Small Business Determination Program: Form 3602N – Section II

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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 with step-by-step guidance for completing Section 2 of Form FDA 3602N.

Section 2 covers information about your business, and your affiliate businesses.

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

This module—Form 3602N, Section 2—is the third 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.

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Let's go over some important information about Section 2 of the form 3602N.

Section 2 provides space for information about your business, and your affiliate businesses.

You will need to provide each business's taxpayer identification number and the reported gross receipts or sales.

For U.S businesses, this information is found in IRS Federal U.S. Income Tax Returns.

For all non-U.S. businesses, this information should be provided in Section 3 of this form, and it must be certified by the National Taxing Authority in the country where the business is located.

Therefore, if you are a non-U.S. business and/or have non-U.S. affiliates, you may need to complete Section 3 of this form before completing Section 2.

As a reminder, you are expected to provide copies of all IRS forms and National Taxing Authority Certifications for your business and for each affiliate in your SBR.

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An “affiliate” is defined as 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 of the 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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Please note that in Column “d”, Line 21 of Section 2 is designed to auto-calculate the total sum of gross receipts or sales for your business and its affiliates.

Section 2 provides space for 19 business affiliates.

If you have more than 19 business affiliates, do not type in column “d”.

Instead, print enough copies of Section 2 to account for all your affiliates and manually write in the gross receipts or sales for you and for each affiliate.

Next, add up the total amount in Line 21 of the last copy of Section 2.

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Let’s begin with Section 2 of Form 3602N.

Line 1a, the Name of your business.

Input the full legal name of the business requesting small business status.

This name must match the name of the business you listed in your User Fee System account.

If you do not have a User Fee System account, you must create one.

This is the account where your small business fee reductions or waiver will be applied.

Click on the link to go the User Fee System webpage and to begin creating your account.

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Line 1b, the country.

Input the country where your business is physically located.

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Line 1c, the Taxpayer ID Number.

Input your business’s Taxpayer Identification Number here.

If you are a U.S business, input the Employer Identification Number, or EIN, from your business’s Federal U.S. income tax return.

If you are a foreign business, input the number assigned to your business by your country's National Taxing Authority.

If your country does not have a National Taxing Authority, put "No NTA" in Line 1c.

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Line 1d, your gross receipts or sales.

Input your business's gross receipts or sales in U.S. dollars.

If you are a U.S business, you'll find this amount in your most recent Federal U.S. income tax return.

The table to the right provides a list of common IRS forms and the line number where you can find your gross receipts or sales on the form.

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If you are a foreign business, provide the amount you reported to your National Taxing Authority for the most recent tax year, and convert it to U.S. dollars.

For your conversion calculations, use the exchange rate from the end date of the period when receipts or sales were collected.

You will need to show the exchange rate you used in Section 3 of this form.

If you are unsure about the exchange rate to use, please contact your National Taxing Authority.

The FDA cannot provide exchange rate information for you.

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If you have any business affiliates, you must list them starting on Line 2 and ending in Line 20.

For Line 2a, input the full legal name of the affiliate business.

If you need additional copies of Section 2 because you have more than 19 affiliates, be sure to continue listing your affiliates starting on Line 2 of the additional pages.

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Line 2b, the affiliate's country.

Input the country where the affiliate business is physically located.

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Line 2c, the affiliate's taxpayer ID number.

Input your affiliate business's taxpayer ID number.

If your affiliate is a U.S business, input the Employer Identification Number, or EIN, from the business's Federal U.S. income tax return.

If your affiliate is a foreign business, input the number assigned to the business by the affiliate's National Taxing Authority.

If their country does not have a National Taxing Authority, put "No NTA" in Line 2c.

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Line 2d, the affiliate's gross receipts or sales

Input your affiliate business's gross receipts or sales in U.S. dollars.

If your affiliate is a U.S business, you'll find this amount in their most recent Federal U.S. income tax return.

The table to the right provides a list of common IRS forms and the line number where you can find their gross receipts or sales on the form.

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If your affiliate is a foreign business, provide the amount they reported to their National Taxing Authority for the most recent tax year, and convert it to U.S. dollars.

For the conversion calculations, use the exchange rate from the end date of the period when receipts or sales were collected.

They will need to show the exchange rate they used in Section 3 of this form.

If they are unsure about the exchange rate to use, they should contact their National Taxing Authority.

The FDA cannot provide exchange rate information for your affiliate.

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Congratulations! You have completed Section 2 of Form 3602N.

If you are a foreign business or have any non-U.S. affiliates, your next step is to complete Section 3 of this form.

For step-by-step instructions, we recommend watching the next CDRH Learn module of the SBD program series titled "Form 3602N, Section 3".

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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.