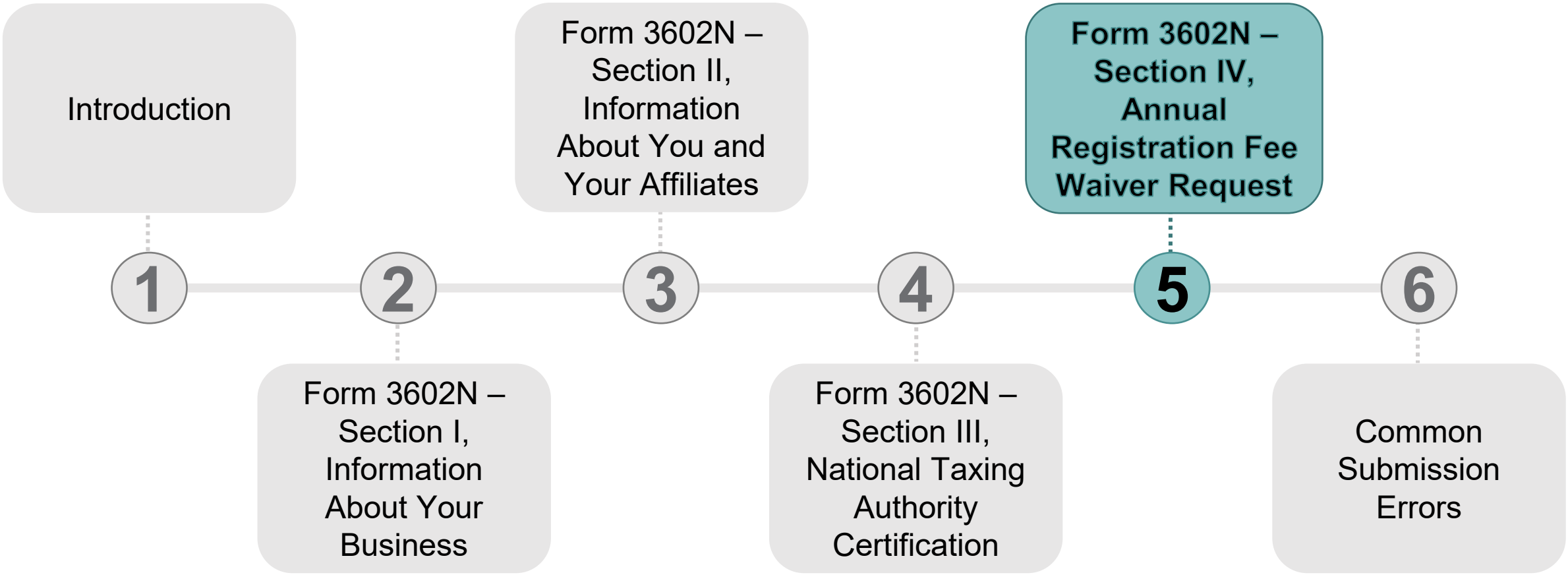
Form 3602N – Section IV
Annual Registration Fee Waiver Request

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



Navigating this Module

- Information boxes are color coded

Yellow box content applies to **both**
- U.S business applicants
- Foreign (non-U.S.) business applicants.

Blue box content applies to **U.S. business** applicants.

Green box content applies to **foreign (non-U.S.) business** applicants.

