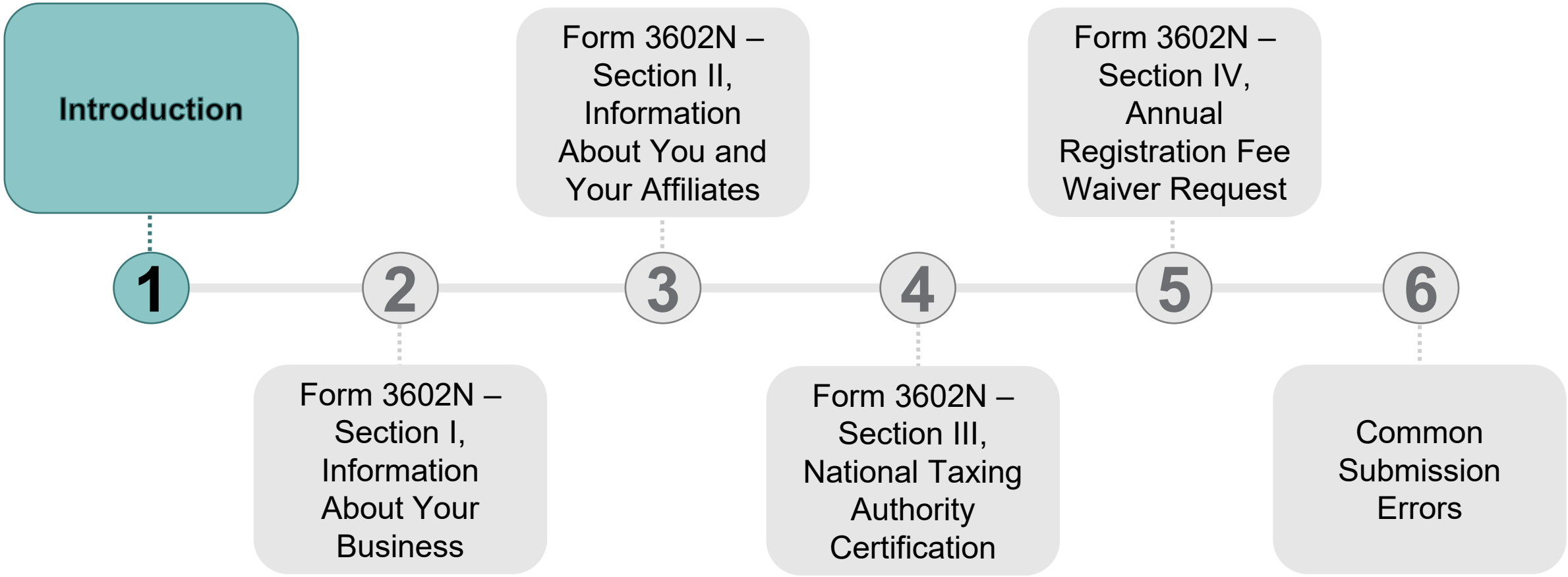
Small Business Determination (SBD) Program: Introduction

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Division of Industry and Consumer Education (DICE)

Navigating the SBD Program Series



Introduction: MDUFA Fees

- “MDUFA” = Medical Device User Fee Amendments
- MDUFA requires payment of a user fee for most premarket medical device applications and for establishment registration.
- A business that is qualified as a “small business” through the FDA’s MDUFA SBD program is eligible for a substantial reduction or waiver of the MDUFA user fee for certain medical device applications.
- To request “small business” status, submit a Small Business Request (**SBR**) to the SBD program through the CDRH Portal.

Definition of "Small Business"

- A "small business" is a business with gross receipts or sales of no more than **$100 million, $30 million, or $1 million** U.S. dollars for the most recent tax year (depending on the benefit being sought).
  - 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, $30 million, or $1 million.
- An "affiliate"[1] is a business entity that has a relationship with a second business entity if, directly or indirectly:
  - one business entity controls, or has the power to control, the other business entity; **or**
  - a third party controls, or has power to control, both business entities.

1. Medical Device User Fee Small Business Qualification and Determination guidance document.

SBD Program Benefits

- Qualified U.S. and foreign small businesses may be eligible for one or more of the following three benefits:

    1. Reduced application/report fees,
    2. A "first premarket application/report" fee waiver,
    3. An annual registration fee waiver.

