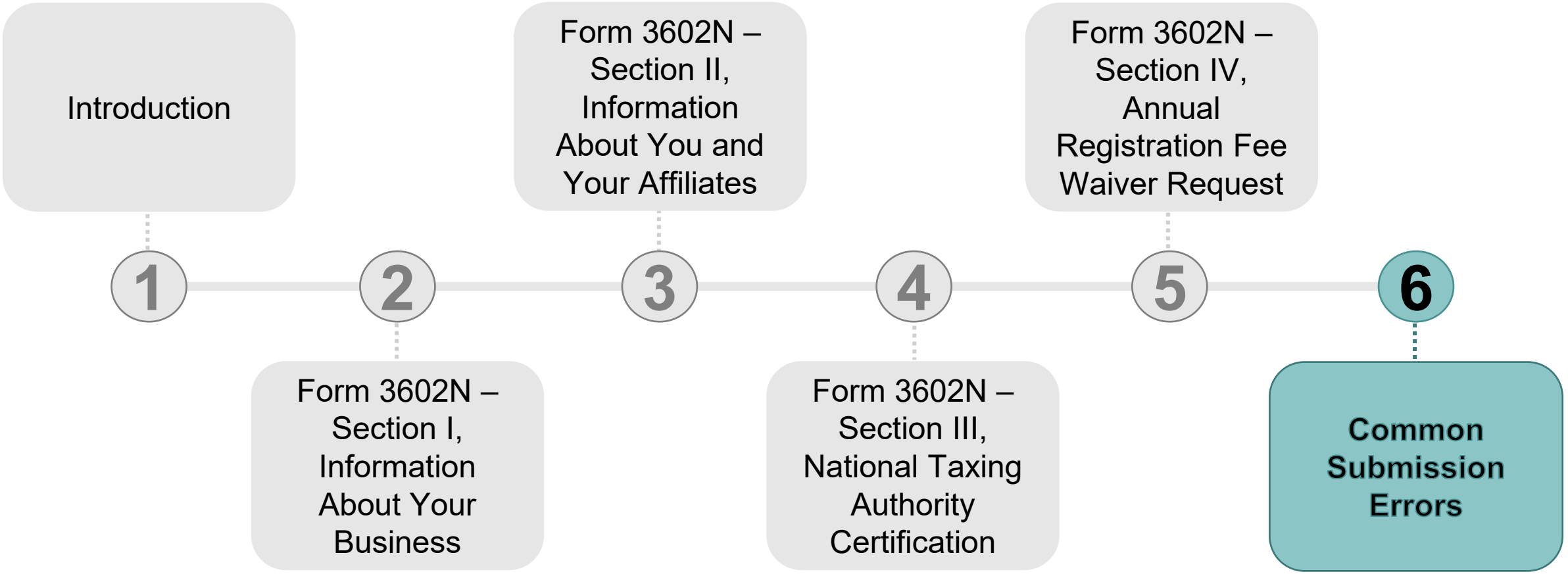
Common Submission Errors

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Division of Industry and Consumer Education (DICE)

Navigating the Small Business Determination (SBD) Program Series



SBR Overview

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

- Form FDA 3602N (MDUFA Small Business Request Form).
- Federal (U.S.) income tax return(s) or National Taxing Authority's stamped certification.
- Your business affiliates' Federal (U.S.) income tax returns, and/or National Taxing Authority's stamped certifications.
- Proof of financial hardship *(recommended evidence of active bankruptcy for registration fee waiver requests).*
- Proof of a prior year's registration fee payment *(for registration fee waiver requests)*.
- Other supporting documents (e.g. certified translations, business name changes).

