DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS DETERMINATION REQUEST

OMB No. 0910-XXXX
Expiration Date: Month XX, 20XX
See PRA Statement on Page 4

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 ID Number (Org ID)
4. Full name of person Certifying this Small Business Determination 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.)*	**Designer note:** This form will be made as a "508 compliant" Adobe Acroform PDF with entry fields after FDA (along with OMB, if applicable) gives final approval to this "layout design" version.
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 Determination 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 Determination Request:

I certify that the business, listed in 1. above, has only the affiliates, if any, listed in section II of this Small Business Determination Request, and together with those affiliates have: ***(Check all that apply)***

- ☐ reported total "gross receipts or sales" listed in Section II of no more than $100,000,000 (in U.S. dollars) in its most recent tax year. (Qualifies for reduced premarket submission User Fees)
- ☐ reported total "gross receipts or sales" listed in Section II of no more than $30,000,000 (in U.S. dollars) in its most recent tax year AND have never submitted a premarket application/report. (Qualifies for waived first premarket application/report fee)
- ☐ reported total "gross receipts or sales" listed in Section II of no more than $1,000,000 (in U.S. dollars) in its most recent tax year, AND have proof of financial hardship, AND has paid to register each of your facilities listed in Section IV in a prior year. (Qualifies for waived annual establishment registration fee)

I have attached a true and accurate copy of the business's most recent Federal (U.S.) income tax return, or a Foreign Small Business Certification, for 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 Determination 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)*

PSC Publishing Services (301) 443-6740 EF

SECTION II – INFORMATION ABOUT YOU AND YOUR AFFILIATES

(Must be completed by US and Foreign businesses)

a. Name of Firm	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)			

I have included a separate Section III - National Taxing Authority Certification - for Non-Us Business and Affiliates or a U.S. Federal income tax return for yourself and each of your affiliates.

Certifier Initial here:_____

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

This Certification Must be Completed by the National Taxing Authority (Fields 7 through 12)

(Fields 1 through 6 must be completed by the firm)

(Fields 1 through 3 and 5.b must match entries in Section II)

1. List Line Number from Section II:
2. Name of business from Section II:
3. Taxpayer Identification Number from Section II:
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	$

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

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

No more than $1,000,000 in Section II, Line 21,

AND

Have proof of financial hardship (evidence of active bankruptcy),

AND

Has paid to register each of your facilities below in a prior fiscal 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 (evidence of active bankruptcy).

Certifier Initial here:_____

INSTRUCTIONS FOR COMPLETING FORM FDA 3602N

(MDUFA Small Business Determination Request for Foreign and Domestic Businesses)

Please complete the electronic PDF (portable document format) form and then submit it online through the CDRH Portal. Once you have submitted this form, you will be able to track the progress and status of its review.

If you cannot complete the PDF version on your computer, you may download and print a paper copy of the form, fill out the information in **clear** handwriting or with a typewriter, and scan and convert the image into a PDF. Please take care to write all numbers and digits clearly.

To complete the form with a computer:

A. Locate the current version of Form FDA 3602N at: http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm

B. Download and save the PDF version of the form on your computer.

   i. Open the saved PDF file on your computer (using the Adobe Acrobat PDF reader).

   ii. To complete the appropriate form:

      1. Type directly onto the form.

      2. If you are unable to type directly onto the form.

         a. Go to the top right side of the page and Select “Tool”.

         b. Click on “Content”.

         c. Click on “Add or Edit Text Box”.

   iii. Save the form that you just updated to your computer.

C. Date and sign the form. Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature. 21 CFR 11.3(7). Handwritten signature means the scripted name or legal mark of an individual, handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument, such as a pen or stylus, is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark. 21 CFR 11.3 (8).

D. Once the form is completed, save or print your copies of Section III of the form and route to the appropriate National Taxing Authorities for completion.

E. Access the CDRH Portal and complete submitting your request online.

(Please identify the Fiscal Year for which the Small Business Determination Request is applicable in the upper right section of the header of the form.)

Small Business Certification Request 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.** 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 ID Number (Org ID) provided in 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.

2a. The Organization ID Number (Org ID). 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 Determination 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 ID Number (Org ID) provided in 2a.

