

**FY 2016 MDUFA FOREIGN SMALL BUSINESS
QUALIFICATION AND CERTIFICATION**
For a Business Headquartered Outside the United States

OMB Number 0910-0508
Expiration Date: March 31, 2016
PRA Statement: See page 3.

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:			
4. Name of person making this Certification:		5. Your telephone number (Include country code & area code):	
Check one response: <input type="checkbox"/> Head of Firm <input type="checkbox"/> Chief Financial Officer			
6. Your mailing address: <input type="checkbox"/> Check if same as item 3.		7. Your e-mail 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)	
7.	Gross Receipts or Sales of the Business Making this Certification	
8.	Total Gross Receipts or Sales Used to Determine Qualification as a Small Business (sum of lines 6 and 7)	

9. Have you attached a separate FY 2016 MDUFA Foreign Small Business Qualification and Certification 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 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 (in U.S. dollars) in its most recent tax year.

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 (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 Certification 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: _____

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:

7. Your telephone number:

b. Your title:

8. Your e-mail 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: _____

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

SBD16 _____

- 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:

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

Instructions for Completing Form FDA 3602A for FY 2016 (FY 2016 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States)

You should complete and submit Form FDA 3602A for FY 2016 (FY 2016 MDUFA Foreign Small Business Qualification and Certification) if you wish to be eligible for reduced or waived fees for medical device submissions you make during FY 2016 (submissions received by FDA from October 1, 2015 through September 30, 2016). If you have any affiliates, you should also submit additional supporting documentation:

- 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 FY 2016 MDUFA Foreign Small Business Qualification and Certification for *each* of your foreign affiliates.

FDA will use these materials to decide whether you qualify as a small business within the meaning of MDUFA.

You should mail your FY 2016 MDUFA Foreign Small Business Qualification and Certification and all supporting documentation to FDA at this address:

FY 2016 MDUFA Small Business Qualification
Division of Industry and Consumer Education
10903 New Hampshire Avenue
Building 32, Room 3215
Silver Spring, MD 20993
U.S.A.

If you need assistance, please contact the Division of Industry and Consumer Education at 1-800-638-2041 or 1-301-796-7100.

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.

3. Address where business is physically located. This is the address where the business is physically located (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 can 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 whom FDA will contact for all communications regarding your FY 2016 MDUFA Small Business Qualification and Certification.

5. Your telephone number. This is the telephone number where FDA can reach you if we have a question concerning your FY 2016 MDUFA Small Business Qualification and Certification.

6. Your mailing address. This is the address to which you want FDA to send its decision letter informing you that you are, or are not, a small business. If your mailing address is the same as item 3, you can just check the box rather than repeating the information.

7. Your e-mail address. This is the e-mail address where FDA can reach you if we have a question concerning your FY 2016 MDUFA Small Business Qualification and Certification.

Section II – Information about You and 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 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 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	<i>Please contact FDA.</i>

- **What is the most recent tax year of an affiliate headquartered in the United States?** The most recent tax year will be **2015**, except:

- If you submit your FY 2016 MDUFA Small Business Qualification and Certification *before* April 15, 2016, *and* your affiliate has not yet filed its return for 2015, you may use tax year 2014.
- If you submit your FY 2016 MDUFA Small Business Qualification and Certification *on or after* April 15, 2016, *and* your affiliate has not yet filed your 2015 return because it obtained an extension, you may submit its most recent return filed prior to the extension, provided that you include IRS Form 7004 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.

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. 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.

9. Have you attached a separate FY 2016 MDUFA Foreign Small Business Qualification and Certification or a U.S. Federal 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. 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 FY 2016 MDUFA Foreign Small Business Qualification and Certification, 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 FY 2016 MDUFA Foreign Small Business Qualification and Certification to you. You are responsible for sending your completed FY 2016 MDUFA Foreign Small Business Qualification and Certification and all required supporting documentation to FDA.

