Contains Nonbinding Recommendations

FY 2018 Medical Device User Fee Small Business Qualification and Certification

Guidance for Industry, Food and Drug Administration Staff and Foreign Governments

Document issued on August 29, 2017

As of September 30, 2017, this document supersedes "FY 2017 Medical Device User Fee Small Business Qualification and Certification; Guidance for Industry, Food and Drug Administration Staff and Foreign Governments" dated August 1, 2016.

For questions about this document regarding CDRH-regulated devices, contact CDRH's Division of Industry and Consumer Education at 800-638-2041 or DICE@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2017-N-0007. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 2017 to identify the guidance you are requesting.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach and Development (OCOD) 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993, or by calling 1-800-835-4709 or 240-420-8010, or by e-mail at ocod@fda.hhs.gov or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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Guidance for Industry, Food and Drug Administration Staff, and Foreign Governments

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Medical Device User Fee Amendments (MDUFA) require the payment of a user fee for most types of medical device applications. A business that is qualified and certified as a "small business" is eligible for a substantial reduction in most of these user fees. Application types eligible for reduced small business fee are: Premarket Notification (510(k)), De Novo request, Premarket Applications (Premarket Approval Application [PMA], Biologics License Application [BLA], Product Development Protocol [PDP]), Premarket Report (PMR), PMA/BLA Supplements and PMA Annual Reports, and 513(g) request for classification information. See the full list of eligible application types at the MDUFA User Fees website.[1] This guidance describes the process for how a business may request qualification and certification as a small business.

For purposes of this guidance, note, there should be a National Taxing Authority within the Foreign Government who will be responsible for completion of the appropriate sections of the Form FDA 3602A. In this guidance, we will refer to "Foreign Government" and "National Taxing Authority" interchangeably.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and

[1] http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/default.htm

should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Overview

Information about the process based on your role is described in the following sections of this guidance:

- **for a U.S. Business**:
  - see Section II(B) and Section IV
  - use **Form FDA 3602 for FY 2018**: FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States
  - if you have foreign affiliates, use **Form FDA 3602A,** FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States **for each foreign affiliate**
- **for a Foreign Business**:
  - see Section II(C) and Section V
  - use **Form FDA 3602A for FY 2018**: FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States
- **for a National Taxing Authority**:
  - see Section II(D) and Section VI
  - work with your Foreign Business/Affiliate to complete **Form FDA 3602A for FY 2018**: FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States

As you review this guidance, please follow the instructions and complete the form(s) appropriate for your business.

For additional information about medical device user fees, see FDA's Medical Device User Fees web site at:

http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/default.htm

This site provides an overview of the laws establishing medical device user fees, links to additional guidance documents, answers to frequently-asked questions, and more.

A. Eligibility

To be eligible for a reduced small business fee, you must qualify as a "small business." This is defined as having gross receipts or sales of no more than $100 million for the most recent tax year. If you have any affiliates, you must add their gross receipts or sales

to yours, and the total must be no more than $100 million.[2] More information about the general applicability may be found in **Section III** (Small Business Fees: 2018 Fee Schedule, Benefits and "First Premarket Application" Fee Waiver) and **Section VII** (Frequently-Asked Questions) of this guidance.

The establishment registration fee is not eligible for a reduced small business fee. If the only user fee you expect to pay in FY 2018 is the establishment registration fee (i.e., you do not plan to submit a marketing application requiring a user fee), you receive no benefit from submitting an FY 2018 Small Business Qualification and Certification request. Please do not submit such requests.

Finally, please be advised of the following regarding the scope and eligibility of this Guidance:

- requests for an FY 2018 Small Business status must be received by September 30, 2018;
- a granted FY 2018 Small Business status expires on September 30, 2018; and
- a sponsor must be granted the FY 2018 Small Business status prior to submitting a medical device submission that requires a user fee, if the sponsor wishes to apply any applicable reduction in user fee for that submission.[3]

B. U.S. Businesses

If your business is headquartered in the United States, you should follow the guidance in **Section IV** (Guidance for U.S. Businesses). To qualify as a small business, please complete Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States), and submit the completed form to FDA. Appendix 1 of this guidance contains a copy of Form FDA 3602 and Appendix 2 of this guidance contains instructions for how to complete the form.

If you have any foreign affiliates, please complete Form FDA 3602A for each foreign affiliate (see Appendix 3 for Form FDA 3602A and Appendix 4 for instructions).

