Small Business Determination Program: Form 3602N – Section I

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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 1 of Form 3602N.

Section 1 covers information about the business requesting “small business” status.

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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 1—is the second 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 begin with Section 1 of Form 3602N.

Section 1 provides space for information about the business requesting “small business” status.

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At the top of Section 1, input the fiscal year for which you are seeking “small business” status.

The fiscal year runs from October 1st through September 30th.

For example, the fiscal year 2027 runs from October 1st 2026 through September 30th 2027.

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Box 1, the name of the business requesting MDUFA small business status.

Input the full legal name of your business.

For U.S. businesses, this name must match the name on the business’s federal U.S. income tax return.

For foreign businesses this name must match the name in Item 2 of Section 3 from the National Taxing Authority.

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If your business's name differs from your tax documents, please provide government documentation showing the legal business name change.

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Box 2, Taxpayer Identification Number

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

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

If your country does not have a National Taxing Authority, input "No NTA" in the box.

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Box 2a, Organization number, also referred as the "Org ID Number".

Input your business's Org ID number.

The Org ID is an FDA-system generated number assigned to a new organization during the User Fee System account creation process.

Org IDs are between four to six digits long.

The Org ID is not the same as your Registration Number, Employer Identification Number, Taxpayer Identification Number, or your DUNS number.

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If your business does not have a User Fee System account, you must create one to get an Org ID

Most importantly, this is the system where your small business fee reductions or waiver will be applied when you make payments to the FDA.

For guidance on creating a User Fee System account, please refer to the downloadable Step-by-Step Instructions available on the User Fee System webpage.

The picture to the right of the slide shows a screenshot highlighting the location of the document on the webpage.

If you require User Fee System account assistance, please contact the User Fees helpdesk at UserFees@fda.gov.

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If your business has a User Fee System account, it will have an Org ID.

Log into your account to find the Org ID in your 'Profile' section under 'Business Information'.

The picture to the right of the screen is an example screenshot highlighting where the Org ID will be located in your account's profile page.

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

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

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

The address should match the business's address you used in your User Fee System account.

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Box 4, the full name of the person certifying the Small Business Request.

Input the full name of the person who is legally responsible for the accuracy and completeness of the information provided in the SBR.

This person must be an employee of the business requesting small business status.

This is also the primary person the FDA will contact for all communications regarding your SBR.

However, if you prefer to list a different primary contact for your SBR, you'll have the option to specify this in Box 8 of this section.

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Box 4a, the Certifier's title.

Input the Certifier's title describing their position in the business.

For example, if they are the Head of the Firm, or the Chief Financial Officer, put "Head of Firm" or "Chief Financial Officer".

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Box 5, the certifier's telephone number.

Input the certifier's telephone number including country code and area code.

This is the number where FDA may reach you if we have a question regarding your SBR.

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Box 6, the certifier's email address.

Input a valid and functioning email address where FDA can reach you.

This is the email address we will use to communicate with you about your SBR, unless a different Primary Contact is specified in Box 8 of this section.

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Box 7, the certifier's mailing address.

Input the certifier's mailing address here.

If your address is the same address as in Box 3 you can mark the check box and leave the field blank.

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Boxes 8 through 11, the Primary Contact's information.

The Primary Contact is the person who will submit the SBR and who FDA will contact for all communications regarding the application.

Only complete Boxes 8 – 11 if the Primary Contact is not the person identified in Box 4.

If the person identified in Box 4 will be the Primary Contact, leave these sections blank.

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Box 8, the full name of the primary contact making the SBR on behalf of the business.

Input the Primary Contact's full name in this box.

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Box 9, the Primary Contact's telephone number.

Input the Primary Contact's telephone number including the country code and area code.

This is the number FDA may reach you if we have a question regarding your SBR.

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Box 10, the Primary Contact's mailing address.

Input the Primary Contact's mailing address here.

If your mailing address is the same as Box 3, you can mark the check box instead of providing the information again.

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Box 11, the Primary contact's email address.

Input the Primary Contact's valid email address here.

This is the email address the FDA will use to communicate with you about your SBR.

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Item 12, the Certifier's certifications.

