

Small Business Determination Program: Common Submission Errors

Slide 1

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 an overview of common errors that result in deficiencies in these applications.

After you watch this presentation, we hope the information will encourage you to review your SBR and avoid potential errors prior to its submission.

Taking these steps, will help streamline your SBR's review and timing to receive a decision.

Slide 2

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

This short module—Common Submission Errors—is the sixth part of this series.

If you haven't already, we highly recommend watching the previous modules before continuing with this one.

Slide 3

Let's briefly review what an SBR is.

An SBR is a compilation of documents to support your request for "small business" status and for specific benefits.

The following documents make a complete SBR.

A complete Form FDA 3602N also known as the MDUFA Small Business Request Form, or just "Form 3602N".

Your business's signed Federal U.S income tax return(s) or National Taxing Authority's stamped certification.

Your business affiliates' signed Federal U.S income tax returns, and/or National Taxing Authority's stamped certifications.

Proof of financial hardship, such as the recommended evidence of active bankruptcy, if you are requesting a registration fee waiver.

Proof of a prior year's registration fee payment, only if you are requesting a registration fee waiver.

And other supporting documents such as certified translations, or official business name changes.

Slide 4

Before submitting your SBR, you should ensure that you've gathered all supporting documents.

You should review your Form 3602N for potential errors and correct them before submitting.

The FDA cannot add any missing information for you, nor can we make corrections to your SBR on your behalf.

Missing information and documents may result in denial of your SBR.

To help you conduct a pre-check of your SBR, we will cover some of the most common errors made in SBR applications and describe how you can avoid them.

Slide 5

The most common error observed is an incorrect Org ID number.

Please verify that you have input the correct Org ID in Section 1, box 2a of Form 3602N.

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

Slide 6

The Org ID is not your Registration Number, Employer Identification Number, Taxpayer Identification Number, or your DUNS Number.

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

If your business does not have a User Fee System account, you must create one so that you can obtain an Org ID.

The User Fee system is where your small business fee reductions or waiver will be applied.

Slide 7

Once your User Fee System account is created, you'll find the Org ID in your 'Profile' section under 'Business Information'.

Slide 8

Another common error is an incorrect or missing fiscal year.

You should verify that you have input the correct fiscal year in the top right corner of Section 1 of Form 3602N.

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

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

Slide 9

Another common error is omitting the requesting business in Section 2 of Form 3602N.

Please verify that you have listed your business in Line 1, Section 2 of the form.

You should list your business affiliates starting in Line 2.

Slide 10

Another common error is submitting incomplete tax returns for U.S. businesses or U.S. affiliates.

You must submit original copies of Federal U.S. income tax returns.

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

E-filed forms submitted to the IRS are acceptable.

Each IRS form must include the signature and the date of an officer, partner, or member of the company.

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

Slide 11

Another common error is reporting “Net Sales” instead of gross receipts or sales.

For a U.S. business or affiliate, you must provide all IRS Forms that contain the business’s gross receipts or sales.

Do not report net sales as this is not the same information.

The table on the right lists the IRS Forms and the respective Line Number that contains a U.S. business’s gross receipts or sales.

Slide 12

We’ve reached the conclusion of the common errors made in SBR applications.

We hope the information in this module encourages you to review your SBR to catch these potential errors.

Your next steps are to upload and submit all your SBR’s documents electronically through the CDRH Portal.

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

Slide 13

Below are links to the resources that were mentioned or are relevant to this module.

Slide 14

We’ve reached the conclusion of this module. Thank you for watching.