C. Foreign Businesses

If your business is a foreign business headquartered outside the United States and does not file a Federal (U.S.) income tax return, you should follow the guidance in **Section V** (Guidance for Foreign Businesses). To qualify as a small business, please follow these sequential steps:

[2] See Sections 738(d)(2)(A) and 738(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
[3] See Section 738(a)(2)(C) of the FD&C Act.

1. You complete Sections I and II of Form FDA 3602A for FY 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States).

2. You submit Form FDA 3602A for FY 2018 to your National Taxing Authority (the equivalent of the U.S. Internal Revenue Service), who then completes Section III of that form (i.e., National Taxing Authority Certification).

3. The National Taxing Authority returns the completed Form FDA 3602A to you.

4. You submit the completed Form FDA 3602A, with Sections I, II, and III fully completed, to FDA for review. Appendix 3 of this guidance includes a copy of Form 3602A and Appendix 4 includes instructions for how to complete this form. In addition, if your business has any foreign affiliates, you must send a separate certified Section III of Form FDA 3602A for each foreign affiliate. If your business has any U.S. affiliates, you must send a Federal U.S. income tax return for each U.S. affiliate.

We recommend that you review **Section VI** (Guidance for Foreign Governments - How to Prepare a National Taxing Authority Certification) to understand the responsibility of your National Taxing Authority and, specifically, Section III of the Form FDA 3602A.

D. National Taxing Authority

If you are a National Taxing Authority, you should review **Section VI (**Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification) for instructions on your responsibilities. Complete Section III for the Form FDA 3602A (National Taxing Authority Certification) submitted to you by a business headquartered in your nation and return the completed form back to the business that sent you the form.

E. Important Note for Submitters of Prior Year(s) Small Business Applications

The process and principles described in the FY 2018 Guidance are substantially similar to the FY 2017 Guidance. Please be advised that starting with FY 2015, FDA has made quality improvements in the program, in areas such as administrative completeness and consistency of documentation. As a result, it is important for FY 2018 applicants to understand the instructions described in this guidance document.

III. Small Business Fees: FY 2018 Fee Schedule, Benefits, and "First Premarket Application" Fee Waiver

This section identifies the 2018 fee schedule, explains the benefits of qualifying as a small business and defines the "first premarket application/report" fee waiver.

A. FY 2018 Fee Schedule

The FY 2018 fees are shown at the FDA MDUFA User Fees[4] website and are set by law.[5] If your application is subject to a fee, the law requires you to pay the standard fee unless FDA determines that you qualify as a small business. If you qualify as a small business for FY 2018, you are eligible to pay a reduced fee for any application types listed at the FDA MDUFA User Fees Website, from the date of FDA's determination of your small business status through the end of FY 2018 (i.e., September 30, 2018).

B. Benefits of Qualifying as a Small Business

If you qualify as a small business, you will pay a lower user fee than the standard fee for applicable submissions [i.e., PMA, PDP, PMA and PDP Supplements (Panel-Track, 180-day, Real-Time and 30-day Notice), Modular PMA, BLA, BLA Efficacy Supplement, 510(k) (Traditional, Abbreviated, and Special), PMR, 513(g) and De Novo request].

C. "First Premarket Application/Report" Fee Waiver

If the FDA determines that you are eligible for a "first premarket application/report" fee waiver, this means that you will be eligible to waive the fee for your first premarket application/report (i.e., PMA, including Modular PMA, BLA, PDP, or PMR). This fee waiver may only be applied once. The "first premarket application/report" is defined as the first PMA (including Modular PMA), BLA, PDP, or PMR received by FDA from a business entity or any of its affiliates. If a second business entity (or any of its affiliates) acquires another business entity that has previously submitted a premarket application/report, then the second business entity is not eligible for a "first premarket application/report" waiver.

To qualify for the "first premarket application/report" fee waiver, you must meet **both** of these criteria:

1. You must qualify as a small business with gross receipts or sales of no more than $30 million, including the gross receipts or sales of all of your affiliates[6].

   Note: This means that some businesses may qualify as a **small business** because their gross receipts or sales are less than $100 million but would not qualify for the **"first premarket application/report" fee waiver** if their gross receipts or sales are more than $30 million.

2. FDA must determine that this is your first premarket application/report (i.e., PMA, including Modular PMA, BLA, PDP, or PMR). Specifically, if you or any affiliate previously submitted a premarket application/report, then your next application does

[4] See the FDA MDUFA User Fees Website located at https://www.fda.gov/forindustry/userfees/medicaldeviceuserfee/ucm452519.htm
[5] See Sections 738(b) and 738(d) of the FD&C Act.
[6] See Section 738(d)(1) of the FD&C Act.

not qualify for the "first premarket application/report" fee waiver, and you must pay the fee that would otherwise apply.

