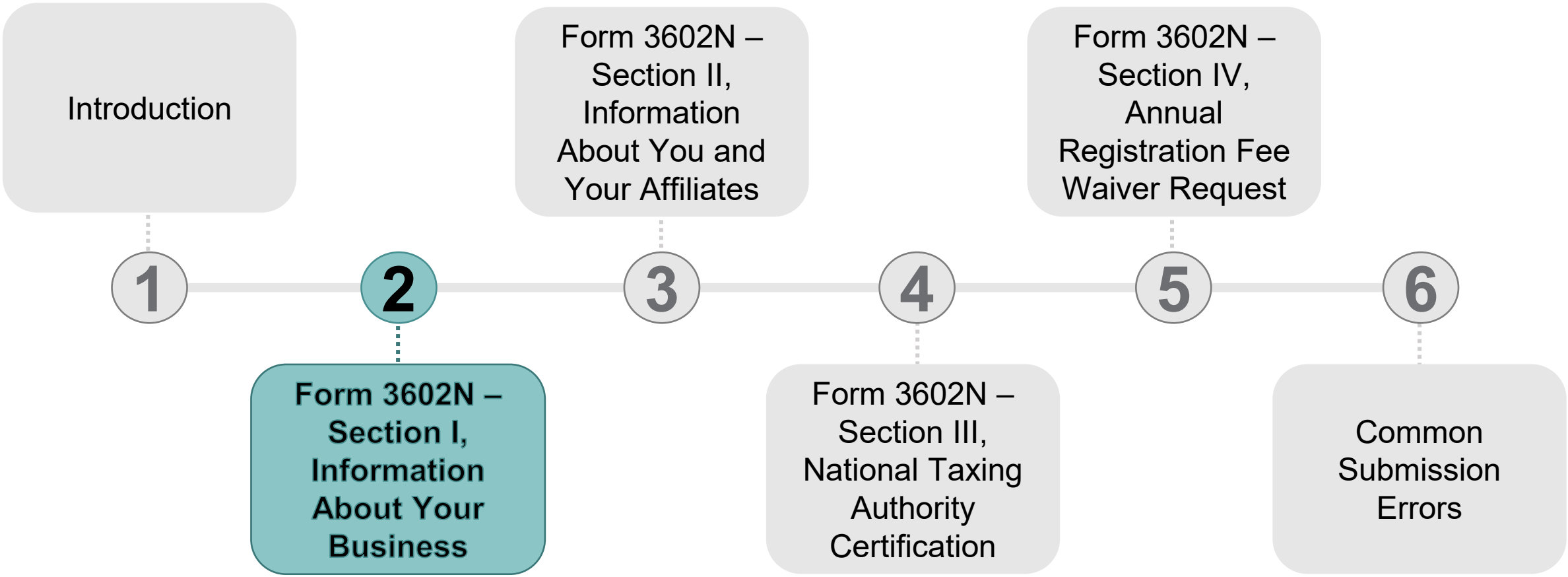
Form 3602N – Section I
Information About Your Business

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.

