Guidance for Industry, FDA, and Foreign Governments:

FY 2009 Medical Device User Fee Small Business Qualification and Certification

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This document supersedes "Guidance for Industry, FDA, and Foreign Governments: FY 2008 Medical Device User Fee Small Business Qualification and Certification," October 17, 2007.

OMB control numbers 0910-0508 (expires December 31, 2010)
and 0910-0613 (expires May 31, 2011).
See additional PRA statement at the end of this guidance.

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

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to —

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Please identify your comments with the docket number listed in the notice of availability that publishes in the Federal Register announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance, contact —

Mr. Gene Allen
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Additional copies are available from the Internet at: www.fda.gov/cdrh/mdufma/guidance. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (2009) to identify the guidance you are requesting.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at —

www.fda.gov/cdrh/ombudsman

Additional Information About Medical Device User Fees

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

www.fda.gov/cdrh/mdufma

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.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance explains how your business may qualify as a "small business" and pay most FY 2009 medical device user fees at substantially discounted rates; if you qualify as a small business, you may also qualify to obtain a one-time waiver of the fee for your first (ever) premarket application (premarket approval application, biologics license application, product development protocol, or premarket report). The standard and small business fees for FY 2009 are shown in the table on p. 4.

Your business may qualify as a small business if you reported "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. Section I, Benefits of Qualifying as a Small Business, and Section V, Frequently-asked Questions, provide information of general applicability.

If your business if headquartered in the United States, you should follow the guidance in Section II, Guidance for U.S. Businesses, beginning at p. 6. You will complete an FY 2009 MDUFMA Small Business Qualification and Certification, Form FDA 3602 (for FY 2009), and submit it to FDA for review; a copy of this form and instructions for its completion are provided in the Appendix. FDA will review your Small Business Qualification Certification within 60 days of receipt.

If your business is a foreign business headquartered outside the United States, you should follow the guidance in Section III, Guidance for Foreign Businesses, beginning at p. 9. To qualify as a small business, you should complete Section I and II of an FY 2009 MDUFMA Foreign Small Business Qualification and Certification, Form FDA 3602A (for FY 2009), and submit it first to your National Taxing Authority (the equivalent of the U.S. Internal Revenue Service), and after the National Taxing Authority has returned the form to you with Section III completed (providing a National Taxing Authority Certification concerning your business), you should then submit the 3602A to FDA for review; a copy of this form and instructions for its completion are

provided in the Appendix. You should also review Section IV, Guidance for Foreign Governments — Preparation of a National Taxing Authority Certification, to understand the role played by your national taxing authority (particularly regarding Section III of the 3602A, which provides the National Taxing Authority Certification concerning the information you intend to submit to FDA). FDA will review your Small Business Qualification Certification within 60 days of receipt.

If you are a National Taxing Authority, you should review the guidance provided in Section IV, Guidance for Foreign Governments — Preparation of a National Taxing Authority Certification; you will complete Section III, National Taxing Authority Certification, of each 3602A submitted to you by a business headquartered in your nation, which you should return to the business seeking small business status.

Important Changes to the FY 2009 Guidance

This guidance provides improved instructions for completing the FY 2009 MDUFMA Foreign Small Business Qualification and Certification; the instructions immediately follow the form, in the Appendix (the Appendix begins at p. 15).

Where necessary, we have changed the dates cited throughout the guidance to reflect those that apply to the new fiscal year. We have also updated the information on standard and small business fees to reflect the new fee rates for FY 2009 (see the table on p. 4).

Enactment of the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007 ("the 2007 Amendments") created additional types of fees and has led to several important changes in how you qualify as a small business for FY 2009. The following considerations are particularly significant:

- The guidance explains that there is no small business discount for the new establishment registration fee. See section I of the guidance, p. 3. If this is the only fee you expect to pay during FY 2009, *you should **not** submit* an FY 2009 Small Business Qualification Certification.
- A foreign business may qualify as a small business, even if you have not submitted a Federal (U.S.) income tax return. See section III, p. 9.
- Guidance is provided for foreign governments, explaining how to prepare a "National Taxing Authority Certification" for a foreign business that is trying to qualify as a MDUFMA small business. See section IV, p. 11.

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

I. Benefits of Qualifying as a Small Business

What are the benefits of qualifying as a small business under MDUFMA?