Examples of situations that do not qualify for "first premarket application/report":

A. Business A has an approved PMA and is acquired by Business B. Business B has not submitted a PMA, BLA, PDP or a Modular PMA to FDA. Because Business A has submitted a PMA, Business B is not eligible for the first premarket application/report fee waiver.

B. A business with Name A has submitted a BLA and then changes its name to Name B. Under Name B, the business submits a Modular PMA. This is considered the same Business. The business is not eligible for the first premarket application/report fee waiver.

C. A business submits a PMA that is not approved and then submits a Modular PMA for a different product. The business is not eligible for the first premarket application/report fee waiver because it has already submitted a premarket application regardless of whether it was approved.

IV. Guidance for U.S. Businesses

A U.S. business is a business headquartered in the United States. If you are a U.S. business, you should follow the guidance provided in this section. If your business is headquartered in a foreign country, you should follow the guidance in **Section V** (Guidance for Foreign Businesses).

If you believe you qualify as a small business and want to pay reduced fees or waived fees (for your first premarket application/report), you should submit the following documents to the FDA:

- a completed Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States)
  - include your Organization ID Number (Org ID) in box 2a of FDA Form 3602. Your Org ID is separate and distinct from any other number that may be associated with your company. See **Section VII** (Frequently-Asked Questions) of this guidance for instructions on obtaining your Org ID;
- a copy of your original Federal (U.S.) income tax return for the most recent tax year;
- a separate Federal (U.S.) income tax return for each U.S. affiliate; and
- certified Section III of Form 3602A for each foreign affiliate.

FDA will review your Form FDA 3602 and supporting materials within 60 calendar days. Upon completion of our review, we will send you a letter that indicates whether or not your business has been qualified under MDUFA as a small business. A qualified small

business is then eligible for a reduced or waived fee for submissions made during FY 2018 (i.e., submissions received by FDA from October 1, 2017 through September 30, 2018). If your business is qualified as a small business, FDA's decision letter will assign you a Small Business Decision number. You should provide this number to FDA each time you want to receive a small business fee discount for any of your eligible applications or, if you qualify, when you want to obtain a fee waiver for your first premarket application/report.

What is an affiliate?

The term "affiliate" is defined in Section 737(12) of the FD&C Act. An affiliate means a business entity that has a relationship with a second business entity whether, 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 power to control, both of the business entities.

You must include the gross receipts or sales of all of your affiliates with your own gross receipts or sales when you prepare your Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States).

Why does FDA require me to submit Federal (U.S.) income tax returns?

Sections 738(d)(2)(B) and 738(e)(2)(B) of the FD&C Act require an applicant to pay the standard fees for its submissions *unless* it demonstrates it is a small business by submitting a copy of its most recent Federal (U.S.) income tax returns (and returns of all affiliates). A consequence of this requirement is that you cannot qualify as a small business under MDUFA if you have not submitted a Federal (U.S.) income tax return. Until you file a Federal (U.S.) income tax return, you cannot qualify as a small business and, therefore, the law requires you to pay the standard fee for any medical device application you submit that is subject to a fee. FDA cannot accept a foreign tax return in place of a Federal (U.S.) income tax return.

What is an acceptable copy of Federal (U.S.) income tax returns?
An acceptable copy of Federal (U.S.) income tax returns is an identical signed copy of the entire original Federal (U.S.) income tax returns submitted to the United States Internal Revenue Service (IRS). Please do not include your state tax return only the Federal (U.S) income tax return is needed.

The copy must include the signature and the date of the signature of an officer, partner, or member of the company. Alternatively, you may submit a copy of the e-file form submitted to the IRS, if your documentation includes a dated signature of an officer, partner or member.

What is the most recent tax year?
The most recent tax year will be 2017, with these exceptions:

- If you submit your Form FDA 3602 for FY 2018 and supporting materials *before* April 17, 2018 and you have not yet filed your return for 2017, then you may use tax year 2016.

- If you submit your Form FDA 3602 for FY 2018 and supporting materials *after* April 17, 2018 and you have not yet filed your 2017 return because you obtained an extension, 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.