Program Benefit 1: Reduced Application/Report Fees

- For small businesses with total gross receipts or sales (including affiliates') not exceeding **$100 million** U.S dollars for the most recent tax year.
- Reduced fees are available for the applications listed in the table*:
- For the current user fees, including reduced fees visit: **MDUFA Fees**.

Application Type
Premarket Notification (510(k))
Premarket Approval (PMA)
Product Development Protocol (PDP)
Premarket Report (PMR)
Biologics License Application (BLA)
De Novo request
513(g) Request for Information
PMA annual report
30-Day Notice
PMA/BLA supplement

*** Reduced fees are NOT available for the annual registration fee.**

Program Benefit 2:
1st Premarket Application/Report Fee Waiver

- For small businesses with gross receipts or sales (including affiliates') not exceeding **$30 million** U.S dollars for the most recent tax year.

- A **one-time** waived fee for your "first premarket application/report"[1].

"First Premarket Application or Report"
Premarket Approval (PMA)
Biologics License Application (BLA)
Product Development Protocol (PDP)
Premarket Report (PMR)

1. Medical Device User Fee Small Business Qualification and Determination guidance document.

Program Benefit 2:
1st Premarket Application/Report Fee Waiver

Limitations:

- If you or any affiliate previously submitted a premarket application/report, then your next application does not qualify.

- **The "first premarket application/report" benefit does NOT waive other applications outside the SBD program's definition**.
  - For example, a first time 510(k) application is not included in the definition of the "first premarket application/report".
  - Therefore, a first 510(k) application cannot receive a 510(k) user fee waiver.

Program Benefit 3: Annual Registration Fee Waiver

- Only for **certain small businesses experiencing financial hardship, such as those in active bankruptcy**[1]**.**
- FDA believes that **active bankruptcy** represents financial hardship that is shown by a clear, objective standard with publicly verifiable records.
- Recommend providing documentation for **all three criteria** below:

1. Evidence that you have filed a petition for bankruptcy and evidence that the bankruptcy action is active, and
2. Your business's most recent income tax return (including affiliates') showing a total of $1,000,000 or less in gross receipts or sales, and
3. Evidence that your firm has paid the annual registration fee in a prior fiscal year and registered under your owner/operator number with the FDA.

1. Medical Device User Fee Small Business Qualification and Determination guidance document.

Summary of SBD Benefits

Fee Type	Reduced Fee	Fee Waiver
510(k)	Yes	No
513(g)	Yes	No
PMA, PDP, PMR, BLA	Yes	Yes †
De Novo Classification Request	Yes	No
Panel-track Supplement	Yes	No
180-Day Supplement	Yes	No
Real-Time Supplement	Yes	No
BLA Efficacy Supplement	Yes	No
30-Day Notice	Yes	No
Annual Fee for Periodic Reporting on a Class III device (PMAs, PDPs, and PMRs)	Yes	No
Establishment Registration	No	Yes ‡

† For small business that meet the "first premarket application/report" eligibility criteria.
‡ For small businesses that meet the "financial hardship" eligibility criteria.

Documents for an SBR

- Form FDA 3602N (MDUFA Small Business Request Form).
- Federal (U.S.) income tax return(s) or National Taxing Authority's stamped certification.
- Your business affiliates' Federal (U.S.) income tax returns, and/or National Taxing Authority's stamped certifications.
- Proof of financial hardship *(recommended evidence of active bankruptcy for registration fee waiver requests).*
- Proof of a prior year's registration fee payment *(for registration fee waiver requests)*.
- Other supporting documents (e.g., certified translations, business name changes).

Document Submission Standards

- All documents in your SBR must be in **English**.
  - If any document is not in English, provide a certified English translation completed by an independent translator who is not affiliated with your company or any affiliate.
  - You must provide **both** the original and English-translated copy.

- All documents must be in **PDF format**.

- Submit all documents electronically though the **CDRH Portal**.