In this part, the person identified in Box 4, the Certifier, will indicate which benefits they are seeking and certify that they meet the specific eligibility criteria for the benefits being sought.

In the next three slides, we will briefly cover each benefit and certification.

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Item 12, Box 1, requests Reduced Application and/or Report Fees.

To meet this benefit's criteria, your business, including your affiliate's, reported total gross receipts or sales cannot exceed more than 100 million U.S. dollars for the most recent tax year.

Note that you will report your total gross receipts or sales in Section 2, line 21 of this form and the value cannot exceed 100 million U.S. dollars.

Mark the box if your business meets this criterion and if you wish to apply for this benefit.

If you qualify, you would be eligible for reduced medical device application and/or report fees.

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Item 12, Box 2, requests the "First Premarket Application and/or Report" Fee Waiver.

To meet this benefit's criteria, your business, including all affiliates', reported total gross receipts or sales can be no more than 30 million U.S. dollars in its most recent tax year.

You will report your total gross receipts or sales in Section 2, line 21 of this form and the value cannot exceed 30 million U.S. dollars.

In addition to this criterion, you or your affiliates must have never submitted a premarket application or report.

It is important to highlight that this benefit does not apply to all first premarket applications.

Please carefully review the SBD program's definition of a "first premarket application or report" which is provided in the guidance document linked here.

Mark the box if your business meets these criteria and if you wish to apply for this benefit.

If your business qualifies, you would be eligible for a one-time "first premarket application and/or report" fee waiver.

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Item 12, Box 3, requests the Annual Registration Fee Waiver.

To qualify for this benefit, you must meet the following three criteria:

One, your business, including all affiliates', reported total gross receipts or sales can be no more than 1 million U.S. dollars in the most recent tax year.

Two, you have proof of financial hardship, and;

Three, you have paid registration fees for each of your facilities in a prior year.

For the second criterion, “proof of financial hardship”, refer to the SBD program guidance document for information regarding the documentation you should provide.

Mark the box only if your business meets all 3 criteria and if you wish to qualify for this benefit.

Please note, that you must also complete Section 4 of Form 3602N.

If you qualify for this benefit, you may be eligible for a one-time establishment registration fee waiver.

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Item 12, the certification statement.

Please carefully review this statement before signing.

You must provide a copy of your business’s and all affiliates’ most recent reported total gross receipts or sales.

We will cover the required documentation in the next few slides.

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If you are a U.S business, you must provide a copy of your business’s most recent U.S. Federal income tax return.

You should provide all IRS Forms that contain information on your gross receipts or sales.

The table on the right lists the IRS Forms that may contain information on your gross receipts or sales. Please note that this list is not all-inclusive.

If you have any U.S. affiliates, you must provide a complete, signed, and dated copy of the affiliate’s most recent Federal (U.S.) income tax return.

If you have any non-U.S. affiliates, you must provide a certified Section III of Form 3602N completed by the affiliate’s National Taxing Authority.

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All Federal (U.S.) income tax returns must include the dated signature of an officer, partner, or member of the company.

The signature may be handwritten in ink or a valid digital signature.

If the return was filed electronically, you must provide a copy of IRS Form 8879, the e-file Signature Authorization, bearing a dated signature of an officer, partner or member of the company.

Tax returns with watermarks such as “do not file”, “client copy”, or "taxpayer's copy" cannot be accepted.

If you filed for an extension, you must also provide IRS Form 7004.

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If you are a foreign business, you must provide a copy of your business’s certified Section 3 of Form 3602N.

If you have any U.S. affiliates, you must provide a copy of each affiliate's most recent Federal (U.S.) income tax return.

If you have any non-U.S. affiliates, you must provide a separate certified Section 3 of Form 3602N for each foreign affiliate.

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Item 12, the Certifier's signature.

The person identified in Box 4 of this form must sign this section.

Your signature may be handwritten in ink or provided as a valid digital signature.

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Item 12, the date the form was signed.

Input the date the Certifier signed the form.

The date must be in month, day and year format.

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Congratulations! You have completed Section 1 of Form 3602N.

Your next step is to complete Section 2 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 2".

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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.