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

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. 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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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.

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

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
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		

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

Certifier Initial here:_____

INSTRUCTIONS FOR COMPLETING FORM FDA 3602N

(MDUFA Small Business Request)

Please complete the PDF (Portable Document Format) form and submit it online through the CDRH Portal. Learn more about and access the CDRH Portal at: https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal. Once you have sent this form through the CDRH Portal, you will be able to track the progress of its review.

To complete the form on a computer:

1. Locate the current version of Form FDA 3602N at: http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm
2. Download the form to your computer.
3. Open the saved PDF file using a PDF editing program.
4. Fill out the form by typing directly into the fields on the form.
5. Date and sign the form. Your signature may be electronic or handwritten. For the legal definitions of each type of signature, see 21 CFR 11.3(7) and 21 CFR 11.3(8).
6. Once the form is complete, save or print your copies of Section III and send them to the appropriate National Taxing Authorities for completion, when applicable.
7. Access the CDRH Portal and submit your MDUFA Small Business Request with the completed Form FDA 3602N.

If you cannot complete the PDF on your computer, you may download and print a paper copy of the form, write the information clearly by hand or with a typewriter, and scan the form to create a PDF. Please write all numbers and digits clearly.

For additional information and frequently asked questions, visit the Small Business Determination Program website: 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.

SECTION I – INFORMATION ABOUT THE BUSINESS REQUESTING SMALL BUSINESS STATUS

Form Header

- **Application Fiscal Year.** In the upper right corner of Page 1, please enter the last two-digits of the Fiscal Year (FY) for which the Small Business Request is being submitted.

  Note: The fiscal year is a 12-month period that runs from October 1 through September 30.

  Application for FY 20__

  FY- October 1 through September 30

1. **Name of business requesting MDUFA Small Business status.** Provide the full legal name of the business:
   - If the business is a corporation, limited liability company, partnership, or other legal entity, provide the name used in its articles of incorporation, articles of organization, partnership registration, or other similar instrument filed with the government under whose laws the business was created.
   - If the business is a sole proprietorship owned entirely by one individual, provide the name used when filing income taxes.
   - Note: This name must match the name of the business as shown in the User Fee System under the Organization Number (Org ID) provided in item 2a.
   - Note: If you are preparing this document on behalf of another entity, this is the entity that is receiving the benefit of the reduced fees.
2. **Taxpayer Identification Number.** This is the identification number used by your National Taxing Authority to uniquely identify your business.
   - If the business is headquartered in the United States, provide the Employer Identification Number (EIN) assigned to the business by the U.S. Internal Revenue Service.
   - If the business is headquartered outside the United States, provide the Taxpayer Identification Number assigned by the National Taxing Authority where the business has its headquarters.
   - If the country in which the business is headquartered does not have a National Taxing Authority, enter “No NTA” in this field.

2a. **Organization Number (Org ID).** The Org ID is a system-generated number assigned to a new organization during the User Fee account creation process that uniquely identifies your business in the FDA User Fee Website. See Section VII (Frequently-Asked Questions) of the guidance Medical Device User Fee Small Business Qualification and Determination for instructions on obtaining your Org ID. The Org ID is used by FDA to interact with an organization to ensure proper payment of the organization’s medical device application and registration fees. If this number is incorrect, there could be a delay in processing your Small Business request.

3. **Address where business is physically located.** This is the address where the business is physically located (i.e., the address you would give to a person who needed to travel directly to the business’s primary establishment).
   - Note: This should match the address of the business as shown in the User Fee System under the Organization Number (Org ID) provided in item 2a.
4. **Full name of person Certifying this Small Business Request.** This is the person who is legally responsible for the accuracy and completeness of the information provided in the Certification and who must sign the Certification (see item 12). This is the person FDA will contact for all communications regarding your MDUFA Small Business Request, unless a different Primary Contact is specified in item 8.
5. **Certifier’s telephone number.** This is the telephone number where FDA may reach you if we have a question concerning your MDUFA Small Business Request.
6. **Certifier’s email address.** This is the email address that the FDA will use to communicate with you about your MDUFA Small Business Request and send your decision letter unless a different Primary Contact is specified in item 8. Our primary means of communicating with you is via email, therefore, please make sure your email address is correct and functioning.
7. **Certifier’s mailing address.** This is the address to which FDA would mail any correspondence unless a different Primary Contact is specified in item 8. If your mailing address is the same as item 3, you may check the box, instead of providing the information again in item 7.
   Fill in items 8-11 only if the Primary Contact is different from the Certifier.

