

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 3602. This is the MDUFA Small Business Certification Request Form, for a Business Headquartered in the United States.

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

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

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 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.

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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 3602

To apply for a Small Business Certification, you must submit a MDUFA Small Business Certification Request to CDRH, which includes Form 3602.

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 3602:

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.

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

There are two 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 10 boxes to complete, and we'll go through them, one by one.

Name of Business

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

Please enter the full legal name of the business.

This name must match the name on the business's federal U.S. income tax return.

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EIN

Box 2. The Taxpayer Identification Number.

This is the business's Federal Employer Identification Number, or EIN.

The EIN is assigned to a business by the U.S. Internal Revenue Service. It uniquely identifies the business.

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

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 Form 3602 is putting the wrong number as the Org ID. This error can delay processing your request, so please make sure to enter 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. This is the 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.

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Enter the name of the person who is responsible for the accuracy and completeness of the information provided in the Certification 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.

Phone Number

Box 5. Your telephone number, including 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're able to reach you quickly if we have questions.

Mailing Address

Box 6. Your mailing address.

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

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

Email Address

Box 7. Your email address.

Enter a valid, functioning email address. FDA will use this email address to communicate with you about the Certification Request and send 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.

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Relation

Box 8. Your relation, or Title, to the business claiming MDUFA Small Business Status.

Briefly describe your position or title with the business seeking the Small Business Status. For example, this may be President, Chief Financial Officer, or other title that explains your business relationship with the company.

Affiliates

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

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

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

Check “This business has no affiliates” if you have no 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.

If you have any affiliates, check yes. If you do not, check, this business has no affiliates.

Name of Business

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 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 and sales of you and all your affiliates must be less than 100 million US dollars in gross sales for the most recent tax year.

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

Tax Return

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.

If any of the affiliates are located outside the United States, you must also complete Form FDA 3602A. Click the button to learn where you can find your gross receipts.

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

Continuing in Box 10. Signature and date of person making this certification.

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/or dating the form. Please make sure to fill out Box 10 completely, so you avoid any delays in our ability to process your Small Business Request.

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

Section II

Section II of Form 3602 is Information about You and Your Affiliates.

Section II provides space for you to list up to 15 affiliates. If you have more than 15 affiliates, print another copy of Section II and fill out the information there.

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

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Name of Affiliate

Do not include the name of the business requesting the Small Business Status here. Only list the affiliates.

EIN for Affiliate

In Column B, Taxpayer ID Number, enter the Federal Employer Identification Number assigned to the affiliate by the U.S. Internal Revenue Service.

Remember, the EIN is assigned to a business by the U.S. Internal Revenue Service and it uniquely identifies the business.

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

For any affiliates located outside of the United States, enter their tax ID number given to them by their National Taxing Authority if this is known. If unknown, please enter "N/A."

Gross Receipts or Sales for Affiliate

In Column C, enter the gross receipts or sales from the most recent federal U.S. income tax return for each affiliate.

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

Click the button to learn where to find gross receipts.

This table identifies which line number of the business's federal tax return in which 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 of all Affiliates

In Row 16 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 15. If you have no affiliates, please enter "0".

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Please enter dollar amounts in whole numbers, no cents. Please round to the nearest dollar.

Gross Receipts or Sales of the Business Making this Certification

In Row 17, 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. This is the business making the Small Business request.

Please make sure this dollar amount matches the gross sales and receipts on your business's tax return.

Click the button to learn where to find gross receipts.

This table identifies which line number of the business's federal tax return in which 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 Used to Determine Qualification as Small Business

In Row 18, you'll enter the sum of Lines 16 and 17. This is the total gross receipts or sales used to determine the business's Qualification as a Small Business.

For you to qualify as a MDUFA small business, the dollar amount listed in Row 18 must be no more than \$100 million.

We've reached the end of Section II and Form 3602.

What are your next steps?

Next Steps

First, complete, sign, and date the form using the information you just learned.

Second, mail the original 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 copies of all federal U.S. income tax returns and certifications from foreign National Taxing Authorities that are related to your Certification.

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. To assist us in meeting your needs, please evaluate this course. We need and value your feedback.

Please click Exit to return to CDRH Learn.