Small Business Determination Program: Form 3602N – Section III

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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 guidance for completing Section 3 of Form 3602N.

Section 3 covers the National Taxing Authority certification for non-U.S. businesses and for non-U.S. business affiliates.

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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 3—is the fourth 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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Let's begin with Section 3 of Form 3602N.

Section 3 provides space for foreign businesses, including foreign affiliates, to report their gross receipts or sales and for their National Taxing Authority, or NTA, to certify the amounts reported.

A separate certified Section 3 must be provided for each foreign affiliate.

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Please note that Section 3 has specific instructions.

The foreign business should complete Lines 1 through 6.

The foreign business's NTA must complete Lines 7 through 12.

Lines 1 through 3 and 5c must match the foreign business's entry in Section 2 of this form.

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All documents in your SBR, including Section 3 of this form, 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 include both the original and English-translated copy in your SBR.

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Let’s begin filling Section 3 of Form 3602N.

Line 1, the Line Number from Section 2.

Input the Line Number where the foreign business is listed in Section 2 of this form.

If you manually completed Section 2, manually write in the line number and the page number to help us identify the correct affiliate from Section 2.

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Line 2, the name of the foreign business from Section 2.

Line 2 will auto-populate the business name after inputting the Line Number from Section 2.

If you manually completed Section 2, manually write in the business name in the extra space.

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Line 3, the foreign business’s Taxpayer Identification Number. Line 3 will auto-populate the Taxpayer Identification Number after inputting the Line Number from Section 2.

If you manually completed Section 2, manually write in the Taxpayer Identification Number in the extra space.

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Line 4, the address where the business is physically located.

Input the address and country where the foreign business is physically located.

This is the address you would give to someone who needs to travel to the business.

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Line 5a, the business’s local currency unit and amount reported.

Input the country’s local currency unit and the amount of gross receipts or sales reported to the National Taxing Authority for the most recent tax year.

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Line 5b, the exchange rate per U.S. dollar.

Input the exchange rate used to calculate the business’s gross receipts or sales in U.S. dollars.

Use the exchange rate from the end date of the period when gross receipts or sales were collected.

The FDA cannot provide exchange rate information.

If you need help finding this information, please contact the National Taxing Authority to determine the correct rate to use.

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Line 5c, the U.S. currency

The U.S. currency will auto-populate after inputting the business's Line Number from Section 2.

If you manually completed Section 2, manually write in the gross receipts or sales in U.S. dollars.

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Box 6a and 6b, the period during which reported receipts or sales were collected.

In Box 6a, input the starting date for the reporting period in month, day, year format.

In Box 6b, input the ending date for the reporting period also in month, day, year format.

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Boxes 7 through 12 must be completed by the foreign business's National Taxing Authority.

If you have a National Taxing Authority, you should submit Section 3 to your agency.

Your National Taxing Authority can refer to section six, Guidance for Foreign Governments of the SBD program guidance document for additional information.

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If you have a National Taxing Authority, but they are unable or unwilling to certify Section 3 of Form 3602N, alternative forms of certification will be considered on a case-by-case basis.

Such alternative forms of certification must include all the information that would otherwise be reported and certified in Section 3 of Form 3602N.

Specifically, the certification must but be in English, or accompanied by a certified English translation completed by an independent translator who is not affiliated with your company or any affiliate and include the following information:

One, the line number from Section 2 of this form that the certification relates to.

Two, the name of the business as it appears in Section 2 of this form.

Three, the business' Taxpayer Identification Number as it appears in Section 2 of this form;

Four, the business's gross receipts or sales for the most recent tax year, reported in both U.S. dollars as reported in Section 2 of this form and local currency.

Five, the exchange rate used to convert local currency to U.S. dollars.

Six, the specific start and end dates of the period during which the reported receipts or sales were collected; and

Seven, a certification signed and dated by an official of the relevant National Taxing Authority bearing the official stamp or seal of the National Taxing Authority attesting to; "A" the following information relating to the National Taxing Authority official making the certification, such as their name, telephone number, title, and email address. "B" whether the National Taxing Authority is aware of any affiliates of the business. And "C", that the information provided is complete and accurate to the best of the certifier's knowledge.

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If your country does not have a National Taxing Authority, you may submit evidence of your gross receipts or sales such as, the end of fiscal year financial statements, or shareholder reports, and a signed affidavit explaining there is no National Taxing Authority in your country.

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Congratulations! You have completed Section 3 of Form 3602N.

You may move on to Section 4 of this form to complete a financial hardship registration fee waiver request.

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

Please note that Section 4 of Form 3602N is optional and can be left blank if you are not requesting a registration fee waiver.

You may then move on to the subsequent CDRH Learn module of the SBD program series titled “Common Submission Errors” to learn about the common errors made in SBRs.

You may also proceed to submit your SBR electronically through the CDRH Portal.

For step-by-step instructions on submitting your SBR through the CDRH Portal, visit the SBD program webpage.

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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.