

Transcript of How to Complete Form FDA 3602A

Online Training Module

Title

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

This training module provides step-by-step instructions on how to complete Form FDA 3602A. This is the MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States.

Throughout this module, we'll refer to the form by its short name "Form 3602A."

After you watch this presentation, we hope you'll have a better understanding of how to complete Form 3602A.

Please click the Start button to begin.

MDUFA Fee Information

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

A business that is qualified and certified as a "small business" is eligible for a substantial reduction or waiver of the MDUFA user fee for certain premarket applications.

To be eligible for the reduced or waived fee, the business must first qualify as a "small business."

To apply for a Small Business Certification, a business must submit a MDUFA Small Business Certification Request to the Center for Devices and Radiological Health, or CDRH, at FDA.

Here are the types of premarket applications eligible for a Small Business reduced/waived user fee.

For further information on which premarket applications are eligible for a

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reduced or waived fee, please refer to the MDUFA Small Business Qualification and Certification Guidance, which you may find at the Guidance Database on fda.gov, and in the Resources in this module.

How to Navigate this Module

To navigate this module, click the Next and Previous buttons.

Click the Menu icon to see additional resources.

Control the volume and turned closed captions on or off using the icons below.

Form 3602A

To apply for a Small Business Certification for a business located outside the United States, you must submit a MDUFA Small Business Certification Request to CDRH, which includes Form 3602A.

You can locate and download a PDF of the form using the link shown here.

Watch this eLearning module to learn how to fill out the form correctly.

Fiscal Year

To begin completion of Form 3602A:

In the upper right section of the top of the form, fill in the fiscal year for which you're seeking the small business status. Fiscal year is abbreviated as FY.

Note that a fiscal year runs from October 1 through September 30 of the next calendar year.

For example, FY 2019 starts on October 1, 2018 and ends on September 30, 2019.

There are three Sections of the Form to complete. Let's start with Section I, which is Information about the Business Requesting Small Business Status. There are a total of 8 Boxes to complete, and we'll go through them, one by one.

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Name of Business

Box 1. The Name of the business requesting the Small Business Certification.

To complete Box 1, please enter the full legal name of the business.

This name **must** match the name in box 1 of Section III from the National Taxing Authority.

Tax ID

Box 2. The Taxpayer Identification Number.

This is the business's Taxpayer Identification Number.

The Taxpayers Identification Number is assigned to a business by their National Taxing Authority. It uniquely identifies the business.

ORG ID

Box 2a. the Organization ID Number, or ORG ID.

The Org ID is a number assigned to a business during the FDA User Fee account creation process. It is generated by the FDA User Fee system and uniquely identifies the business.

Please note: The Org ID is separate and distinct from any other number that may be associated with the business.

The most common error applicants make in completing the Form 3602A is putting the wrong number as the Org ID. This error can delay processing your request, so please make sure to enter your businesses correct Org ID in this field correctly.

For information on obtaining or retrieving the business's Org ID, click the [FDA User Fee System](#) button below.

Address

Box 3. The address where the business is physically located.

Enter the physical address of your business. Make sure to include the country. This is the

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place of your business, or in other words, the address you'd give to someone who needs to travel to your business.

Name of Person Making Certification

Box 4. The name of the person making this certification.

Enter the name of the person who is responsible for the accuracy and completeness of the information provided in the Certification Request and who has the authority to sign it. This is also the person the FDA will contact for all communications regarding your Small Business Certification Request.

Check the appropriate box describing your position with the business: either Head of Firm or Chief Financial Officer.

Phone Number

Box 5. Your telephone number, including Country code and area code.

Enter the phone number of the person identified in Box 4.

Please make sure the phone number is a working number and that you enter the digits correctly, so we are able to reach you quickly if we have questions.

Mailing Address

Box 6. Your mailing address.

If the mailing address is the same as what you enter in Box 3, please check the box instead of providing the information again. If the address is different than the address in box 3, please enter the mailing address.

Please make sure the address is current and correct, the FDA will use this address to communicate with you, if you don't have an email address.

