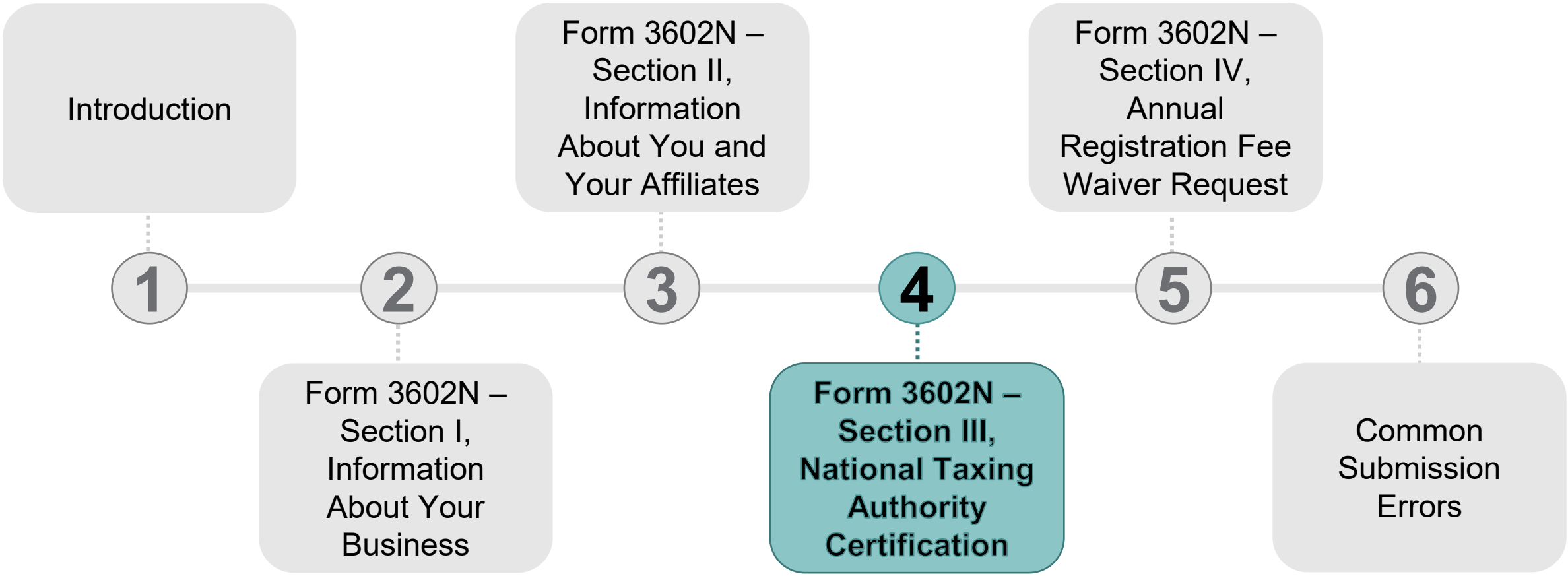
Form 3602N – Section III
National Taxing Authority Certification

