Small Business Determination Program: Introduction

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Welcome to CDRH Learn, the Center for Devices and Radiological Health resource for multimedia industry education.

This training module provides an introduction to CDRH's Small Business Determination program.

After you watch this presentation, we hope you'll have a better understanding of the program's benefits, eligibility criteria, important deadlines, and how you can prepare to submit a Small Business Request to the program.

Please note that throughout this module, we will refer to the Small Business Determination program, as the "SBD program."

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There are six parts to the SBD Program series. This short module—the Introduction—is the first part of this series.

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Let's begin by describing MDUFA user fees.

"MDUFA" stands for Medical Device User Fee Amendments. MDUFA requires the payment of a user fee for most types of premarket medical device applications and for establishment registration.

A business that is qualified as a "small business" through 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, your business must submit a Small Business Request, or SBR, to the SBD program through the CDRH Portal.

However, before submitting a request to the portal, let's go over what qualifies as a small business and cover the three SBD program benefits and the important deadlines you should be aware of.

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The definition of a "small business" depends on what benefits are being sought. In general, 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.

If you have any affiliates, you must add the gross receipts or sales of all affiliates to yours, and the total must be no more than 100 million, 30 million, or 1 million U.S. dollars.

An "affiliate" 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.

For example, if there is a parent company that owns a holding company and that company in turn owns other companies, all companies would be considered affiliates of each other.

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Qualified U.S. and foreign small businesses may be eligible for one or more of the following three SBD program benefits. One, reduced application and/or report user fees, two, a "first premarket application and/or report" fee waiver, and three, an annual registration fee waiver.

In the next few slides, we will elaborate the eligibility criteria for each benefit of the SBD program.

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To qualify for reduced applications fees, your business's total gross receipts or sales, including all affiliates', cannot exceed 100 million U.S. dollars for the most recent tax year.

Please note that reduced fees are only available for the applications listed in the table to the right. Reduced fees are not available for the annual registration fee.

For the current standard and reduced user fee amounts, please visit the MDUFA Fees webpage linked here.

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To qualify for the First Premarket Application or Report fee waiver, your business's total gross receipts or sales, including all affiliates', cannot exceed 30 million U.S. dollars for the most recent tax year.

If your business qualifies for this benefit, you will receive a one-time waived fee for your first premarket application or report.

Please note that the SBD program defines a "first premarket application or report" as the first: Premarket Approval, Biological License Application, Product Development Protocol, or Premarket Report.

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You should be aware that there are specific limitations to the "first premarket application or report" fee waiver. If you or any of your affiliates have previously submitted a premarket application or report, then your next application does not qualify.

It is also important to understand that the first premarket application or 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 or report. Therefore, a first 510(k) application cannot receive a 510(k) user fee waiver.

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To qualify for consideration for the registration fee waiver, your business must be experiencing financial hardship that meets a clear and objective standard that is publicly transparent.

The only situation the FDA is currently aware of that meets this standard is where the small business is in active bankruptcy.

The FDA believes active bankruptcy represents financial hardship that is shown by a clear, objective standard with publicly verifiable records.

Therefore, to request a registration fee waiver, it is highly recommended you provide documentation for all three criteria below. These criteria include:

One, evidence that you have filed a petition for bankruptcy and evidence that the bankruptcy action is active, and

Two, your business's most recent income tax returns, including all affiliates' tax returns, showing a total of 1 million U.S dollars or less in gross receipts or sales, and

Three, 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.

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The table on this slide summarizes the three benefits of the SBD program.

As we covered, some fees may be reduced and some fees may be waived—this will depend on whether your business meets the specific eligibility criteria we discussed.

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Now that we've covered the benefits offered by the SBD program, let's cover the documents you should provide in your Small Business Request.

Please note that for the remainer of this module we may refer to the Small Business Request as the "SBR".

An SBR is a compilation of documents to support your request for "small business" status and for specific benefits.

The following documents make a complete SBR.

A complete Form FDA 3602N also known as the MDUFA Small Business Request Form, or just "Form 3602N".

Your business's signed federal U.S income tax return(s) or National Taxing Authority's stamped certification.

Your business affiliates' signed federal U.S income tax returns, and/or National Taxing Authority's stamped certifications.

Proof of financial hardship, such as the recommended evidence of active bankruptcy, only if you are requesting a registration fee waiver.

Proof of a prior year's registration fee payment, only if you are requesting a registration fee waiver.

And other supporting documents such as certified translations, or official business name changes.

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Let's go over the document submission standards.

All documents in your SBR must be in English.

If any document is not in English, you will need to 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 in your SBR.

All documents must be provided in PDF format.

You'll then submit all documents supporting your SBR electronically through the CDRH Portal.

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There are important SBD program dates and deadlines to be aware of.

Let's begin with the fiscal year.

The fiscal year runs from October 1st through September 30th.

This is the period where small business determinations can be effective.

The effective date may begin on October 1st or the date your SBR was approved, whichever is later.

Notice that you can submit your SBR two months early before the start of the fiscal year.

Depending on the SBD benefit being sought, there are different SBR submission periods.

Specifically, if you are seeking the reduced application fees and/or the first premarket application or report waiver, you should submit your SBR 60 days before the fee is due.

SBRs for a given fiscal year may be submitted between August 2nd before the start of the fiscal year and August 1st of that fiscal year.

If you are seeking the registration fee waiver benefit, you must submit your SBR between August 2nd and November 1st.

We'd like to emphasize that November 1st is the statutory deadline.

The FDA does not have the authority to consider registration fee waiver requests after this deadline.

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There are SBD program timelines to be aware of after you submit your SBR.

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

SBR reviews cannot be expedited, so please plan your submission accordingly!

After your SBR's review, the SBD program will issue a decision letter indicating whether your request was approved or denied.

If you receive approval, your letter will indicate which program benefits your business qualified for.

If you receive a denial, you can submit a new application if you have additional information to support your SBR.

Remember, if you are requesting a registration fee waiver, you must resubmit before the November 1st deadline.

However, while you may submit new applications with additional information, the final waiver determination for each application is at the FDA's discretion and is not renewable.

If you are not requesting a registration fee waiver, you may resubmit before the August 1st deadline.

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As we come to the conclusion of this module, we'd like to remind you that you must provide a completed Form 3602N in your SBR.

You can find the form on the FDA's Forms webpage.

To find the form on the webpage, type in "3602" in the search bar, then click on the hyperlinked form to begin downloading.

For step-by-step instructions on completing Form 3602N, we recommend watching the next CDRH Learn module of the SBD program series titled "Form 3602N – Section 1".

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Below are links to the resources that were mentioned or are relevant to this module.

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We've reached the conclusion of this module. Thank you for watching.