Email Address

Box 7. Your email address.

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Enter a valid, functioning email address. FDA will use this email address to communicate with you about your Certification Request and send you the decision letter, so it's important for this address to be correct.

Email is our primary means of communicating with you. Be sure to check your Spam or Junk folder to ensure that emails sent from FDA don't accidentally get placed there and you miss them.

If you do not have an email address or you provide one that is not functioning, we will communicate by written mail to the address you provide in Box 6.

Congratulations! You've now completed Section I of Form 3602A. Let's move on to Section II.

Section II

Let's now begin Section II of Form 3602A. This section is Information about You and Your Affiliates.

Click the button for an explanation of an affiliate.

An affiliate is a business that has a relationship with another business where, they have direct or indirect, control, or the power to control, the other business.

List Affiliates

In this table, lines 1 through 5 provide space for you to list all your affiliates. This includes affiliates located both in the U.S. and outside the U.S. If you have more than 5 affiliates, print another copy of Section II and fill out the information there.

Legal Name of Affiliate

In Column A, list the full legal name of each affiliate. List each affiliate on a separate line.

Do not include the name of the business requesting for the Small Business Status here.

Only list the affiliates.

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Taxpayer Identification Number for Affiliate

In Column B, list the Taxpayer Identification Number for each affiliate.

For any affiliates located outside of the United States, enter their taxpayer ID number given to them by their National Taxing Authority.

Remember, the Taxpayers Identification Number is assigned to a business by their National Taxing Authority and it uniquely identifies the business.

For any affiliates located in the United States, enter the Federal Employer Identification Number, referred to as an EIN. The EIN is assigned to a business by the U.S. Internal Revenue Service and it uniquely identifies the business.

You can locate the EIN on the business's federal U.S. income tax return.

Gross Receipts or Sales for Affiliate

In Column C, enter the gross receipts or sales.

For each affiliate located outside the United States, you should copy the information from item 3b of the National Taxing Authority Certification for the affiliate.

For each affiliate located in the United States, you should copy this number from the most recent federal U.S. income tax return for the affiliate.

Please note that even if their gross receipts are zero, they must be listed as zero on the form.

The dollar amounts must be in U.S. currency, that is, U.S. dollars. You should use the exchange rate in effect as of the ending date of the period during which the reported receipts or sales were collected; this is the date shown in response to item 5.b. of the National Taxing Authority Certification.

Click the button to learn where to find gross receipts for businesses headquartered in the U.S.

This table identifies the line number of the business's federal tax return where

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you'll find the gross sales or receipts.

The column on the left identifies the IRS Form. The column on the right lists the Line Number in that IRS Form where you'll find the gross sales and receipts.

Total Gross Receipts or Sales of all Affiliates

In Row 6 of Column C, enter the total gross receipts or sales of all affiliates.

This is the sum of each entry of Gross Receipts or Sales listed in Column C, adding up the amounts from Lines 1 through 5.

If you have no affiliates, please enter "0".

Please enter dollar amounts in whole numbers, no cents, and in U.S. currency; that is, U.S. dollars. Please round to the nearest dollar.

Gross Receipts or Sales of Business Making this Certification

In Row 7, enter the gross receipts or sales of the business making this Certification.

This is the business identified in Section I, Box 1 of this form; the business making the Small Business request.

Total Gross Receipts or Sales Used to Determine Qualification as Small Business

In Row 8, enter the sum of Lines 6 and 7. This is the total gross receipts or sales used to determine the business's Qualification as a Small Business.

To qualify as a MDUFA small business, the dollar amount listed in Row 8 must be NO more than 100 million U.S. dollars.

Affiliates

Box 9. Have you listed all of the business affiliates in Section II of this form?

Please check only one response: either "Yes" or "This business has no affiliates."

Check "Yes" if you have any affiliates. List those affiliates in Section II of Form 3602A.

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Check "This business has no affiliates" if you have no affiliates.