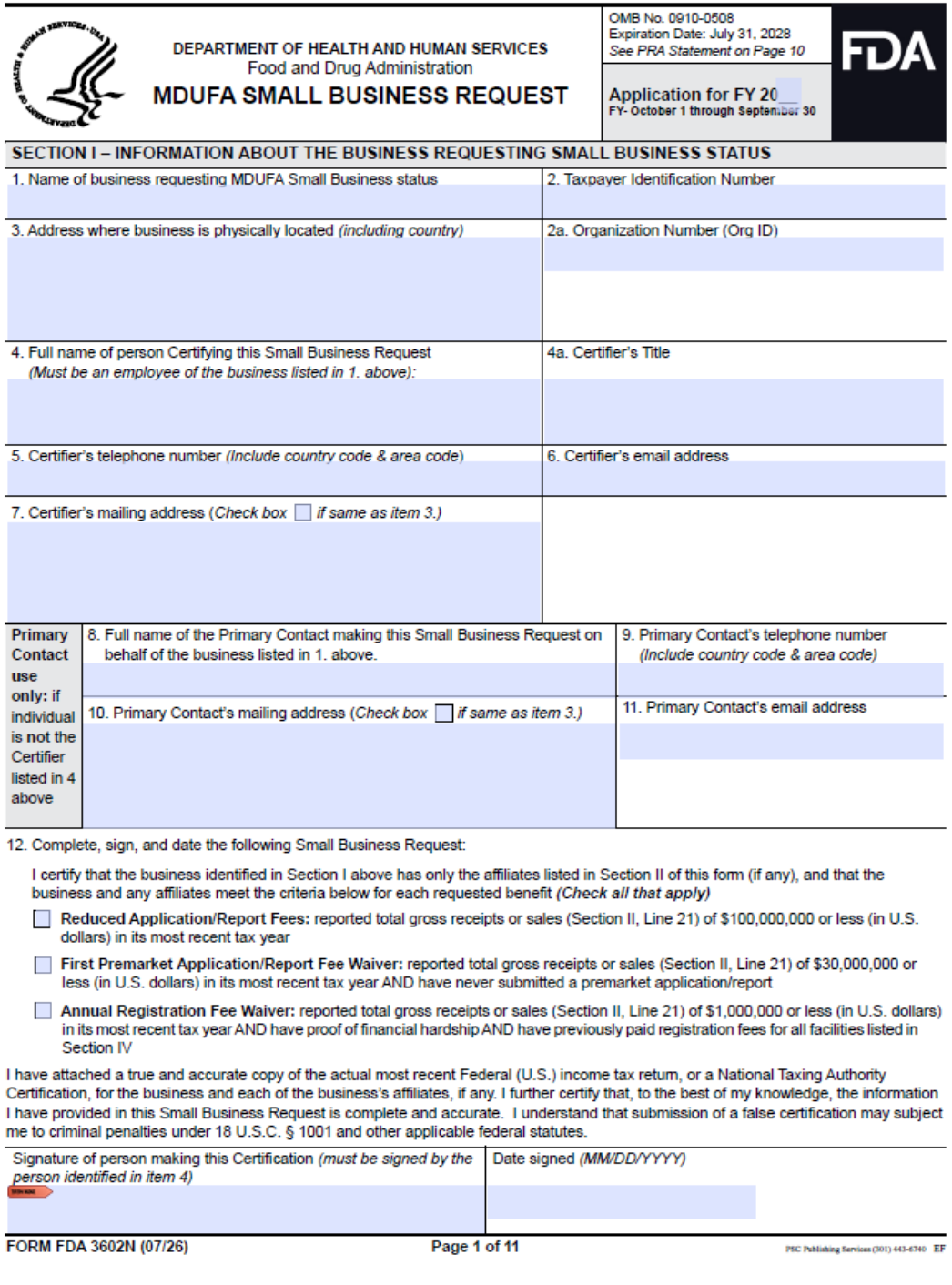
Blue box content applies to **U.S. business** applicants.

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

Section I

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

Find form “3602N” here.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS REQUEST

OMB No. 0910-0508
Expiration Date: July 31, 2028
See PRA Statement on Page 10

FDA

Application for FY 20__
FY- October 1 through September 30

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SMALL BUSINESS STATUS

1. Name of business requesting MDUFA Small Business status	2. Taxpayer Identification Number
3. Address where business is physically located *(including country)*	2a. Organization Number (Org ID)
4. Full name of person Certifying this Small Business Request *(Must be an employee of the business listed in 1. above):*	4a. Certifier's Title
5. Certifier's telephone number *(Include country code & area code)*	6. Certifier's email address
7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*	

Primary Contact use only: if individual is not the Certifier listed in 4 above	8. Full name of the Primary Contact making this Small Business Request on behalf of the business listed in 1. above.	9. Primary Contact's telephone number *(Include country code & area code)*
	10. Primary Contact's mailing address (*Check box* ☐ *if same as item 3.)*	11. Primary Contact's email address

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

- ☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year
- ☐ **First Premarket Application/Report Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $30,000,000 or less (in U.S. dollars) in its most recent tax year AND have never submitted a premarket application/report
- ☐ **Annual Registration Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $1,000,000 or less (in U.S. dollars) in its most recent tax year AND have proof of financial hardship AND have previously paid registration fees for all facilities listed in Section IV

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority Certification, for the business and each of the business's affiliates, if any. I further certify that, to the best of my knowledge, the information I have provided in this Small Business Request is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Signature of person making this Certification *(must be signed by the person identified in item 4)*	Date signed *(MM/DD/YYYY)*

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OMB No. 0910-0508
Expiration Date: July 31, 2028
See PRA Statement on Page 10

Application for FY 20__
FY- October 1 through September 30

Input the **fiscal year (FY)** for which you are seeking "small business" status.

The FY runs from
October 1st – September 30th.