8. **Full name of the Primary Contact making this Small Business Request on behalf of the business listed in item 1. above.** This is the individual who has populated the Form FDA 3602N and is advancing this Small Business Request to the FDA. This is also a person FDA will contact for all communications regarding your MDUFA Small Business Request.

9. **Primary Contact's telephone number *(Include country code & area code)*.** This is the telephone number where FDA may reach you if we have a question concerning your MDUFA Small Business Request.

10. **Primary Contact's mailing address.** This is the address to which FDA would mail any correspondence. If your mailing address is the same as item 3, you may check the box instead of providing the information again in item 10.

11. **Primary Contact's email address.** This is the email address that the FDA will use to communicate with you about your MDUFA Small Business Request and send your decision letter. Our primary means of communicating with you is via email, therefore, please make sure your email address is correct and functioning.

12. **The applicant's signature on the Form FDA 3602N in item 12 may be a wet (i.e., ink) signature or a valid digital signature. Complete, sign, and date the following Certification.** In this Certification, you must provide the following information:

    - Check all that apply to indicate whether the business is certifying that they meet the qualifications for each of the named benefits below:
        - **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.
    - The person identified in item 4 ("Name of person Certifying this Small Business Request ") must sign the Certification.
    - For foreign businesses not submitting IRS tax returns, only the head of your business or your chief financial officer may make and sign the statement that the business has submitted National Taxing Authority certifications for all of its affiliates, or that the applicant has no affiliates. See Sections 738(a)(3)(B)(ii)(IV), 738(d)(2)(B)(iii), and 738(e)(2)(B)(iii)
    - Date of the Certification (this is the date you signed the Certification).

SECTION II – INFORMATION ABOUT THE REQUESTING BUSINESS AND ITS AFFILIATES

Section II of the form provides space for listing up to 20 entities; if you have more than 20 entities, you may provide the additional information on one or more additional copies of Section II.

Line 1:

Complete line 1 with information about your business as provided in Section I:

Lines 2 through 20:

List each affiliate on a separate line. For each, you should provide the following information:

A. **Name of Affiliate.** Provide the full legal name of the affiliate:

- **What is an affiliate?** This term is defined by Section 737(13) of the FD&C Act. Affiliate means a business entity that has a relationship with a second business entity (whether domestic or international) if, either directly or indirectly:

  a. one business entity controls, or has the power to control, the other business entity; or

  b. a third party controls, or has the power to control, both of the business entities.

- If the affiliate is a corporation, limited liability company, partnership, or other legal entity, you should provide the name used in its articles of incorporation, articles of organization, partnership registration, or other similar instrument filed with the Nation, State, or other government under whose laws the business was created.
- If the affiliate is a sole proprietorship (that is, it is owned by an individual), you should provide the name used when filing Foreign, Federal (U.S.), State, or other taxes.

B. **Country.** This is the country where the business is physically headquartered.

C. **Taxpayer ID Number.** This number uniquely identifies each business:

- If the affiliate is headquartered in the United States, provide the Employer Identification Number (EIN) assigned to the affiliate by the U.S. Internal Revenue Service.
- If the affiliate is headquartered outside the United States, provide the Taxpayer Identification Number assigned by the National Taxing Authority where the affiliate has its headquarters.
- If the country in which the affiliate is headquartered does not have a National Taxing Authority, enter “No NTA” in this field.

D. **Gross Receipts or Sales.**

- **U.S.-Headquartered Affiliates.** Copy the gross receipts or sales figure directly from the affiliate’s most recent Federal (U.S.) income tax return, and submit the applicable tax form:
  - **Sole proprietors:** Schedule C (Form 1040)
  - **Partnerships:** Form 1065 or Form 1065-B
  - **Corporations:** Form 1120, Form 1120-F (Section II), or Form 1120-S
  - **Tax-exempt organizations:** Form 990.

  Please note that this list is not all-inclusive. You should provide all IRS Forms that contain information on the 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
Any other form	*contact FDA*

- **Non-U.S.-Headquartered Affiliates.** Use the gross receipts or sales figure reported in item 5.c. of the completed National Taxing Authority Certification for the affiliate.
- **Which tax year should I use?** Submit your most recently filed tax return. If you are submitting your Small Business Request before this year’s tax filing due date, you may submit the prior year’s return.
- **If you filed for an extension:** You may submit the most recent tax return filed before the extension. In this scenario, you must also include Form 7004 (Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns) with your application.
- **If you e-filed your tax return:** You must also include Form 8879 (IRS e-file Signature Authorization) with your application. Form 8879 must include the signature, date, and PIN of an officer, partner, or member.