4. Full name of person Certifying this Small Business Determination 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 Determination 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 Determination 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 Determination 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 Determination Request on behalf of the business listed in 1. above. This is the individual who has populated the form 3602N and is advancing this Small Business Determination Request to the FDA. This is also a person FDA will contact for all communications regarding your MDUFA Small Business Determination 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 Determination 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 Determination 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 FDA Form 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:
    - reported total "gross receipts or sales" listed in Section II of no more than $100,000,000 (in U.S. dollars) in its most recent tax year. (Qualifies for reduced premarket submission User Fees)
    - reported total "gross receipts or sales" listed in Section II of no more than $30,000,000 (in U.S. dollars) in its most recent tax year AND have never submitted a (list document types). (Qualifies for waived first premarket application/ report fee)
    - reported total "gross receipts or sales" listed in Section II of no more than $1,000,000 (in U.S. dollars) in its most recent tax year, AND have proof of financial hardship, AND has paid to register all of your facilities listed in Section IV in a prior year. (Qualifies for waived annual establishment registration fee.)
- The person identified in item 4 ("Name of person Certifying this Small Business Determination Request ") must sign the Certification.
- Only the head of your firm or your chief financial officer may make and sign the statement that the firm 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 YOU AND YOUR AFFILIATES

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

Line 1:

Complete line 1 with information about your firm 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 firm 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 firm is physically headquartered.

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

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

D. **Gross Receipts or Sales.** For each affiliate headquartered in the United States, you should copy this number from the most recent Federal (U.S.) income tax return for the affiliate. For each affiliate headquartered outside the United States, you should copy the information from item 3.b. of the National Taxing Authority Certification for the affiliate.

- **Where do I find the gross receipts or sales of an affiliate headquartered in the United States?** Your affiliate reported its gross receipts or sales on its most recent Federal (U.S.) income tax return. Please note that the following list is not an all-inclusive list for IRS Forms that may contain information on your gross receipts or sales. You should provide all IRS Forms that contain information on your gross receipts or sales.

IRS Form	See Line Number
Schedule C (Form 1040)	1
Schedule C-EZ (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*

- **What is the most recent tax year of an affiliate headquartered in the United States?** You should submit your most recent tax return. If you submit your Small Business Determination Request prior to the current year's due date for your taxes, you may use the previous year's tax return.

– If you obtained an extension to file your taxes, then you may use your most recent return filed prior to the extension. In this scenario, you should also include your IRS Form 7004: Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns in your application.

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 fees), $30 million (first premarket application/ report fee waiver), or $1 million(registration fee waiver), depending on which of the benefits you are seeking. See Sections 738(a)(3)(B)(ii)(I), 738(d)(2)(A), and 738(e)(2)(A) of the FD&C Act.

Line 22: Have you provided a separate MDUFA Foreign Small Business Determination Request, for a Business Headquartered Outside the United States or a Federal (U.S.) income tax return for each of your affiliates? The Certifier shall initial to certify that they have provided all required proof of gross receipts or sales.

SECTION III – NATIONAL TAXING AUTHORITY CERTIFICATION

After you have completed Section I, Section II, and fields 1-6 of Section III of your MDUFA Small Business Determination Request, you should submit it to your National Taxing Authority.

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.

Your National Taxing Authority is responsible for completing fields 7-12 the National Taxing Authority Certification. You are responsible for identifying and contacting your National Taxing Authority. Your National Taxing Authority can complete Section III and return your completed MDUFA Small Business Determination Request to you. You are responsible for sending your completed MDUFA Small Business Determination Request and all required supporting documentation to FDA.

Once you have completed your Form FDA 3602N, print and sign the form. Mail the completed form and your supporting documentation, including the following, to CDRH's Medical Device User Fee Small Business Determination Request address, which is available at the following website: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm

- a copy of the most recent Federal (U.S.) income tax return for each of your affiliates headquartered in the United States, *and*
- a copy of a MDUFA Small Business Determination Request Section III for each of your foreign affiliates.

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

ONLY complete this section if ALL of the following apply:

- **You have reported no more than $1,000,000 in Section II, Line 21,**
  AND
- **Have proof of financial hardship (evidence of active bankruptcy),**
  AND
- **Has paid to register your listed facilities in any prior fiscal 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 firm, 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 (evidence of active bankruptcy)? The Registration Fee waiver eligibility criteria requires the certifier to provide proof of financial hardship.

If you need assistance, 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 _____ (expires _____).

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 address to the right:

"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