Example:
FY 2027 runs from
October 1st 2026 – September 30th 2027.

SECTION I – INFOR … MALL BUSINESS STATUS

1. Name of business re… | Taxpayer Identification Number

3. Address where busin… | Organization Number (Org ID)

4. Full name of person … *(Must be an employee of the business listed in 1. above):* | Certifier's Title

5. Certifier's telephone number *(Include country code & area code)* | 6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS REQUEST

OMB No. 0910-0508
Expiration Date: July 31, 2028
See PRA Statement on Page 10

Application for FY 20__
FY- October 1 through September 30

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING S

1. Name of business requesting MDUFA Small Business status

3. Address where business is physically located *(including country)*

4. Full name of person Certifying this Small Business Request *(Must be an employee of the business listed in 1. above):*

5. Certifier's telephone number *(Include country code & area code)*

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

Input the **full legal name of your business**.

U.S. businesses:

This name MUST match the name on the business's Federal (U.S.) income tax return.

Foreign businesses:

This name MUST match the name provided in Item 2 of Section III from the National Taxing Authority.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS REQUEST

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Expiration Date: July 31, 2028
See PRA Statement on Page 10

Application for FY 20__
FY- October 1 through September 30

FDA

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SMALL BUSINESS STATUS

1. Name of business requesting MDUFA Small Business status	2
3. Address where business is physically located *(including country)*	2
4. Full name of person Certifying this Small Business Request *(Must be an employee of the business listed in 1. above):*	4a. Certifier's Title
5. Certifier's telephone number *(Include country code & area code)*	6. Certifier's email address
7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*	

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS REQUEST

OMB No. 0910-0508
Expiration Date: July 31, 2028
See PRA Statement on Page 10

Application for FY 20__
FY- October 1 through September 30

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SMALL BUSINESS STATUS

1.

2. Taxpayer Identification Number

3.

2a. Organization Number (Org ID)

4.

4a. Certifier's Title

5.

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.*)

Taxpayer Identification Number

U.S. businesses:

Input the Employer Identification Number (EIN) from the business's Federal (U.S.) income tax return.

Foreign businesses:

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".

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

OMB No. 0910-0508
Expiration Date: July 31, 2028
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Application for FY 20__
FY- October 1 through September 30

NG SMALL BUSINESS STATUS

2. Taxpayer Identification Number

2a. Organization Number (Org ID)

4a. Certifier's Title

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.*)

Input the **Organization Number (Org ID)**.

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

It is **NOT** the same as the:

- × Registration Number
- × Employer Identification Number (EIN)
- × Taxpayer Identification Number (TIN)
- × DUNS Number

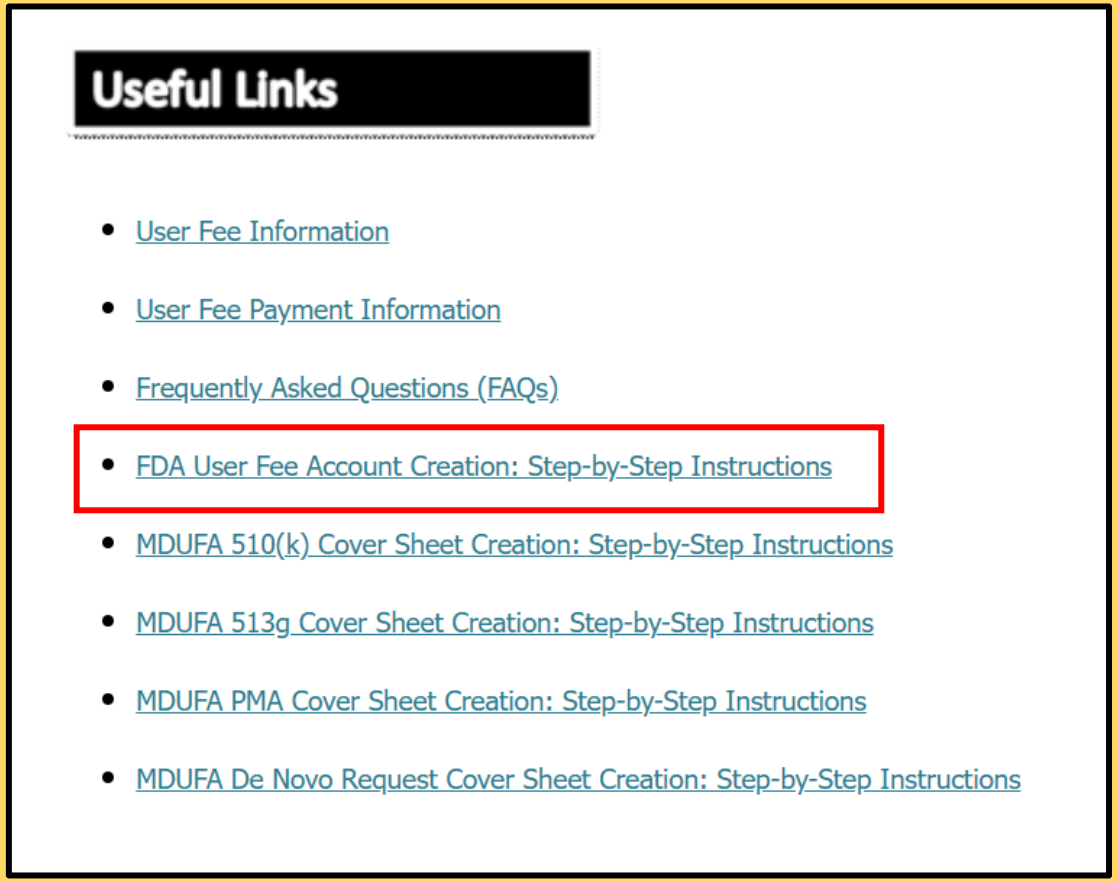
OMB No. 0910-0508
Expiration Date: July 31, 2028

If your business does NOT have a User Fee System account:
you MUST create one to get an Org ID.

This system is where your small business fee reductions or waiver will be applied.

Refer to the downloadable Step-by-Step Instructions on the User Fee System webpage.

For account assistance, contact UserFees@fda.gov.



7. Certifier's mailing address (*Check box* ☐ *if same as item 3.*)

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’.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS REQUEST

OMB No. 0910-0508
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Application for FY 20__
FY- October 1 through September 30

FDA

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SMALL BUSINESS STATUS

1. Name of business requesting MDUFA Small Business status	2. Taxpayer Identification Number
3. Address where business is physically located *(including country)*	2a.
4. Full name of person Certifying this Small Business Request *(Must be an employee of the business listed in 1. above):*	4a.
5. Certifier's telephone number *(Include country code & area code)*	6. C
7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*	

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

OMB No. 0910-0508
Expiration Date: July 31, 2028
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MDUFA SMALL BUSINESS REQUEST

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SM

1. Name of business requesting MDUFA Small Business status

2. T

3. Address where business is physically located *(including country)*

2a.

4. Full name of person Certifying this Small Business Request
(Must be an employee of the business listed in 1. above):

4a.

5. Certifier's telephone number *(Include country code & area code)*

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

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

This is the person FDA will contact for all communications regarding your SBR (unless a different Primary Contact is specified in Box 8).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS REQUEST

OMB No. 0910-0508
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Application for FY 20__
FY- October 1 through September 30

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SMALL BUSINESS STATUS

1. Name of business requesting MDUFA Small Business status	2. Taxpayer Identification Number
3. Address where business is physically located *(including country)*	2a. Organization Number (Org ID)
4. Fu *(M*	4a. Certifier's Title
5. Certifier's telephone number *(Include country code & area code)*	6. Certifier's email address
7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*	

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

Example: Head of Firm or Chief Financial Officer.

5. Certifier's telephone number *(Include country code & area code)*

6. Ce

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

Primary Contact use only: if individual is **not** the Certifier listed in 4 above	8. Full name of the Primary Contact making this Small Business Request behalf of the business listed in 1. above.	
	10. Primary Contact's mailing address (*Check box* ☐ *if same as item 3.)*	11. Primary Contact's email address

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

Input the Certifier's **telephone number**.

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

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).

Tip: To receive FDA emails, whitelist our domains:

- @fda.hhs.gov,
- @cdrh.fda.gov, and
- @fda.gov in your email's security settings.

6. Certifier's email address

9. Primary Contact's telephone number
(Include country code & area code)

11. Primary Contact's email address

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

Reduced Application/Report Fees: reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

5. Certifier's telephone number *(Include country code & area code)*

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

Primary Contact use only: if individual is **not** the Certifier listed in 4 above

8. Full name of the Primary Contact making this Small Business Reque
behalf of the business listed in 1. above.

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 3*

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

Input the Certifier's **mailing address**.

OR

Mark the check box (☒) if it's the same address as in Box 3 and leave the field blank.

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

Complete Boxes 8 – 11 only 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.

Primary Contact use only: if individual is **not** the Certifier listed in 4 above	8. Full name of the Primary Contact making this Small Business Request on behalf of the business listed in 1. above.	9. Primary Contact's telephone number *(Include country code & area code)*
	10. Primary Contact's mailing address (*Check box* ☐ *if same as item 3.)*	11. Primary Contact's email address

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

(must be an employee of the business listed in 1. above).

5. Certifier's telephone number *(Include country code & area code)*

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

Primary Contact use only: if individual is **not** the Certifier listed in 4 above

8. Full name of the Primary Contact making this Small Business Request on behalf of the business listed in 1. above.

9. P (

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 3.)*

11. Primary Contact's email address

Input the **Primary Contact's full name.**

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

5. Certifier's telephone number *(Include country code & area code)*

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

Primary Contact use only: if individual is **not** the Certifier listed in 4 above

8. F… b… …t on

9. Primary Contact's telephone number *(Include country code & area code)*

10. … …)

11. Primary Contact's email address

Input the **Primary Contact's telephone number**.

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

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S.

5. Certifier's telephone number *(Include country code & area code)*

6. Certifier's email address

7. Certifier's mailing address (*Check box* ☐ *if same as item 3.)*

Primary Contact use only: if individual is **not** the Certifier listed in 4 above

8. Full name of the Primary Contact making this Small Business Request on behalf of the business listed in 1. above.

9. P

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 3.)*

11.

Input the **Primary Contact's mailing address**.

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

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

5. Certifier's telephone number *(Include country code & area code)*

6. Certifier's email address

7. Certifier's ma

Input the **Primary Contact's valid email address**.

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

Tip: To receive FDA emails, whitelist our domains:

- @fda.hhs.gov,
- @cdrh.fda.gov, and
- @fda.gov in your email's security settings.

Primary Contact use only: if individual is **not** the Certifier listed in 4 above	8. F b	9. Primary Contact's telephone number *(Include country code & area code)*
	10.	11. Primary Contact's email address

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S

individual is **not** the Certifier listed in 4 above

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 5.*)

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year

☐ **First Premarket Appli** Line 21) of $30,000,000 or less (in U.S. dollars) in eport

☐ **Annual Registration F** 00,000 or less (in U.S. dollars) in its most recent tax ye fees for all facilities listed in Section IV

Certifier (from Box 4):
Indicate which certifications you are making for your SBR.

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority Certification, for the business and each of the business's affiliates, if any. I further certify that, to the best of my knowledge, the information I have provided in this Small Business Request is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Signature of person making this Certification *(must be signed by the person identified in item 4)*	Date signed *(MM/DD/YYYY)*

is **not** the Certifier listed in 4 above

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year

☐ **First Premarket Application/Report Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $30,000,000 or less (in U.S. dollars)

☐ **Annual Registration** in its most recent tax Section IV

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

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

I have attached a true and ac Certification, for the business I have provided in this Small me to criminal penalties unde

Signature of person making this Certification *(must be signed by the person identified in item 4)*

Date signed *(MM/DD/YYYY)*

individual is **not** the Certifier listed in 4 above

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 5.*)

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year

☐ **First Premarket Application/Report Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $30,000,000 or less (in U.S. dollars) in its most recent tax year AND have never submitted a premarket application/report

☐ **Annual Registration Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $1,000,000 or less (in U.S. dollars)

Limitation: Benefit does not apply to all first premarket applications. Review the SBD program guidance document for the definition of the "first premarket application/report".

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

If qualified, you would be eligible for a one-time "first premarket application/report fee waiver".

person identified in item 4)

individual is **not** the Certifier listed in 4 above

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 5.*)

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year

☐ **First Premarket Application/Report Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $30,000,000 or less (in U.S. dollars) in its most recent tax year AND have never submitted a premarket application/report

☐ **Annual Registration Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $1,000,000 or less (in U.S. dollars) in its most recent tax year AND have proof of financial hardship AND have previously paid registration fees for all facilities listed in Section IV

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority

For "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.

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

individual is **not** the Certifier listed in 4 above

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 5.*)

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year

☐ **First Premarket A** 21) of $30,000,000 or less (in U.S. dolla

☐ **Annual Registrat** 00 or less (in U.S. dollars) in its most recent t for all facilities listed in Section IV

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

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority Certification, for the business and each of the business's affiliates, if any. I further certify that, to the best of my knowledge, the information I have provided in this Small Business Request is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Signature of person making this Certification *(must be signed by the person identified in item 4)*	Date signed *(MM/DD/YYYY)*

U.S. businesses:
Provide a copy of your business's most recent Federal (U.S.) income tax return.

Provide all IRS Forms that contain information on your gross receipts or sales.

The table on the right lists IRS Forms that may contain information on your gross receipts or sales (not an all-inclusive list).

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

<u>For each U.S. affiliate</u>:
- Provide a complete, signed, and dated copy of the affiliate's most recent Federal (U.S.) income tax return.

<u>For each non-U.S. affiliate</u>:
- Provide a certified Section III of Form 3602N completed by the affiliate's National Taxing Authority.

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

<u>If the return was filed electronically</u>:
You must provide a copy of **IRS Form 8879** (e-file Signature Authorization) bearing a dated signature of an officer, partner or member of the company.

Tax returns with watermarks (e.g. “do not file”, “client copy”, or "taxpayer's copy") cannot be accepted.

<u>If you filed for an extension:</u>
You must also provide **IRS Form 7004** (Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns).

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

Foreign businesses:
Provide a copy of your business's certified (stamped) Section III of Form 3602N.

<u>For each U.S. affiliate</u>:

- Provide a copy of each affiliate's signed and most recent Federal (U.S.) income tax return.

<u>For each non-U.S. affiliate</u>:

- Provide a separate certified Section III of Form 3602N for each foreign affiliate.

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority Certification, for the business and each of the business's affiliates, if any. I further certify that, to the best of my knowledge, the information I have provided in this Small Business Request is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Signature of person making this Certification *(must be signed by the person identified in item 4)*	Date signed *(MM/DD/YYYY)*

individual is **not** the Certifier listed in 4 above

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 5.*)

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

- ☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year
- ☐ **First Premarket Application/Report Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $30,000,000 or less (in U.S. dollars) in its most recent tax year AND have never submitted a premarket application/report
- ☐ **Annual Registration Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $1,000,000 or less (in U.S. dollars) in its most recent tax year AND have proof of financial hardship AND have previously paid registration fees for all facilities listed in Section IV

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority Certification, for the business and each of the business's affiliates, if any. I ation I have provided in this Small Business Request is complete and accurate. ubject me to criminal penalties under 18 U.S.C. § 1001 and other applicable feder

Signature of person making this Certification *(must be signed by the person identified in item 4)*

Da

The **person identified in Box 4** must sign.

May be ink or a valid digital signature.

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individual is **not** the Certifier listed in 4 above

10. Primary Contact's mailing address (*Check box* ☐ *if same as item 5.*)

12. Complete, sign, and date the following Small Business Request:

I certify that the business identified in Section I above has only the affiliates listed in Section II of this form (if any), and that the business and any affiliates meet the criteria below for each requested benefit ***(Check all that apply)***

- ☐ **Reduced Application/Report Fees:** reported total gross receipts or sales (Section II, Line 21) of $100,000,000 or less (in U.S. dollars) in its most recent tax year
- ☐ **First Premarket Application/Report Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $30,000,000 or less (in U.S. dollars) in its most recent tax year AND have never submitted a premarket application/report
- ☐ **Annual Registration Fee Waiver:** reported total gross receipts or sales (Section II, Line 21) of $1,000,000 or less (in U.S. dollars) in its most recent tax year AND have proof of financial hardship AND have previously paid registration fees for all facilities listed in Section IV

I have attached a true and accurate copy of the actual most recent Federal (U.S.) income tax return, or a National Taxing Authority Certification, for the business and each of the business's affiliates, if any. I further certify that, to the best of my knowledge, the information I have provided in this Small Business Request is complete and accurate. I understand that submission of a false certification may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

Signature of person making this Certification *(must be signed by the person identi*	Date signed *(MM/DD/YYYY)*

Input the **date** the Certifier signed the form.

Next Step: Section II of Form 3602N

- To continue filling Form 3602N with step-by-step instructions, go to the CDRH Learn module "Form 3602N – Section II".

Resources

Slide #	Cited Resource	URL
4	Download Form FDA 3602N	https://www.fda.gov/about-fda/reports-manuals-forms/forms
9, 10, 11, 12	User Fee System webpage	https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref=mdufa
24	MDUFA Fees	https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa-fees
25, 26	SBD program guidance document	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination
33	CDRH Learn	https://www.fda.gov/training-and-continuing-education/cdrh-learn
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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