

## Small Business Determination Program: Form 3602N – Section IV

### Slide 1

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

If you are working on a Small Business Request, or SBR, this training module will provide you guidance for completing Section 4 of Form 3602N.

Section 4 covers the annual registration fee waiver request.

### Slide 2

Please note that there are six parts to the Small Business Determination Program, or SBD Program, series.

This short module—Form 3602N, Section 4—is the fifth part of this series.

If you haven't already, we highly recommend watching the previous module before continuing with this one.

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In this module, you will see color-coded information boxes.

Content in the yellow boxes apply to both U.S and Foreign (non-U.S.) business applicants.

Content in the blue boxes specifically apply to U.S. business applicants, and content in the green boxes specifically apply to foreign business applicants.

### Slide 4

Let's go over some important information about Section 4 of Form 3602N.

Section 4 provides space for a registration fee waiver request.

Please keep in mind that registration fee waiver requests are only accepted starting August 2<sup>nd</sup> through November 1<sup>st</sup>.

Please do not submit a registration fee waiver request after November 1<sup>st</sup>, as the FDA lacks the authority to consider these requests after this deadline.

If you do not qualify for the waiver, you will need to pay the full annual registration fee.

Please also note that there are no small business "reductions" for the annual registration fee.

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To qualify for a registration fee waiver, your business must meet three specific criteria.

The criteria are one: your total gross receipts or sales from Section 2, Line 21 are 1 million U.S. dollars or less.

And two: you have proof of financial hardship such as evidence of active bankruptcy.

And three: you previously registered and paid fees for each facility listed below in a prior fiscal year.

You should only complete Section 4 if you meet all three criteria outlined here.

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Please note that the FDA cannot grant a registration fee waiver if you do not meet all three criteria discussed in the previous slide.

You should skip Section 4 if any of the following apply.

One, you have more than 1 million U.S. dollars in Section 2, Line 21 of this form.

Two, you do not have proof of a financial hardship such as active bankruptcy.

And three, you have not paid to register your facility in a prior fiscal year.

If you are certain you qualify for the registration fee waiver benefit, these next few slides will cover what you should provide in your SBR.

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The first criterion is to have no more than 1 million U.S. dollars in Section 2 line 21.

Therefore, to meet this criterion your business and your affiliates combined gross receipts or sales in Section 2, Line 21 of this form cannot exceed 1 million U.S. dollars for the most recent tax year.

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The second criterion is to have proof of financial hardship.

To meet this criterion you must provide proof of financial hardship as described in the SBD program's guidance document.

The guidance document describes that the FDA grants waivers only where financial hardship meets a clear and objective standard that is publicly transparent.

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

The FDA considers active bankruptcy as financial hardship that meets a clear and objective standard with publicly verifiable records.

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If you are a U.S. business, we recommend providing evidence of financial hardship such as that you have filed a petition for bankruptcy in United States Bankruptcy Court and that the bankruptcy is currently active.

If you are a foreign business, we recommend providing evidence of financial hardship, such as that you have filed your jurisdiction's equivalent of a United States bankruptcy action and evidence that the bankruptcy action is active.

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The third criterion is to have paid to register each of your facilities in a prior fiscal year.

To meet this criterion, you should provide a PDF copy of a prior year's registration fee payment for each of your facilities.

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If you meet all three criteria, you can proceed to complete section four of Form 3602N.

In Line 1a, input the full name of your facility.

The name of the facility must match the facility's name in FDA's Unified Registration and Listing System and Device Registration and Listing Module, commonly referred to as FURLS DRLM.

To access FURLS DRLM, click on the link provided in this slide.

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Line 1b, the owner operator number or registration number.

Input the owner operator number or registration number for the facility.

This number must also match with the number on your registration within FURLS DRLM.

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Line 1c, the fiscal year last registered.

Input the fiscal year the facility was last registered with the FDA.

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If your business has multiple facilities registered with the FDA, continue to list them in Lines 2 through 20 of Section 4.

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Certification of Section 4. The Certifier identified in Box 4 of Section 1 of this form, must initial Section 4.

By initialing Section 4, you are certifying that you have included FDA's recommended evidence of financial hardship in your small business request.

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Congratulations! You have completed Section 4 of Form 3602N.

Before submitting your SBR, we recommend doing a final quality check to ensure your entire application package is error-free and complete.

For an overview of the common errors that result in SBR deficiencies, we recommend watching the next CDRH Learn module of the SBD Program series titled "Common Submission Errors".

Finally, you can proceed to submit your SBR electronically through the CDRH Portal.

### **Slide 17**

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

### **Slide 18**

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