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

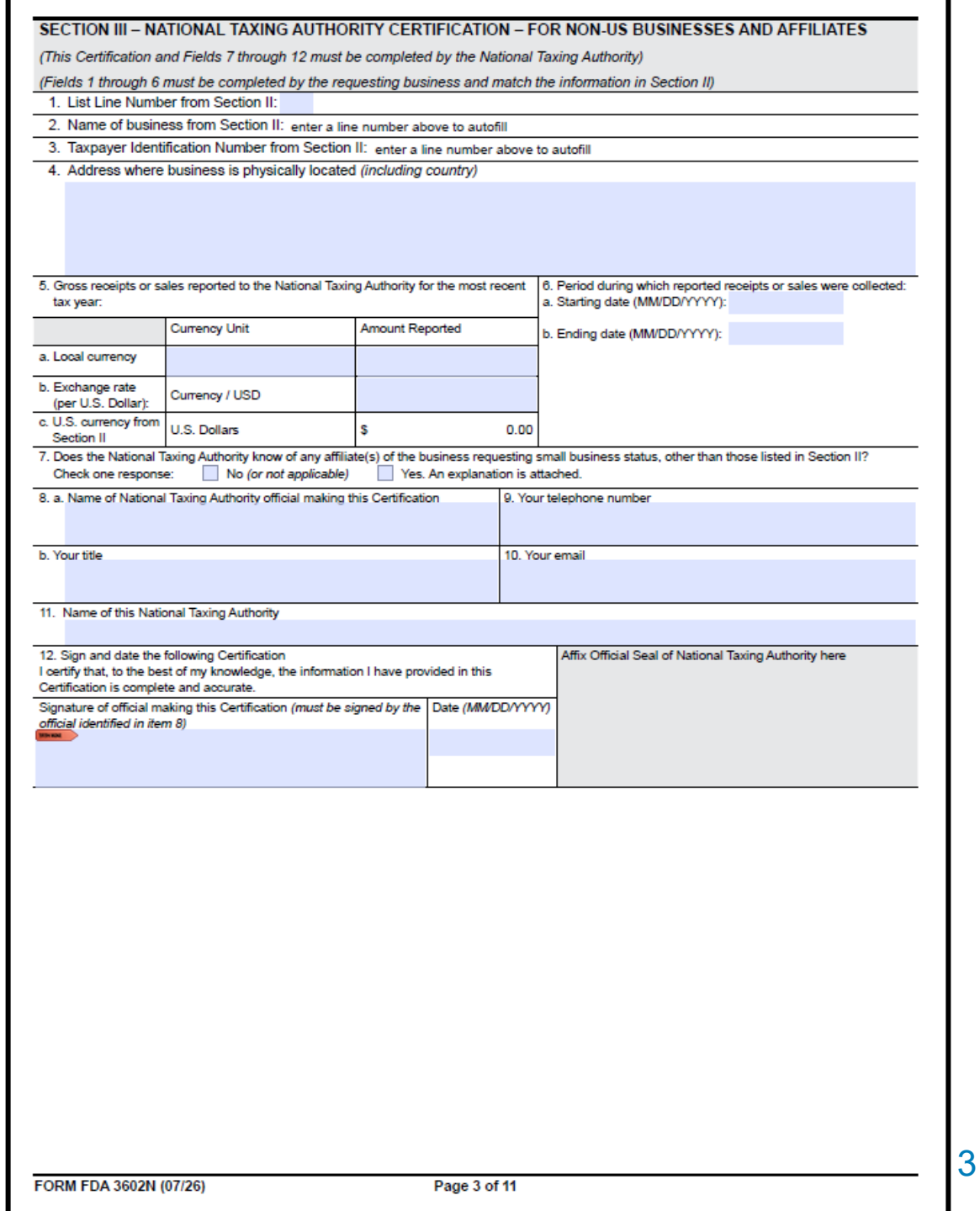


Section III

Section III is the National Taxing Authority (**NTA**) Certification for foreign (non-U.S.) businesses.

A separate certified Section III must be provided for <u>each</u> foreign affiliate.

Find form “3602N” here.



SECTION III – NATIONAL TAXING AUTHORITY CERTIFICATION – FOR NON-US BUSINESSES AND AFFILIATES

(This Certification and Fields 7 through 12 must be completed by the National Taxing Authority)

(Fields 1 through 6 must be completed by the requesting business and match the information in Section II)

1. List Line Number from Section II:
2. Name of business from Section II: enter a line number above to autofill
3. Taxpayer Identification Number from Section II: enter a line number above to autofill
4. Address where business is physically located *(including country)*

5. Gross receipts or sales reported to the National Taxing Authority for the most recent tax year:

	Currency Unit	Amount Reported
a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

6. Period during which reported receipts or sales were collected:
   a. Starting date (MM/DD/YYYY):
   b. Ending date (MM/DD/YYYY):

7. Does the National Taxing Authority know of any affiliate(s) of the business requesting small business status, other than those listed in Section II?
   Check one response: ☐ No *(or not applicable)* ☐ Yes. An explanation is attached.

8. a. Name of National Taxing Authority official making this Certification
9. Your telephone number
   b. Your title
10. Your email
11. Name of this National Taxing Authority

12. Sign and date the following Certification
I certify that, to the best of my knowledge, the information I have provided in this Certification is complete and accurate.