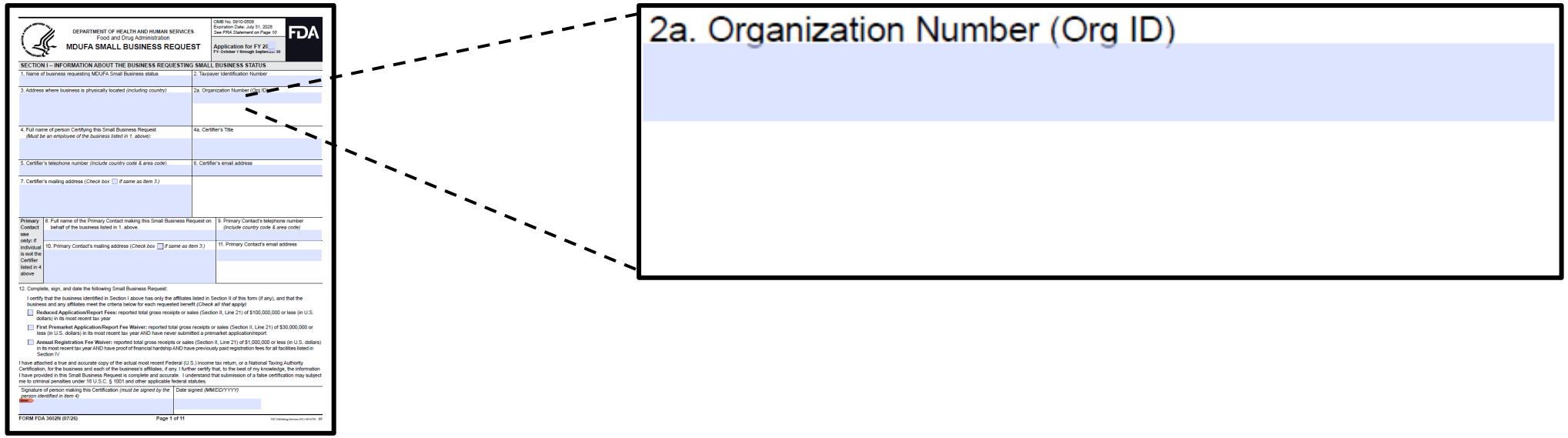
SBR Overview, *continued*

- Ensure you've gathered all supporting documents for your SBR.
- Review your Form 3602N for potential errors and correct them.
- The FDA **cannot** add any missing information for you, nor can we make corrections on your behalf.
- Missing information and documents may result in denial of your SBR.

Common Error: Incorrect Org ID

- Verify that you have input the correct Org ID in Section I 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.



Common Error: Incorrect Org ID, *continued*

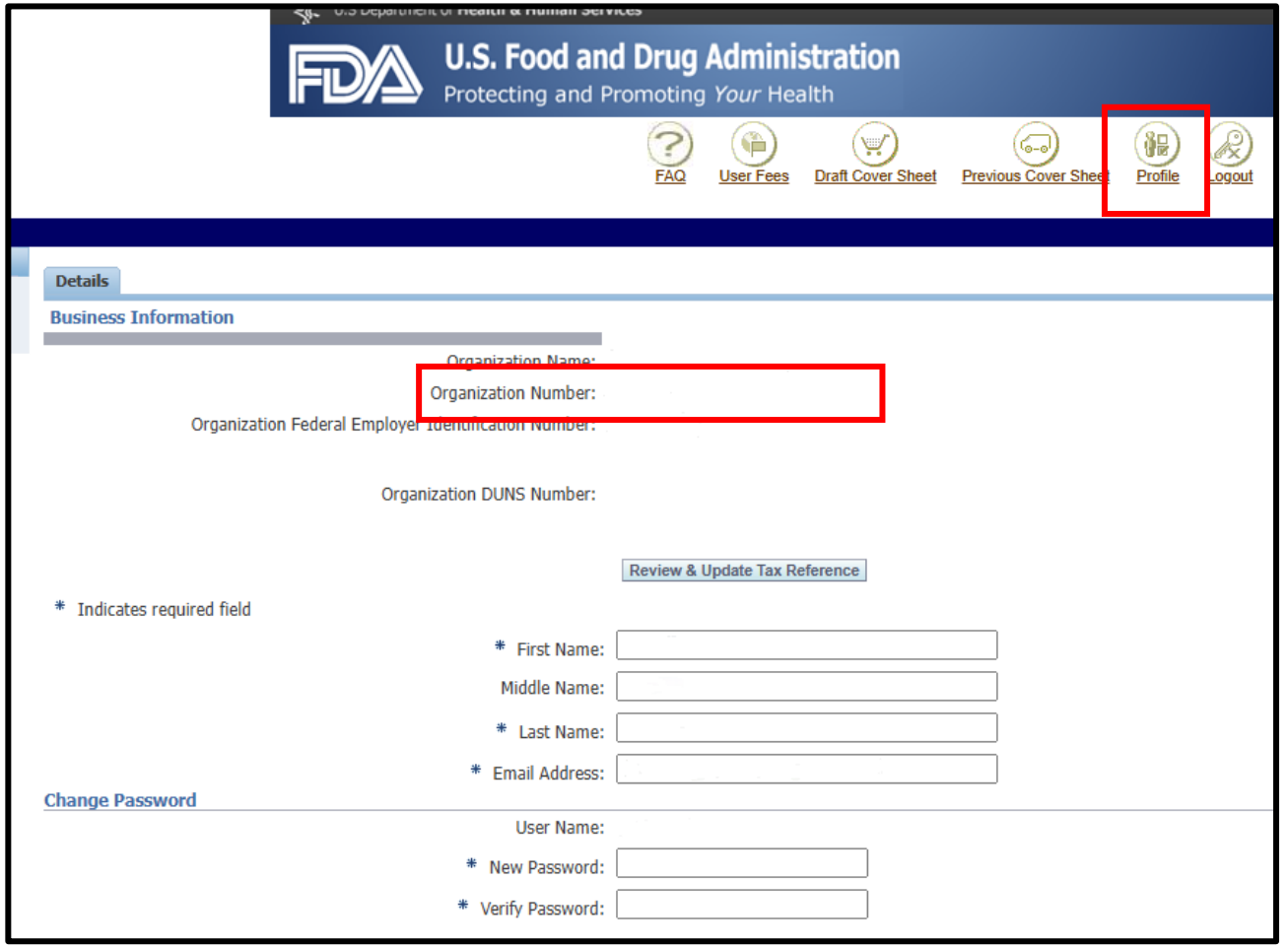
- The Org ID is **not** your:
  - × Registration Number
  - × Employer Identification Number (EIN)
  - × Taxpayer Identification Number (TIN)
  - × DUNS Number.

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

- If your business does not have a User Fee System account, **you must create one**.
  - This is where your small business fee reductions or waiver will be applied.

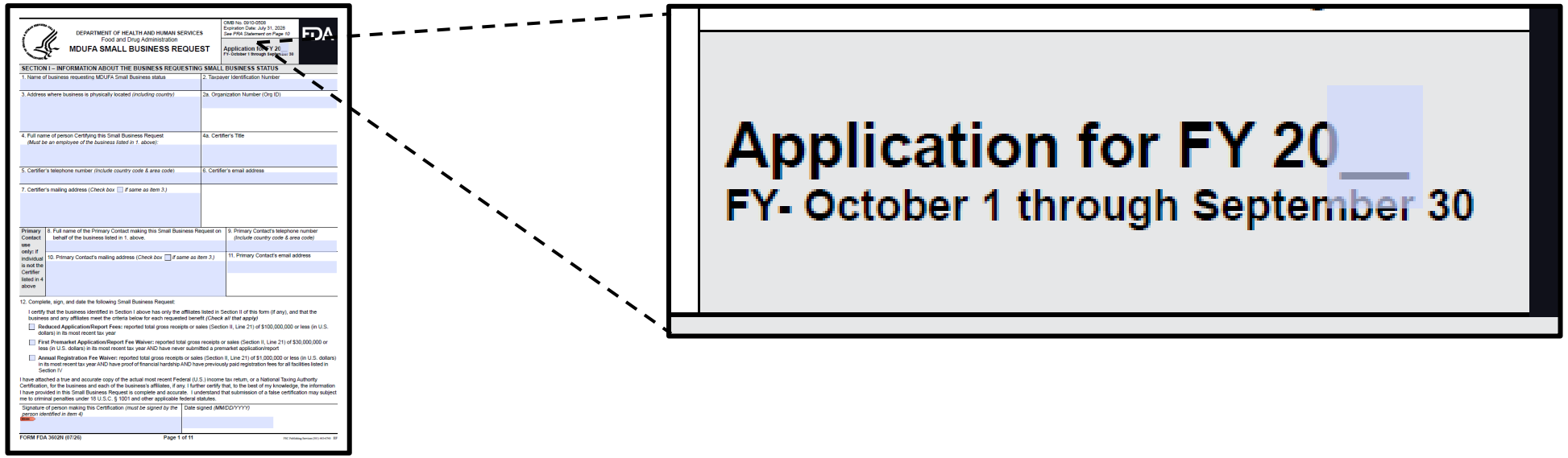
Common Error: Incorrect Org ID, *continued*