Line 21: Total Gross Receipts or Sales Used to Determine Qualification as a Small Business. This is the sum of the Gross Receipts or Sales shown in column d. of lines 1 through 20. For you to qualify for MDUFA small business fee discounts, this sum must be no more than $100 million (reduced application/report fees), $30 million (first premarket application/report fee waiver), or $1 million (annual registration fee waiver), depending on which of the benefits you are seeking. See Sections 738(a)(3)(B)(ii)(I), 738(d)(1), 738(d)(2)(A), and 738(e)(2)(A) of the FD&C Act.

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

A completed Section III is required for each business and/or affiliate headquartered outside the United States.

What is my National Taxing Authority? Your National Taxing Authority is the government Agency that administers your national income tax. Please contact your national government if you need assistance in identifying and contacting your National Taxing Authority.

How to complete this section:

1. Complete Section I, Section II, and fields 1 through 6 of Section III of your Form FDA 3602N MDUFA Small Business Request.
2. Submit the partially completed form to your National Taxing Authority for completion of fields 7 through 12.
3. Your National Taxing Authority will complete fields 7 through 12 and return the form to you.
4. Submit your completed MDUFA Small Business Request, including all required supporting documentation, through the CDRH Portal: https://fda-cdrh.okta.com/app/fda-cdrh_customercollaborationportal_1/exk5t7i49upPRHASh4h6/sso/saml

Required supporting documents include:

- A true and accurate copy of the most recent Federal (U.S.) income tax return for each business or affiliate headquartered in the United States.
- A completed National Taxing Authority Certification (Section III) for each business or affiliate headquartered outside the United States.

You are responsible for identifying and contacting your National Taxing Authority and for ensuring your completed MDUFA Small Business Request is submitted to FDA before any applicable fee is due. Allow sufficient time for your National Taxing Authority to complete Section III of the form and return it to you to include with your application.

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

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.**

Section IV of the form provides space for listing up to 20 facilities; if you have more than 20 facilities, you may provide the additional information on one or more additional copies of Section IV.

Line 1:

Complete line 1 with information about your business, as provided in Section I:

Lines 2 through 20:

List each affiliate on a separate line. For each, you should provide the following information:

a. **Name of Facility.** Provide the full legal name of the facility as it appears in the Registration and Listing system,

b. **Owner Operator Number OR Registration Number.** This is unique Owner Operator Number or the Registration Number of this entity in the Registration and Listing system, and

c. **Fiscal Year last Registered.** This is the date that you last registered this facility.

Line 21: Have you obtained proof of financial hardship (e.g., evidence of active bankruptcy)? The Annual Registration Fee waiver eligibility criteria requires the certifier to provide proof of financial hardship.

For general device questions, please contact the Division of Industry and Consumer Education at 800-638-2041 or 301-796-7100 or e-mail at DICE@fda.hhs.gov.

Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 1 hour, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

The guidance refers to approved collections of information under sections 738(a)(3), 738(d) and 738(e) of the FD&C Act.
The collections of information in Form FDA 3602N has been approved under OMB Control Number 0910-0508. Current expiration date available at https://www.reginfo.gov.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PRIVACY ACT NOTICE

This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 379i and 379j. FDA will use the information to assess qualification as a small business, collect and process user fee payments, and facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice, to other Federal agencies in response to subpoenas issued by such Agencies, to HHS and FDA employees and contractors to perform user fee services, to the National Archives and Records Administration and General Services Administration for records management inspections, to the Department of Homeland Security and other Federal Agencies and contractors in order to detect or respond to system breaches, to banks in order to process payment made by credit card, to Dunn and Bradstreet to validate submitter contact information, and to other entities, as permitted under the Debt Collection Improvement Act.

Furnishing the requested information is mandatory for a business requesting qualification as a "small business." Failure to supply the information could prevent FDA from processing requests for small business determinations and user fee payments. Additional details regarding FDA's use of information are available online: http://www.fda.gov/regulatoryinformation/foi/default.htm

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the email address below:

"An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov