DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA Foreign Small Business Certification Request

For a Business Headquartered Outside the United States

OMB Number 0910-0508
Expiration Date: June 30, 2019
PRA Statement: See next page.

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:
2a. Organization ID Number (Org ID):	3. Address where business is physically located (include country):
4. Name of person making this Small Business Certification Request: Check ***one*** response: ☐ Head of Firm ☐ Chief Financial Officer	5. Your telephone number *(Include country code & area code)*:
6. Your mailing address: ☐ Check if same as item 3.	7. Your email address:

Section II – Information about You and Your Affiliates

	a. Name of Affiliate	b. Taxpayer ID Number	c. Gross Receipts or Sales
1.			$
2.			$
3.			$
4.			$
5.			$
6.	Total Gross Receipts or Sales of All Affiliates *(sum of lines 1 through 5)*		$ 0.00
7.	Gross Receipts or Sales of the Business Making this Small Business Certification Request		$
8.	**Total Gross Receipts or Sales Used to Determine Qualification as a Small Business** *(sum of lines 6 and 7)*		$ 0.00

9. Have you attached a separate MDUFA Foreign Small Business Certification Request *or* a U.S. Federal income tax return for *each* of your affiliates?

Check ***one*** response: ☐ Yes ☐ This business has no affiliates.

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

I certify that _____
Name of business (must be identical to response to item 1)

Check ***one*** response:

☐ has no affiliates and reported "gross receipts or sales" of no more than $100,000,000 (in U.S. dollars) in its most recent tax year.

☐ has only the affiliates listed in this Small Business Certification Request, and together with those affiliates reported total "gross receipts or sales" of no more than $100,000,000 (in U.S. dollars) in its most recent tax year.

I further certify that, to the best of my knowledge, the information I have provided in this Small Business Certification 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 5)*: Date signed:

_____ _____
(MM/DD/YYYY)

Section III – National Taxing Authority Certification

This Certification Must be Completed by the National Taxing Authority

1. Name of business:

2. This business is: Check ***one*** response

☐ The business requesting small business status. *(All of Section I must be completed.)*

☐ An affiliate of a business requesting small business status. *(Items 1 and 2 of Section I must be completed.)*

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

	Currency Unit	Amount Reported
a. Local currency		
b. U.S. currency	U.S. Dollars	$
c. Exchange rate (per U.S. Dollar):		

4. 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.

5. Period during which reported receipts or sales were collected:

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

6. a. Name of National Taxing Authority official making this Certification:

b. Your title:

7. Your telephone number:

8. Your email address:

9. Name of this National Taxing Authority:

10. 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 6)*

Date of this Certification (MM/DD/YYYY):

Affix **Official Seal** of National Taxing Authority here

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 Dun 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 for 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 is available online: http://www.fda.gov/regulatoryinformation/foi/default.htm

U.S. FDA Use Only

Review: ☐ Certification is complete.

☐ Information is not complete.

Decision: ☐ Qualifies for Small Business fee discounts

☐ Qualifies for Small Business fee discounts and fee waiver for first premarket application

SBD _____

☐ Does not qualify

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

Instructions for Completing Form FDA 3602A (MDUFA Foreign Small Business Certification Request, for a Business Headquartered Outside the United States)

Please complete the electronic PDF (portable document format) form.

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

To complete the form with a computer:

1. Locate the Form FDA 3602/3602A at: http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm
2. Download the PDF version of the form and fill it out using your computer.
3. Save file as Adobe Acrobat PDF File on your computer.
4. Open the saved PDF file on your computer.
5. To complete the appropriate form:
   a. Type directly onto the form.
   b. If you are unable to type directly into the form.
      i. Go to the top right side of the page and Select “Tool”.
      ii. Click on “Content”.
      iii. Click on “Add or Edit Text Box”.
6. Save the form that you just updated to your computer.
7. Date and sign the form. You may date and sign the form either using a wet (i.e. ink) or a valid digital signature. 21 CFR 11.3(7) ***Electronic signature*** means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be for the appropriate FY (submissions received by FDA from October 1st, through September 30th for a FY). the legally binding equivalent of the individual's handwritten signature. 21 CFR 11.3 (8) ***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.
8. Once the form is completed, print the form.