My organization filed a Form 990, Return of Organization Exempt from Income Tax. Do I still need to qualify as a Small Business?
Yes. The FD&C Act does not exempt you from medical device user fees or grant you automatic small business status simply because you are exempt from Federal (U.S.) income tax. You are subject to the same "gross receipts or sales" thresholds as other applicants. You should report your Total Revenue (line 12 of Form 990) as your "gross receipts or sales."

Where may I obtain a copy of Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States form)?
You may obtain the PDF (portable document format) version of this form at https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm573420.pdf. You may fill in the form using your computer and then print it. A sample copy is included in Appendix 1 of this guidance.

The information you enter on the PDF version of the Certification form is not saved on your computer and is not sent to FDA. You will not be able to "retrieve" or "open" your completed Certification at a later time unless you save it on your computer. After you complete the electronic version of the Certification, *you will need to print the form*, sign it, date it, and send it to FDA with your supporting Federal (U.S.) income tax returns.

Where do I send my completed Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States form) and supporting materials?
Send your completed Form FDA 3602 for FY 2018 and all supporting materials to:

FY 2018 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.

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

May I submit a foreign income tax return to show I am a small business?
No. Under the law, if your business is headquartered in the United States, you must support your claim that you qualify as a small business "by submission of a copy of [your] most recent Federal (U.S.) income tax return for a taxable year, and a copy of such returns of [your] affiliates…" If your business is headquartered in the United States and you have not filed a Federal (U.S.) income tax return, you cannot qualify as a small business under MDUFA. See sections 738(d)(2)(B) and 738(e)(2)(B) of the FD&C Act.

What do I provide if I have a foreign affiliate?
If you have a foreign affiliate, you should submit a separate FY 2018 Foreign Small Business Qualification and Certification (which includes a National Taxing Authority Certification) for that affiliate.

What do I do if the National Taxing Authority does not provide the certification on Section III of Form 3602A?
See answer in Section V below.

V. Guidance for Foreign Businesses

A Foreign business is a business headquartered outside the United States. If you are a Foreign business, you should follow the guidance provided in this section. If your business is headquartered in the United States, you should follow the guidance in **Section IV** (Guidance for U.S. Businesses).

If you are a foreign business and wish to qualify as a small business, please follow these sequential steps:

1. You complete Sections I and II of Form FDA 3602A for FY 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States). Note you need to generate your Organization ID Number (Org ID) and insert this in the proper field in FDA Form 3602A. Your Org ID is separate and distinct from any other number that may be associated with your company. See **Section VII** (Frequently-Asked Questions) of this guidance for instructions on generating the Org ID.

2. You submit Form FDA 3602A for FY 2018 to your National Taxing Authority (the equivalent of the U.S. Internal Revenue Service), who then completes Section III of that form (i.e., National Taxing Authority Certification). Please ensure all appropriate boxes and lines are filled in.

3. The National Taxing Authority returns the updated form to you.

4. You submit the completed Form FDA 3602A, with Sections I, II, and III fully completed, to FDA for review. Note that Appendix 3 and Appendix 4 of this guidance include a copy of Form 3602A and instructions for how to complete this form. In addition, if your business has any foreign affiliates, you must send a separate certified Section III of Form FDA 3602A for each foreign affiliate. If your business has any U.S. affiliates, you must send a Federal (U.S.) income tax return for each U.S. affiliate.

We recommend that you review **Section VI** (Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification) to understand the responsibility of your National Taxing Authority and, specifically, Section III of Form FDA 3602A.

FDA will complete its review of your completed Form FDA 3602A and supporting evidence within 60 calendar days of receipt. Upon completion of our review, we will send you a letter that indicates whether or not your business has been qualified under MDUFA as a small business. A qualified small business is then eligible for a reduced or waived fee for submissions made during FY 2018 (i.e., submissions received by FDA from October 1, 2017 through September 30, 2018). If your business is qualified as a small business, FDA's decision letter will assign you a Small Business Decision number. You should provide this number to FDA each time you want to receive a small business fee discount for any of your eligible applications or, if you qualify, when you want to obtain a free waiver for your first premarket application/report.

What is an affiliate?

The term "affiliate" is defined by Section 737(12) of the FD&C Act. An affiliate means a business entity that has a relationship with a second business entity if, 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 power to control, both of the business entities.

You must include the gross receipts or sales of all of your affiliates with your own gross receipts or sales when you prepare your Form FDA 3602A (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States).

Who is my National Taxing Authority?
Your National Taxing Authority is the government agency that collects your national income tax. Please contact your national government to identify the appropriate point of contact for your National Taxing Authority.