Section IV

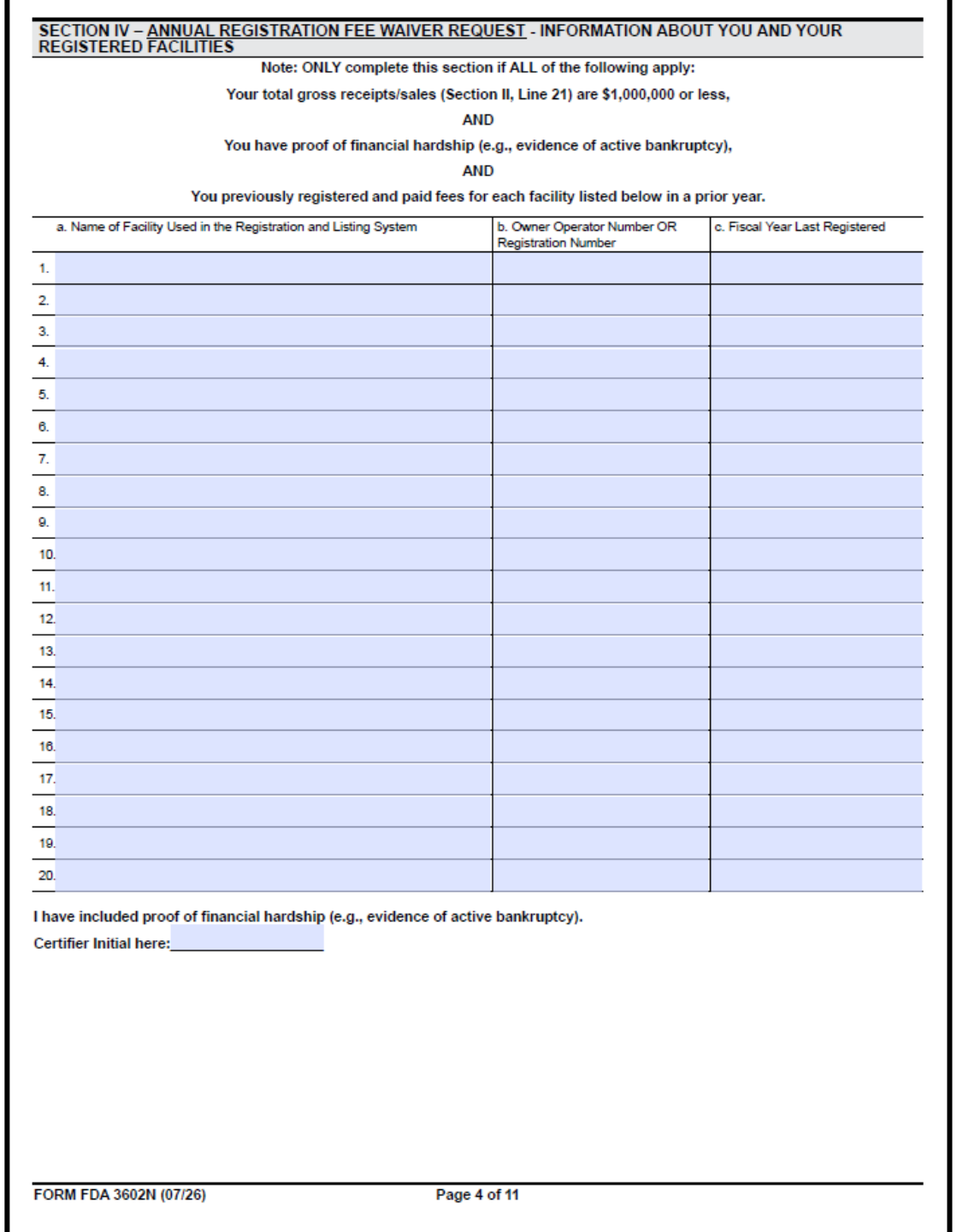
Section IV provides space for a registration fee waiver request.

Registration fee waiver requests are only accepted **Aug 2nd – Nov 1st**.

If you do not qualify for the waiver, you will need to pay the full registration fee.

There are no small business “reductions” for the annual registration fee.

Find form “3602N” here.



SECTION IV – ANNUAL REGISTRATION FEE WAIVER REQUEST - INFORMATION ABOUT YOU AND YOUR REGISTERED FACILITIES

Note: ONLY complete this section if ALL of the following apply:

Your total gross receipts/sales (Section II, Line 21) are $1,000,000 or less,

AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

You previously registered and paid fees for each facility listed below in a prior year.

	a. Name of Facility Used in the Registration and Listing System	b. Owner Operator Number OR Registration Number	c. Fiscal Year Last Registered
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I have included proof of financial hardship (e.g., evidence of active bankruptcy).

Certifier Initial here:_____

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SECTION IV – ANNUAL REGISTRATION FEE WAIVER REQUEST - INFORMATION ABOUT YOU AND YOUR REGISTERED FACILITIES

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AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

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You previously registered and paid fees for each facility listed below in a prior year.

	a. Name of Facility Used in the Registration and Listing System	b. Owner Operator Number OR Registration Number	c. Fiscal Year Last Registered
1.			
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Only complete Section IV if you meet **ALL** of the criteria outlined above.