Signature of official making this Certification *(must be signed by the official identified in item 8)*

Date *(MM/DD/YYYY)*

Affix Official Seal of National Taxing Authority here

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Section III

The foreign business should complete Lines 1 – 6.

The foreign business's NTA must complete Lines 7 – 12.

Lines 1 – 3 and 5c must match the foreign business's entry in Section II.

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Section III

All documents in your SBR, including Section III of Form 3602N must be in **English**.

If any document is not in English, provide a **certified English translation** completed by an independent translator who is not affiliated with your company or any affiliate.

You must **include both** the original and English-translated copy in your SBR.

SECTION III – NATIONAL TAXING AUTHORITY CERTIFICATION – FOR NON-US BUSINESSES AND AFFILIATES

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	Currency Unit	Amount Reported
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(This Certification and Fields 7 through 12 must be completed by the National Taxing Authority)

(Fields 1 through 6 must be completed by the requesting business and match the information in Section II)

1. List Line Number from Section II:

2. Name of business from Section II: enter a line number above to autofill

o autofill

Input the **Line Number** (e.g. 1, 2, 3 …) where the foreign business is listed in Section II.

<u>If you manually completed Section II:</u>
Manually write in the line number and the page number to help us identify the correct affiliate from Section II.

5.

6. Period during which reported receipts or sales were collected:
a. Starting date (MM/DD/YYYY):

b. Ending date (MM/DD/YYYY):

a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

7. Does the National Taxing Authority know of any affiliate(s) of the business requesting small business status, other than those listed in Section II?
Check one response: ☐ No *(or not applicable)* ☐ Yes. An explanation is attached.

8. a. Name of National Taxing Authority official making this Certification

9. Your telephone number

SECTION III – NATIONAL TAXING AUTHORITY CERTIFICATION – FOR NON-US BUSINESSES AND AFFILIATES

(This Certification and Fields 7 through 12 must be completed by the National Taxing Authority)

(Fields 1 through 6 must be completed by the requesting business and match the information in Section II)

1. List Line Number from Section II:
2. Name of business from Section II: enter a line number above to autofill
3. Taxpayer Identification Number from Section II: enter a line number above to autofill

Line 2 will auto-populate the **business name** after inputting the Line Number from Section II.

<u>If you manually completed Section II</u>:
Manually write in the business name in the extra space.

5. Period during which reported receipts or sales were collected:
   Starting date (MM/DD/YYYY):
   Ending date (MM/DD/YYYY):

a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

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2. Name of business from Section II: enter a line number above to autofill
3. Taxpayer Identification Number from Section II: enter a line number above to autofill
4. Address where business is physically located *(including country)*

Line 3 will auto-populate the **Taxpayer Identification Number** after inputting the Line Number from Section II.

<u>If you manually completed Section II</u>:
Manually write in the Taxpayer ID Number in the extra space.

5. eceipts or sales were collected:

a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

7. Does the National Taxing Authority know of any affiliate(s) of the business requesting small business status, other than those listed in Section II?
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2. Name of business from Section II: enter a line number above to autofill
3. Taxpayer Identification Number from Section II: enter a line number above to autofill
4. Address where business is physically located *(including country)*

Input the **address** and country where the business is physically located (the address you would give to someone who needs to travel to the business).

5. Gross receipts or sales reported to the National Taxing Authority for the most recent			6. Period during which reported receipts or sales were collected:
			(MM/DD/YYYY):
			MM/DD/YYYY):
a.			
b. (per U.S. Dollar):	Currency / USD		
c. U.S. currency from Section II	U.S. Dollars	$ 0.00	

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

5. Gross receipts or sales reported to the National Taxing Authority for the most recent tax year:

	Currency Unit	Amount Reported
a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

6. P… a. S… b. E…

Input the country's **local currency** and the **amount reported** to the NTA.

7. Does the National Taxing Authority know of any affiliate(s) of the business requesting small business status, other than those listed in Section II?
Check one response: ☐ No *(or not applicable)* ☐ Yes. An explanation is attached.