Key Dates & Deadlines

(Previous FY)		Fiscal Year (FY)											
Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
SBR submission period begins		**October 1st - September 30th SBD Effective Period**											

SBD Benefit Being Sought	SBR Submission Period												
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Reduced Application/Report Fees	**August 2nd - August 1st**												*Next FY's SBR submission period*	
First Premarket Application/Report Fee Waiver	**August 2nd - August 1st**												*Next FY's SBR submission period*	
Annual Registration Fee Waiver	**Aug 2nd - Nov 1st ***												*Next FY's SBR submission period*	

* FDA lacks the authority to consider registration fee waiver requests submitted after the November 1st statutory deadline. See Section 738(a)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

SBD Program Timeline

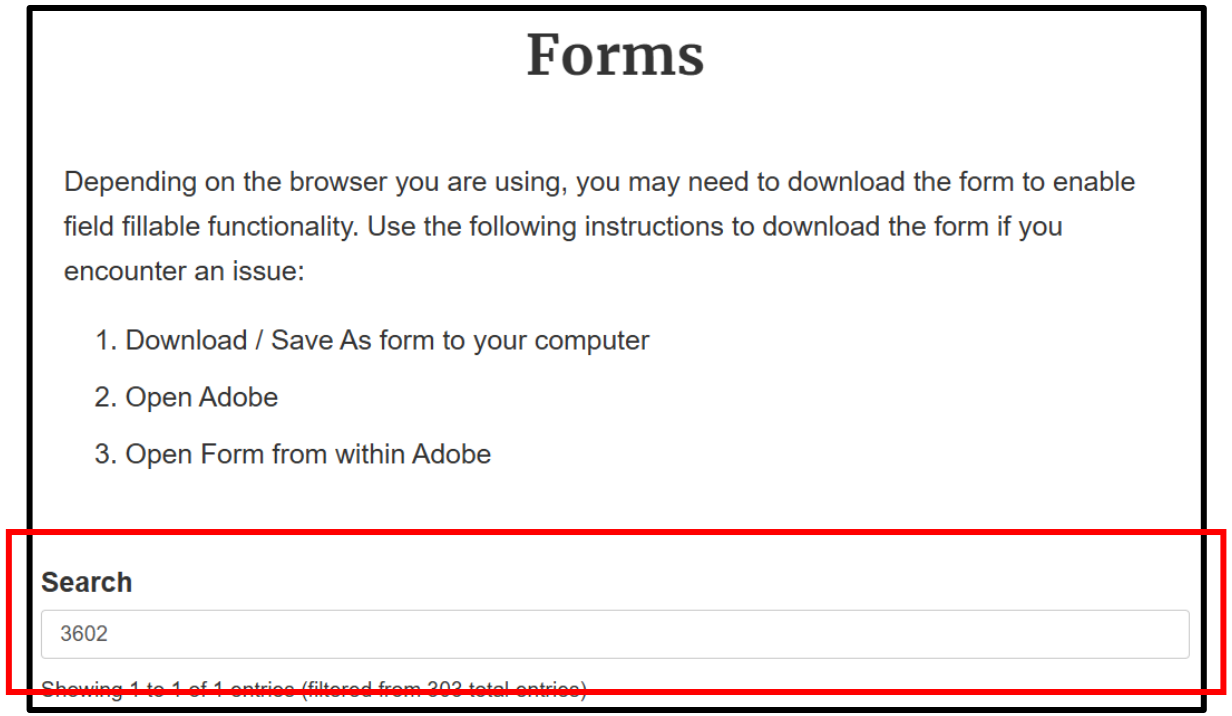
- SBRs are typically reviewed **within 60 calendar days** from the date received by the FDA and are reviewed in the order they are received.

- SBR reviews cannot be expedited. Plan accordingly!

- SBD decision letter**:**
  - If approved – your letter will indicate which benefits your business qualified for.
  - If denied – you can submit a new application if you have additional information to support your SBR.

Next Step:
Getting Started on Your Form 3602N

- As a part of your SBR, you must submit a completed **Form 3602N**.
- Find the form on the FDA's Forms webpage.
- Type in "3602" in the search bar.
- For step-by-step instructions on completing Form 3602N, go to the CDRH Learn module: "Form 3602N – Section I".



Resources

Slide #	Cited Resource	URL
3, 12	CDRH Portal	https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal
4, 7, 9	Medical Device User Fee Small Business Qualification and Determination guidance document.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination
6	MDUFA Fees	https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa-fees
13	Section 738(a)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)	https://www.govinfo.gov/content/pkg/COMPS-973/pdf/COMPS-973.pdf
15	FDA Forms	https://www.fda.gov/about-fda/reports-manuals-forms/forms
15	CDRH Learn	https://www.fda.gov/training-and-continuing-education/cdrh-learn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