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



Common Error:
Incorrect or Missing Fiscal Year (FY)

- Verify that you have **input the correct FY** in the top right corner of Section I of Form 3602N.
  - The FY runs from **October 1 - September 30**.
  - Example: FY 2027 spans from October 1, 2026 – September 30, 2027.



Common Error:
Omitting the Requesting Business

- Verify that you have listed **your business in Line 1,** Section II of Form 3602N.
  - List your affiliates starting in Line 2.

a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.			$

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Enter the requesting business on Line 1 with columns a through d completed and list all affiliates (if any) on the remaining lines.

	a. Name of Business	b. Country	c. Taxpayer ID Number	d. Gross Receipts or Sales
1.				$
2.				$
3.				$
4.				$
5.				$
6.				$
7.				$
8.				$
9.				$
10.				$
11.				$
12.				$
13.				$
14.				$
15.				$
16.				$
17.				$
18.				$
19.				$
20.				$
21.	Total Gross Receipts or Sales Used to Determine Qualification as a Small Business (sum of lines 1 through 20 inclusive)			$ 0.00

Federal (U.S.) income tax returns for all U.S. businesses and affiliates, and/or National Taxing Authority Certifications (Section III) for all non-U.S. businesses and affiliates identified above, must be included with this MDUFA Small Business Request.

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Common Error: Incomplete Tax Returns

- Submit **original** copies of Federal (U.S.) Income Tax Returns.
  - × Tax returns with watermarks (e.g. “do not file”, “client copy”, or "taxpayer's copy") cannot be accepted.
  - ✓ e-file 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.

- Signatures may be in ink or may be a valid digital signature.

Common Error: Reporting "Net Sales"

- For U.S. businesses or affiliates:
  - Provide all IRS Forms that contain the business's **gross receipts or sales**.
  - Do not report "net sales".
  - The table on the right lists the IRS Forms and the Line Number that contains gross receipts or sales.

IRS Form	See Line Number
Schedule C (Form 1040)	1
Form 1065	1a
Form 1065-B	1a
Form 1120	1a
Form 1120-F	Section II, 1a
Form 1120S	1a
Form 990	12

Next Step:
Submit Your SBR to CDRH

- Upload and submit all your SBR's documents electronically through the CDRH Portal.

- For step-by-step instructions visit the SBD program webpage.

Resources

Slide #	Cited Resource	URL
3	Download Form FDA 3602N	https://www.fda.gov/about-fda/reports-manuals-forms/forms
5, 6	User Fee System webpage	https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref=mdufa
12	CDRH Portal	https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal#CDRHPortal
12	SBD program webpage	https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/reduced-or-waived-medical-device-user-fees-small-business-determination-sbd-program
N/A	SBD program guidance document	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination


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