SECTION IV – ANNUAL REGISTRATION FEE WAIVER REQUEST - INFORMATION ABOUT YOU AND YOUR REGISTERED FACILITIES

Note: ONLY complet… …the following apply:

Your total gross recei… …re $1,000,000 or less,

You have proof of fina… …of active bankruptcy),

You previously registered and… …ity listed below in a prior year.

	a. Name of Facility Used in the Registration and Listing System	…ner Operator Number OR Registration Number	c. Fiscal Year Last Registered
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3.			
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Skip Section IV if any of the following apply:

1. You have more than $1,000,000 in Section II, Line 21.
2. You do not have proof of financial hardship.
3. You have not paid to register your facility in a prior fiscal year.

SECTION IV – ANNUAL REGISTRATION FEE WAIVER REQUEST - INFORMATION ABOUT YOU AND YOUR REGISTERED FACILITIES

Note: ONLY complete this section if ALL of the following apply:

Your total gross receipts/sales (Section II, Line 21) are $1,000,000 or less,

AND

To meet the first criterion:

Your business and your affiliate's combined gross receipts or sales in Section II **cannot exceed $1,000,000** for the most recent tax year.

	a. Name of Facility Use		Year Last Registered
1.			
2.			
3.			
4.			
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8.			

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AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

To meet this second criterion, provide proof of financial hardship[1]:

The FDA grants waivers only where financial hardship meets a clear and objective standard that is publicly transparent.

The only situation the agency is currently aware of that meets this standard is where the small business is in **active bankruptcy**.

The FDA considers **active bankruptcy** as financial hardship that meets a clear, objective standard with publicly verifiable records.

1. Medical Device User Fee Small Business Qualification and Determination guidance document

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AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

1.			
2.			
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U.S. businesses:

Provide evidence of financial hardship, such as that you have filed a **petition for bankruptcy** in United States Bankruptcy Court and that the bankruptcy is currently active.

Foreign businesses:

Provide evidence of financial hardship, such as that you have filed your jurisdiction's equivalent of a United States **bankruptcy action** and evidence that the bankruptcy action is active.

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Your total gross receipts/sales (Section II, Line 21) are $1,000,000 or less,

AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

You previously registered and paid fees for each facility listed below in a prior year.

	a. Name of Facility Used in the Registration and Listing System	b. Owner Operator Number OR	c. Fiscal Year Last Registered
1.			
2.			
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To meet this criterion:

Provide a PDF copy of a **prior year's registration fee payment** for each of your facilities.

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AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

You previously registered and paid fees for each facility listed below in a prior year.

	a. Name of Facility Used in the Registration and Listing System	b. R
1.		
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Input the **full name** of your facility.

It must match the facility's name in FDA's Unified Registration and Listing System/ Device Registration and Listing Module (FURLS/DRLM).

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AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

You previously registered and paid fees for each facility listed below in a prior year.

	a.	b. Owner Operator Number OR Registration Number	c. Fiscal Year Last Registered
1.			
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Input the **Owner Operator Number** or **Registration Number** for the facility.

This number must match the number on your registration in FURLS/DRLM.

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AND

You have proof of financial hardship (e.g., evidence of active bankruptcy),

AND

You previously registered and paid fees for each facility listed below in a prior year.

	a. Name of Facility Used in the Registration	c. Fiscal Year Last Registered
1.		
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Input the **fiscal year** the facility was last registered with the FDA.

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1.			
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If your business has **multiple facilities** registered with the FDA, continue to list them in Lines 2 – 20.

15.			
16.			
17.			
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19.			
20.			

I have included proof of financial hardship (e.g., evidence of active bankruptcy).

Certifier Initial here:_____

The **Certifier identified in Box 4** of Section I must initial Section IV.

Next Steps: Check for Common Errors, and Submit

- For an overview of the common errors that result in SBR deficiencies, watch the CDRH Learn module "Common Submission Errors".

- Submit your SBR electronically through the CDRH Portal.

Resources

Slide #	Cited Resource	URL
4	Download Form FDA 3602N	https://www.fda.gov/about-fda/reports-manuals-forms/forms
8	SBD program guidance document	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination
11	FURLS/DRLM login	https://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1
16	CDRH Learn	https://www.fda.gov/training-and-continuing-education/cdrh-learn
16	CDRH Portal	https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal#CDRHPortal
N/A	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


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ADMINISTRATION