For affiliates located in the United States, attach a copy of their most recent complete, signed, and dated federal U.S. income tax return to show how you meet the requirement to have gross receipts or sales of no more than \$100 million.

For affiliates located outside the United States, you must complete Form 3602A Section III, The National Taxing Authority Certification for each of the affiliates.

Click the button for an explanation of an affiliate.

An affiliate is a business that has a relationship with another business where, they have direct or indirect, control, or the power to control, the other business.

Certification and Signature Section

Box 10. This is the certification and signature section of the form.

First, enter your business's name. This must be the same name as what you entered in Section 1, Box 1.

Affiliates Checkboxes

Next, indicate whether or not you have any affiliates. You will check only one box.

Check the top box if you have no affiliates.

Check the lower box if you have affiliates. Please note, to be eligible for a small business designation, the gross receipts or sales of you and all your affiliates must be less than 100 million U.S. dollars in gross sales for the most recent tax year.

Please make sure the box you select matches what you chose in Box 9.

Documentation for Affiliates

Make sure you attach a copy of your business's and all affiliate's most recent complete federal U.S. income tax return to show how it meets the requirement to have gross receipts or sales of no more than \$100 million.

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For affiliates located outside the United States, you must complete Form 3602A Section III, The National Taxing Authority Certification for each of the affiliates. Click the button to learn where you can find your gross receipts.

This table identifies the line number of the business's federal tax return where you'll find the gross sales or receipts.

The column on the left identifies the IRS Form. The column on the right lists the Line Number in that IRS Form where you'll find the gross sales and receipts.

Signature and Date

At the bottom of page 1

The person identified in Box 4 **must sign and date the form.** The signature may be in ink or a valid digital signature.

A common error we see is not signing and dating the Form. Please make sure to sign and date the form, so you avoid any delays in our ability to process your Small Business Request.

Congratulations! You've now completed Sections I and II of Form 3602A

Section III

After you have completed Sections I and II of your MDUFA Foreign Small Certification Request, for a Business Headquartered Outside the United States, you should submit it your National Taxing Authority.

For additional instructions for the National Taxing Authority please reference Section IV of the Guidance: [Medical Device User Fee Small Business Qualification and Certification](#)

National Taxing Authority Certification

Your National Taxing Authority is responsible for completing Section III- National Taxing Authority Certification; you cannot complete this section yourself. You are responsible for identifying and contacting your National Taxing Authority.

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Your National Taxing Authority should complete Section III, and should then return your completed MDUFA Foreign Small Business Certification Request to you. You are responsible for sending your completed MDUFA Foreign Small Business Certification Request and all required supporting documentation to the FDA.

All the boxes of Section III must be completed, in English.

Field for Certification

Form FDA 3602A contains a field for Certification from a National Taxing Authority for a foreign business or affiliate. This serves as authentication of the gross receipts or sales for that business or affiliate.

FDA expects you to obtain this official certification.

Question about Certification

What if the National Taxing Authority does not provide the certification on Section III of Form 3602A for my business or my foreign affiliate?

If the National Taxing Authority does not provide the certification, you may provide a written explanation of impossibility for why you were unable to obtain this certification along with Form FDA 3602A.

The explanation should include: documentation from the National Taxing Authority, in English, of their refusal to provide the certification.

What are your next steps?

Next Steps

First, make sure the form is complete, then sign and date the form using the information you just learned.

Second, mail the original hardcopy of the completed form and all supporting documentation to Medical Device User Fee Small Business Qualification and Certification's mailing address. Click the link below to see it.

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Be sure to include complete, signed, and dated copies of all federal U.S. income tax returns and certifications from foreign National Taxing Authorities that are related to your Certification Request.

After submitting your application, please remember to check your email, including your Spam or Junk folder, to look for any correspondence sent from FDA.

Questions?

If you have any further questions related to the MDUFA Small Business Program, such as eligibility, how to complete the Form or the Certification Request process, please contact DICE.

Thank you!

Thank you for your time and attention to this module. We hope it's been helpful.

Please click Exit to return to CDRH Learn.