DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MDUFA SMALL BUSINESS CERTIFICATION REQUEST

For a Business Headquartered in 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:

4. Name of person making this Small Business Certification Request:

5. Your telephone number *(include area code)*:
( )

6. Your mailing address: ☐ Check if same as item 3.

7. Your email address:

8. What is your relation (Title) to the business claiming MDUFA Small Business status?

9. Have you listed all of the business's affiliates in Section II of this form?

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

10. Complete, sign, and date the following Certification:

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 on its most recent Federal (U.S.) income tax return. I have attached a true and accurate copy of the business's most recent Federal (U.S.) income tax return.

☐ has only the affiliates listed in this Certification, and together with those affiliates reported total "gross receipts or sales" of no more than $100,000,000 for the most recent tax year. I have attached a true and accurate copy of the entity's most recent Federal (U.S.) income tax return, and a true and accurate copy of the most recent Federal (U.S.) income tax return, or an Foreign Small Business Certification, for each of the entity's affiliates.

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 false information may subject me to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

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

Date of this Small Business Certification Request: _____
(MM/DD/YYYY)

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.		$
7.		$
8.		$
9.		$
10.		$
11.		$
12.		$
13.		$
14.		$
15.		$
16. Total Gross Receipts or Sales of All Affiliates *(sum of lines 1 through 15)*		$ 0.00
17. Gross Receipts or Sales of the Business Making this Small Business Certification Request		$
18. **Total Gross Receipts or Sales Used to Determine Qualification as a Small Business** *(sum of lines 16 and 17)*		$ 0.00

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

FDA Use Only

Review:
- ☐ Information verified
- ☐ Information not verified

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 EMAIL 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 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 Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Instructions for Form FDA 3602
(MDUFA Small Business Certification Request, for a Business Headquartered in 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 directly onto 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:

When completing the Form FDA 3602 please assure the business name is the same name as the business name on your U.S. Federal Tax Form.

- 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 State or other government under whose laws the firm was created.
- If the business is a sole proprietorship owned entirely by one individual, provide the name used when filing Federal, State, or other taxes.

2. **Federal Employer Identification Number.** Your business's Federal Employer Identification Number (EIN) was assigned to you by the U.S. Internal Revenue Service and uniquely identifies your business.

When completing the Form FDA 3602, please ensure the Federal Employer Identification Number matches the Federal Employer Identification Number (EIN) on your tax form.

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). This is also the person FDA will contact for all communications regarding your MDUFA Small Business Qualification and Certification, for a Business Headquartered in 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 Small Business Qualification and Certification, for a Business Headquartered in the United States.

6. **Your mailing address.** This is the address FDA will use to mail any correspondence regarding the **Small Business Certification Request**. 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.

8. **What is your relation to the business claiming MDUFA Small Business status?** Briefly explain your position within the business (*e.g.*, Chief Financial Officer; Vice President; Chief Counsel; or other relationship that gives you authority to provide a MDUFA Small Business Certification Request, for a Business Headquartered in the United States on behalf of the business).

9. **Have you listed all of the business's affiliates in Section II of this form?** 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.").

- **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.

10. **The applicant's signature on the Form FDA 3602 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. Please make sure this agrees with the response in box 9.
  - Check the first box if the business has no affiliates and you have completed box 9 as "This business has no affiliates".
  - Check the second box if the business has only the affiliates you listed in Section II of the form and you have completed box 9 as "Yes".
- Check *one* response to indicate how the business determined it met the requirement that it have "gross receipts or sales" of no more than $100 million:
  - Check the first box if the entity reported "gross receipts or sales" of no more than $100 million on its most recent Federal (U.S.) income tax return. Attach a true and accurate copy (a complete and unaltered copy) of the business's most recent Federal (U.S.) income tax return. *FDA cannot accept a foreign tax return instead of a Federal (U.S.) income tax return.*
- **Where do I find my *gross receipts* or *sales*?** You reported your gross receipts or sales on your 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*

- Check the second box if the business *and* all its affiliates *together* reported "gross receipts or sales" of no more than $100 million on their most recent Federal (U.S.) income tax returns. You should attach a true and accurate copy (a complete and unaltered copy) of the entity's most recent Federal income tax return *and* a true and accurate copy of each affiliate's most recent Federal income tax return.
- **What is the *most recent* tax year?**
  - You should submit your most recent tax return. If you submit your Small Business **Small Business Certification Request** prior to the current year's due date for your taxes, you may submit your 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.
- The person identified in item 4 ("Name of person making this Certification") must sign the Certification.
- Date 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 15 affiliates; if you have more than 15 affiliates, you may provide the additional information on one or more additional copies of Section II.

Lines 1 through 15:

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:

- 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 State or other government under whose laws the firm was created.
- If the affiliate is a sole proprietorship (that is, it is owned entirely by an individual), you should provide the name used when filing Federal, 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 Federal Employer 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. See the instruction for item 9 to learn where you will find this information on a Federal (U.S.) income tax return. 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.

16. **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 15. If you have no affiliates, please enter "0".

17. **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.

18. **Total Gross Receipts or Sales Used to Determine Qualification as a Small Business.** This is the sum of lines 16 and 17. To qualify as a 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.

Once you have completed your Form FDA 3602, print and sign the form. Mail the completed form and your supporting documentation (copies of the Federal (U.S.) income tax returns) to Medical Device User Fee Small Business Certification Request mailing address which is available at the following website, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm577696.htm.

Be sure to include complete, signed copies of all Federal (U.S.) income tax returns and certifications from foreign national taxing authorities that relate to your Certification.

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.