What do I do if the National Taxing Authority does not provide the certification on Section III of Form 3602A for my business or my foreign affiliate?
Form FDA 3602A contains a field for certification from a National Taxing Authority for a foreign business or affiliate, which serves as authentication of the gross sales and receipts for that business/affiliate. FDA expects you to obtain this official certification.

If the National Taxing Authority does not provide the certification, you may provide a written explanation of impossibility for why you were unable to obtain this certification along with Form FDA 3602A. All explanations should include documentation from the National Taxing Authority, in English, of refusal to provide the certification. All explanations are reviewed on a case-by-case basis.

May a foreign applicant file a Federal (U.S.) income tax return in order to qualify as a small business under MDUFA?
Although the law does not prohibit a foreign business from submitting a Federal (U.S.) income tax return, filing a Federal (U.S.) income tax return may have significant tax and other legal consequences beyond simply making you eligible as a small business under MDUFA. FDA cannot provide advice regarding whether you should or should not file a Federal (U.S.) income tax return. If you are in doubt as to whether it is advisable for you to file a Federal (U.S.) income tax return, you should consider consulting with qualified legal and tax professionals. Additional information on Federal (U.S.) income taxation is available from the United States Internal Revenue Service (www.irs.gov).

Where may I obtain a copy of FDA Form 3602A (FY 2018 MDUFA Foreign Small Business Qualification and Certification form)?
You may obtain the portable document format (PDF) version of this form at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573423.pdf. You may fill in the form using your computer and then print it. Instructions for completing this form are included in Appendix 3 of this guidance.

The information you enter on the PDF version of the Certification form is not saved on your computer and is not sent to FDA. You will not be able to "retrieve" or "open" your completed Certification at a later time unless you save it on your computer. After you complete the electronic version of the Certification, *you will need to print the form,* sign

it, date it, and send it to FDA with your documentation from your National Taxing Authority.

Your National Taxing Authority should complete Section III (National Taxing Authority Certification) of Form FDA 3602A and return the form to you. You should then send Form FDA 3602A, with Sections I, II, and III fully completed and all supportive materials to FDA.

Where do I send my completed Form FDA 3602A for FY 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification form) and supporting materials?
Send your completed Form FDA 3602A for FY 2018, with Sections I, II, and III fully completed, and all supporting materials to:

FY 2018 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.

VI. Guidance for Foreign Governments – How to Prepare a National Taxing Authority Certification

Qualification as a MDUFA small business allows the business to pay reduced medical device user fees. Some small businesses may also qualify to obtain a waiver of the fee for its first premarket application/report. Prior to enactment of the Medical Device User Fee Amendments of 2007, very few foreign businesses could qualify as a small business under MDUFA because the law required the business to submit a Federal (U.S.) income tax return as the only acceptable evidence that its "gross receipts or sales" did not exceed $100 million.

The Medical Device User Fee Amendments of 2007 provide an alternative means for a foreign business to demonstrate that it qualifies as a MDUFA small business. Instead of providing a Federal (U.S.) income tax return, a foreign business may now obtain a certification from its "National Taxing Authority" showing that its gross receipts or sales do not exceed the $100 million qualification threshold. The law requires that this certification, referred to as the "National Taxing Authority Certification," must:

- be in English;
- be from the National Taxing Authority of the country in which the business is headquartered;

- provide the business's gross receipts or sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in converting local currency to U.S. dollars;
- provide the dates during which the reported receipts or sales were collected; and
- bear the official seal of the National Taxing Authority.

See Sections 738(d)(2)(B)(iii) and 738(e)(2)(B)(iii) of the FD&C Act.

Form FDA 3602A for FY 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States) provides space for this required information in Section III — National Taxing Authority Certification.

May the National Taxing Authority Certification be provided in any language other than English?
No. Sections 738(d)(2)(B)(iii)(II) and 738(e)(2)(B)(iii)(II) of the FD&C Act require the certification to be in English.

What are "gross receipts or sales"?
If you are unsure how "gross receipts or sales" relate to your national income taxation system, please contact the United States Internal Revenue Services through the United States Embassy.

What information should the business submit to the National Taxing Authority?
The business should send you a Form 3602A for FY 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States), with Section I and II fully completed. Each National Taxing Authority may require the business to provide additional information and evidence needed by the National Taxing Authority to determine the gross receipts or sales it will report in the National Taxing Authority Certification for the business.

What exchange rate should be used to convert local currency to U.S. dollars?
You should use the exchange rate in effect as of the ending date of the period during which the reported receipts or sales were collected; this is the date shown in response to item 5.b. of the National Taxing Authority Certification. FDA cannot provide this information to you; each National Taxing Authority is responsible for determining the appropriate exchange rate to use.

Why does FDA require the National Taxing Authority Certification to bear the official seal of the National Taxing Authority?
This is a statutory requirement. Sections 738(d)(2)(B)(iii)(II) and 738(e)(2)(B)(iii)(II) of the FD&C Act require the National Taxing Authority Certification to bear the official seal of the National Taxing Authority.

VII. Frequently Asked Questions

What is the purpose of a Small Business Decision number?
The Small Business Decision number is used by FDA to confirm that you have been qualified as a small business and may receive the appropriate user fee reduction or waiver when you submit an application that requires a user fee (as described at the FDA MDUFA User Fees website[7]). You should use your Small Business Decision number to document that you have qualified as a small business for FY 2018. You should include your Small Business Decision number when you submit a Medical Device User Fee Cover Sheet (Form FDA 3601) with an application.

When will my status as a small business begin?
Your status as a small business will begin on the date of FDA's decision letter which qualified you as a small business.

When will my status as a small business expire?
Your status as a small business will expire on September 30, 2018. You should submit a new MDUFA Small Business Qualification and Certification each year to qualify as a small business. This is because:

- Your "gross sales and receipts" will vary from one year to another.
- We will always need a copy of your most recent Federal (U.S.) income tax return (if you are a U.S. business) or your most recent certification of income from your national taxing authority (if you are a foreign business).

What is an Organization ID Number (Org ID)?
The Organization ID Number (Org ID) uniquely identifies your business in the FDA User Fee Website. The Org ID is a system-generated number assigned to a new organization during the account creation process. It is not the same as the Federal Employer Identification Number, Registration Number, or Taxpayer Identification Number. 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 you are a registered company, you should already have an organization ID number. You should use this one - do not create a new one.

Your Org ID may be found in the Profile section, under Business Information on the User Fee System MDUFA screen. Follow these instructions to obtain your organization number:

1. Login to the User Fee System MDUFA screen and enter a valid user name and

[7] See https://www.fda.gov/forindustry/userfees/medicaldeviceuserfee/ucm452519.htm.

password to sign into the Medical Device User Fee Website. Located at: https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp?legalsel=2&ref=.

2. Click the "Go" button for the Medical Device User Fee (MDUFA Cover Sheets (e.g., PMA, De Novo, 510(k), etc.)) option, under the Cover Sheets section.
3. Click the Profile icon located on the top of the page.
4. You will see Business Information under the Details tab. The organization ID number is listed below the organization name.

If your company has never paid a user fee, you should create a new User Fee System account. See the FDA User Fee System (UFS) Account Creation Desk Guide located at: https://userfees.fda.gov/OA_HTML/mdufa_account_creation.pdf for detailed instructions.

If you forgot your user name and/or password or a message displays "Invalid username and/or password" while attempting to login, you may retrieve your user name and/or password online by returning to the User Fee System website and clicking on the "Forgot User Name/Password?" link. You will need to enter your user name and/or email address and then click on the "email My Password" button. If the email address or username is valid, a temporary password will be sent to the user with the requested information. If the message "We're sorry, but we haven't been able to locate your account information" is displayed, you should create a new User Fee account.

Please contact the User Fee Helpdesk at userfees@fda.gov or (301) 796-7200 if you need assistance obtaining your Organization ID Number (Org ID) or there are any issues with your account. Be prepared to provide your organization name and address.

What fee should I pay if I submit an application before FDA determines that I qualify as a small business?

If you submit an application before FDA has qualified you as a small business, you should pay the standard (full) amount of any fee that applies. FDA will **not** refund the difference between the standard (full) fee and the small business fee if you later qualify as a small business. If you want to pay the small business fee for an application, you should not submit your application until you obtain your Small Business Decision number from FDA.

May an applicant request a small business determination for a prior fiscal year?

No, Section 738(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act states that all device user fees are due upon submission of device reports (such as PMA annual report) or device applications. A company must pay the fees before submitting their reports or applications. The process requires an applicant to first submit (and receive) the small business designation, and then submit any user fee-requiring applications in order to obtain the reduced fee. We have no provision for an applicant to retroactively request a

small business status for a prior fiscal year.

What may happen if I submit a false certification concerning my business?
When you make your certification, you are explicitly certifying:

> ". . . 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."

This statement appears immediately above your signature.

A false certification is one where you report information that is *not true* (for example, your gross receipts or sales are actually higher than you state) or if you *fail to disclose* required information (for example, you fail to disclose the existence of a parent, partner, or affiliate).

If FDA determines you submitted a false certification, we may suspend your status as a Small Business, we may suspend the review of any application you submitted until you pay the full fee that applies to that type of application, we may seek payment of the unpaid portion of fees that should have been paid, we may take other legal actions that are appropriate under the circumstances, and you may be subject to criminal penalties under 18 U.S.C. § 1001 and other applicable federal statutes.

If I have a question, whom may I ask?
If you need additional information about becoming a MDUFA small business, contact FDA's Division of Industry and Consumer Education by email at DICE@fda.hhs.gov or by phone at 800-638-2041 or 301-796-7100.

VIII. Appendix — Forms and Instructions

This appendix includes several references for use with this guidance:

#	Document	Instruction
1	**Form FDA 3602 for FY 2018** (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States)	Use this form if your business is headquartered in the U.S.
2	**Instructions for Form FDA 3602 for FY 2018** (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States)	These are instructions to complete Form FDA 3602 for FY 2018 (from Appendix 1).
3	**Form FDA 3602A for FY 2018** (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered	Use this form if your business is headquartered outside the U.S.

	Outside the United States)	
4	**Instructions for Form FDA 3602A for FY 2018** (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States)	These are the instructions to complete Form FDA 3602A for FY 2018 (from Appendix 3).

Overall Instructions

Select the proper form that applies to your business and fill out and complete the form using a pen/typewriter or using a computer. See instructions for each below.

Using a pen/typewriter

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.

Using a computer

To complete the form with a computer: (1) Fill out the form electronically and then (2) print out the form.

(1) **Fill out the form electronically**

Download a PDF (portable document format) version of this form and fill it out using your computer. You may date and sign the form either using a wet (i.e. ink) or a valid digital signature.[8] The PDF version is available at:

http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm

(2) **Print out the Form**

Follow these instructions to print the electronically-completed form:

Instructions

1. Download the form by visiting above link.
2. Save it as a PDF file onto your computer.
3. Open the saved PDF file on your computer.
4. Go to the top right side of the page and Select “Tool”.

[8] 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 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.

5. Click on “Content”.
6. Click on “Add or Edit Text Box”.
7. Type directly onto the form.
8. Print the form when completed.

The information you enter on the PDF version of the Certification form is not saved on your computer and is not sent to FDA. You will not be able to “retrieve” or “open” your completed Certification at a later time. After you complete the electronic version of the Certification, *you should print the form*, date and sign the form either a wet (i.e., ink) or a valid digital signature and send in to FDA with your supporting documentation.

1: Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States)

Department of Health and Human Services
Food and Drug Administration

FY 2018 MDUFA Small Business Qualification and Certification

For a Business Headquartered in the United States

OMB No. 0910-0508
Expiration Date: June 30, 2019
PRA Statement: See next page.

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 Certification:

5. Your telephone number (include area code):

_____
Area Code Telephone Number

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 FY 2018 Foreign Small Business Qualification 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 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 of this Certification: _____ (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)	$
17	*Gross Receipts or Sales of the Business Making this Certification*	$
18	*Total Gross Receipts or Sales Used to Determine Qualification as a Small Business* (sum of lines 16 and 17)	$

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/PrivacyAct/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

SBD18_____

□ 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

2: Instructions for Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States)

You should complete and submit Form FDA 3602 for FY 2018 (FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States) if you wish to be eligible for reduced or waived fees for medical device submissions you make during FY 2018 (submissions received by FDA from October 1, 2017 through September 30, 2018).

You should also submit:

- a copy of your most recent Federal (U.S.) income tax return, *and*
- if you have any affiliates:
    - a copy of the most recent Federal (U.S.) income tax return of *each* of your domestic (U.S.) affiliates, *and*
    - a copy of a FY 2018 MDUFA Foreign Small Business Qualification and Certification for *each* of your foreign affiliates

See Sections 738(d)(2) and 738(e)(2) of the FD&C Act.

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

You should mail your FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States and copies of the Federal (U.S.) income tax returns that support your Certification, to FDA at this address:

FY 2018 MDUFA Small Business Qualification
Division of Industry and Consumer Education
10903 New Hampshire Avenue
Building 32, Room 3215
Silver Spring, MD 20993

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.

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) uniquely identifies your business in the FDA User Fee Website. The Org ID is a system-generated number assigned to a new organization during the account creation process. It is not the same as the Federal Employer Identification Number, Registration Number, or Taxpayer Identification Number. See **Section VII** (Frequently-Asked Questions) of this guidance for instructions how to obtain an 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.

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 FY 2018 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 FY 2018 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 application. 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 FY 2018 MDUFA Small Business Qualification and Certification 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 e-mail 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 an FY 2018 MDUFA Small Business Qualification and Certification, 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 Federal Food, Drug, and Cosmetic 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 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 of its affiliates *together* reported "gross receipts or sales" of no more than $100 million on their most recent Federal income tax returns. You should attach a true and accurate copy (a complete and unaltered copy) of the entity's most recent Federal (U.S.) 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?
  The most recent tax year will be 2017, except:
  - If you submit your FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States before April 17, 2018 and you have not yet filed your return for 2017, you may use tax year 2016.

  - If you submit your FY 2018 MDUFA Small Business Qualification and Certification, for a Business Headquartered in the United States on or after April 17, 2018 and have not yet filed your 2017 return because you obtained an extension, you may submit your most-recent return filed prior to the extension, provided that you 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 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 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 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.

3: Form FDA 3602A for FY 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States)

Contains Nonbinding Recommendations

Department of Health and Human Services *Food and Drug Administration* **FY 2018 MDUFA Foreign Small Business Qualification and Certification** *For a Business Headquartered Outside the United States*	OMB No. 0910-0508 Expiration Date: June 30, 2019 PRA Statement: See next page.

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 Certification: Check *one* response: □ Head of Firm □ Chief Financial Officer	5. Your telephone number: (include country code and 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)		$
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 2018 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: _____ Date signed: _____
(Signature of the person identified in item 4) (MM/DD/YYYY)

Contains Nonbinding Recommendations

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/PrivacyAct/default.htm

(U.S. FDA Use Only)

Review: □ Certification is complete. □ Information not complete.

Decision: □ Qualifies for Small Business fee discounts. □ Qualifies for Small Business fee discounts and fee waiver for first premarket application.

SBD18_____

□ 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

4: Instructions for Completing Form FDA 3602A for FY 2018 (FY 2018 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 2018 (FY 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States) if you wish to be eligible for reduced or waived fees for medical device submissions you make during FY 2018 (submissions received by FDA from October 1, 2017 through September 30, 2018). 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 2018 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 2018 MDUFA Foreign Small Business Qualification and Certification, for a Business Headquartered Outside the United States and all supporting documentation to FDA at this address:

FY 2018 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 or e-mail at DICE@fda.hhs.gov.

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) uniquely identifies your business in the FDA User Fee Website. The Org ID is a system-generated number assigned to a new organization during the account creation process. It is not the same as the Federal Employer Identification Number, Registration Number, or Taxpayer Identification Number. See **Section VII** (Frequently-Asked Questions) of this guidance for instructions to obtain an 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.

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 FD&C Act. This is also the person FDA will contact for all communications regarding your FY 2018 MDUFA Foreign Small Business Qualification and Certification 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 FY 2018 MDUFA Foreign Small Business Qualification and Certification 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 FY 2018 MDUFA Small Business Qualification and Certification 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 e-mail 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 Federal Food, Drug, and Cosmetic 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 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 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. 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? The most recent tax year will be 2017, except:

    - If you submit your FY 2018 MDUFA Foreign Small Business Qualification and Certification for a Business Headquartered Outside the United States before April 17, 2018 and your affiliate has not yet filed its return for 2017, you may use tax year 2016.

    - If you submit your FY 2018 Foreign MDUFA Small Business Qualification and Certification for a Business Headquartered Outside the United States on or after April 17, 2018 and your affiliate has not yet filed its 2017 return because it obtained an extension, you may submit its most-recent return filed prior to the extension, provided that you include your Application for Automatic Extension of Time To File Certain Business Income Tax, Information, and Other Returns (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. 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 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 2018 MDUFA Foreign Small Business Qualification and Certification, 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 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 2018 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 FY 2018 MDUFA Foreign Small Business Qualification and Certification for a Business Headquartered Outside the United States to you. You are responsible for sending your completed FY 2018 MDUFA Foreign Small Business Qualification and Certification for a Business Headquartered Outside the United States and all required supporting documentation to FDA.

IX. 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:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
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.