Please identify the Fiscal Year for which the Small Business Certification 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.

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. Available at https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref See **Section VII** (Frequently-Asked Questions) of this guidance for instructions on obtaining your Org ID; The Org ID is used by FDA to interact with an organization to ensure proper payment of its medical device applications that require the payment of a user fee. If this number is incorrect there could be a delay in processing your Small Business Certification reduced user fee for an application.

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).

4. **Name of person making this Certification.** This is the person who is responsible for the accuracy and completeness of the information provided in the Certification and who must sign the Certification (see item 10). Only the head of your firm or your chief financial officer may make and sign the Certification; see Sections 738(d)(2)(B)(iii) and 738(e)(2)(B)(iii) of the Federal Food, Drug, and Cosmetic (FD&C) Act. This is also the person FDA will contact for all communications regarding your MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States.

5. **Your telephone number.** This is the telephone number where FDA may reach you if we have a question concerning your MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States.

6. **Your mailing address.** This is the address that FDA will use to mail any correspondence to. If your mailing address is the same as item 3, you may check the box instead of providing the information again in Box 6.

7. **Your email address.** This is the email address that the FDA will use to communicate with you about your MDUFA Small Business Certification 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. If you do not have an email address or provide one that is functioning, we will communicate by standard mail.

Section II – Information about Your Affiliates

Section II of the form provides space for listing up to 5 affiliates; if you have more than 5 affiliates, you may provide the additional information on one or more additional copies of Section II.

Lines 1 through 5:

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 § 737(12) of the FD&C Act. *Affiliate* means a business entity that has a relationship with a second business entity where, 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. **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.

c. **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 Certification Request prior to the current year's due date for your taxes, you may use the previous year's tax return. You may submit your previous years' 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.

6. **Total Gross Receipts or Sales of All Affiliates.** This is the sum of the Gross Receipts or Sales shown in column c. of lines 1 through 5. If you have no affiliates leave blank.

7. **Gross Receipts or Sales of the Business Making this Certification.** This is the gross receipts or sales of the business identified in Section I, item 1, as reported to your National Taxing Authority.

8. **Total Gross Receipts or Sales Used to Determine Qualification as a Small Business.** This is the sum of items 6 and 7. For you to qualify for MDUFA small business for fee discounts, this sum must be ***no more than*** $100 million. See Sections 738(d)(2)(A) and 738(e)(2)(A) of the FD&C Act.

9. **Have you attached a separate MDUFA Foreign Small Business Certification Request, for a Business Headquartered Outside the United States or a Federal (U.S.) income tax return for each of your affiliates?** If you have any affiliates, check the first box ("Yes") *and list them in Section II of the form*. If you do not have any affiliates, check the second box ("This business has no affiliates.").

10. **The applicant's signature on the FDA Form 3602A in box 10 may be a wet (i.e., ink) signature or a valid digital signature. Complete, sign, and date the following Certification.** In this Certification, you should provide the following information:

- The name of the business that is claiming MDUFA Small Business status. This should be identical to your response to item 1.
- Check *one* response to indicate whether the business has any affiliates:
  - Check the first box if the business has no affiliates.
  - Check the second box if the business has only the affiliates you listed in Section II of the form.
- The person identified in item 4 ("Name of person making this Certification") must sign the Certification.
- Date of the Certification (this is the date you signed the Certification).

Section III – National Taxing Authority Certification

After you have completed Sections I and II of your MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States, 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 Section III – National Taxing Authority Certification; you cannot complete this section yourself. You are responsible for identifying and contacting your National Taxing Authority. Your National Taxing Authority should complete Section III, and should then return your completed MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States to you. You are responsible for sending your completed MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States and all required supporting documentation to FDA.

Once you have completed your Form FDA 3602A, 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 Certification 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 an MDUFA Foreign Small Business Certification Request for *each* of your foreign affiliates.

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 2 hours, 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(d) and 738(e) of the FD&C Act. The collections of information in Form FDA 3602 and Form FDA 3602A have both been approved under OMB Control Number 0910-0508 (expires June 30, 2019).

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.