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	Currency Unit	Amount Reported
a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

6. P
a. S
b. E

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Check one response: ☐ No *(or not applicable)* ☐ Yes. An explanation is attached.

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9. Your telephone number

Input the **exchange rate** used to calculate the business's gross receipts or sales in U.S. dollars (**USD**).

Use the exchange rate from the end date of the period when gross receipts or sales were collected.

The FDA cannot provide exchange rate information—contact the NTA to determine the correct rate to use.

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

5. Gross receipts or sales reported to the National Taxing Authority for the most recent tax year:

	Currency Unit	Amount Reported
a. Local currency		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

6. a. b.

7. Does the National Taxing Authority know of any affiliate(s) of the business requesting small business status, other than those listed in Section II?
Check one response: No *(or not applicable)* Yes. An explanation is attached.

8. a. Name of National Taxing Authority official making this Certification

9. Your telephone number

Line 5c, **U.S. currency**, will auto-populate after inputting the business's Line Number from Section II.

<u>If you manually completed Section II</u>:
Manually write in the gross receipts or sales in USD.

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1. List Line Number from Section II:
2. Name of business from Section II: enter a line number above to autofill
3. Taxpayer Identification Number from Section II: enter a line number above to autofill
4. Address where business is physically located *(including country)*

Input the **start and end dates** when the reported gross receipts or sales were collected.

5. Gross r… tax yea… …ecent		
a. Local c…		
b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

6. Period during which reported receipts or sales were collected:
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b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

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Check one response: ☐ No *(or not applicable)* ☐ Yes. An explanation is attached.

8. a. Name of National Taxing Authority official making this Certification	9. Your telephone number

b. Y

11.

12.
I ce
Certification is complete and accurate.

Signature of official making this Certification *(must be signed by the official identified in item 8)*	Date *(MM/DD/YYYY)*

Foreign Businesses with an NTA:
Submit Section III to the NTA.

The NTA can refer to section VI, *Guidance for Foreign Governments* of the SBD program guidance document for additional information.

If the NTA is unable or unwilling to certify Section III of Form 3602N:

alternative forms of certification will be considered on a case-by-case basis. Such alternative forms must include all the information that would otherwise be reported and certified in Section III of Form 3602N.

Specifically, the certification must but be in English, or accompanied by a certified English translation completed by an independent translator who is not affiliated with your company or any affiliate, and include the following information:

1. The line number from Section II of Form 3602N that the certification relates to;
2. The name of the business as it appears in Section II of Form 3602N;
3. The business's Taxpayer Identification Number as it appears in Section II of Form 3602N;
4. The business's gross receipts or sales for the most recent tax year, reported in both USD (as reported in Section II of Form 3602N) and local currency;
5. The exchange rate used to convert local currency to USD;
6. The specific start and end dates of the period during which the reported receipts or sales were collected; and
7. A certification signed and dated by an official of the relevant NTA bearing the official stamp or seal of the NTA attesting to:
    a) the following information relating to the NTA official making the certification:
        i. Name;
        ii. Telephone number;
        iii. Title;
        iv. Email address;
    b) whether the NTA is aware of any affiliates of the business; and
    c) the information provided is complete and accurate to the best of the certifier's knowledge.

b. Exchange rate (per U.S. Dollar):	Currency / USD	
c. U.S. currency from Section II	U.S. Dollars	$ 0.00

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Check one response: ☐ No *(or not applicable)* ☐ Yes. An explanation is attached.

8. a. Name of

b. Your title

11. Name of

12. Sign and
I certify that, t
Certification i

Signature of
official identif

Foreign Businesses WITHOUT an NTA:

Submit evidence of the business's gross receipts or sales such as:

- end of fiscal year financial statements, or
- shareholder reports, and
- a signed affidavit explaining there is no NTA in your country.

Next Steps:
Section IV, Final Checks, and Submit

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

- CDRH Learn module "Common Submission Errors".

- Submit your SBR 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
14	SBD program guidance document	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination
17	CDRH Learn	https://www.fda.gov/training-and-continuing-education/cdrh-learn
17	CDRH Portal	https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal#CDRHPortal
17	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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U.S. FOOD & DRUG
ADMINISTRATION