If you qualify as a small business, you will be able to pay significantly lower user fees than you would otherwise pay:

- You may pay reduced small business fees instead of the standard fees. If you qualify as a small business, you will be eligible to pay a reduced fee for —
  - each of your medical device submissions that is subject to a user fee;
  - each of your class III devices that is subject to periodic reporting.

  To pay a reduced small business fee, you must qualify as a small business with gross receipts or sales of no more than $100 million, including the gross receipts or sales of all of your affiliates. See sections 738(d)(2)(A) and 738(e)(2)(A) of the Act.

- You may obtain a one-time waiver of the fee for your first (ever) premarket application (premarket approval application, biologics license application, product development protocol, or premarket report). To qualify for this fee waiver, 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. See section 738(d)(1) of the Act.

Is there a reduced small business fee for the new establishment registration fee? No. Every establishment that is subject to the registration fee will pay the same fee. If the registration fee is the only fee you expect to pay during FY 2009, you should not submit an FY 2009 Certification.

What are the standard and small business fees for FY 2009? The fees for FY 2009 are shown in the following table, and are set by law. If your submission is subject to a fee, the law requires you to pay the standard fee unless FDA determines you qualify as a small business. If you qualify as a small business for FY 2009, you are eligible to pay a reduced fee for any submissions or reporting from the date of FDA's determination through the end of FY 2009.

Medical Device Fees for FY 2009		
Fees Relating to Medical Device Applications		
Application Type	**Standard Fee**	**Small Business**
Premarket Application (PMA, BLA, PDP)	$200,725	$50,181
Premarket report (for a reprocessed single-use device)	$200,725	$50,181
Panel-track PMA supplement	$150,544	$37,636
BLA efficacy supplement	$200,725	$50,181
180-day PMA supplement	$30,109	$7,527
Real-time PMA supplement	$14,051	$3,513
510(k) premarket notification	$3,693	$1,847
30-day notice	$3,212	$1,606
513(g) request for classification information	$2,710	$1,355
Annual fee for periodic reporting on a class III device	$7,025	$1,756
Establishment Registration Fee — There is *no reduced fee for a small business*. If this is the only fee you expect to pay during FY 2009, you should not submit an FY 2009 Certification.		
Type of Fee	**Annual Fee**	
Establishment registration fee	$1,851	

Who can qualify as a small business under MDUFMA? Both domestic (U.S.) and foreign businesses may qualify as a small business. For FY 2009, you can qualify for small business fee discounts if you reported *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. See sections 738(d)(2)(A) and 738(e)(2)(A) of the Act. If your gross receipts or sales are no more than $30 million (including the gross receipts or sales of all of your affiliates), you will also qualify for a waiver of the fee for your *first* (ever) premarket application (PMA, BLA, PDP, or Premarket Report). See section 738(d)(1) of the Act.

How can I obtain an FDA decision that I am a small business for FY 2009? The qualification process depends on whether you are a domestic (U.S.) or foreign business:

- If you are a domestic business headquartered in the United States, you should submit an FY 2009 MDUFMA Small Business Qualification Certification (Form FDA 3602) and copies of your most-recent Federal (U.S.) income tax returns directly to FDA. You

should also submit a Federal (U.S.) income tax return or an FY 2009 MDUFMA Foreign Small Business Qualification Certification for each of your affiliates. See Section III, p. .

- If your business is headquartered in a foreign country, you will first submit your evidence of qualification to the National Taxing Authority of the country in which you are headquartered. The National Taxing Authority is responsible for determining your gross receipts or sales in U.S. dollars and will provide the National Taxing Authority Certification that you will send to FDA as part of your FY 2009 MDUFMA Foreign Small Business Qualification Certification. You should also submit a Federal (U.S.) income tax return or an FY 2009 MDUFMA Foreign Small Business Qualification Certification for each of your affiliates. See Section III, p. 9.

When does my premarket application qualify for the "first premarket application" fee waiver? There are two important considerations here. First, your gross receipts or sales (including your affiliates) must be no more than $30 million. See section 738(d)(1) of the Act. This means that some firms that *do* qualify for small business fee discounts (because their gross receipts or sales are less than $100 million) will *not* qualify for the "first premarket application" fee waiver (because their gross receipts or sales are more than $30 million).

Second, you should count prior premarket applications made by your affiliates when determining whether a premarket application is your "first." If you *or any affiliate* previously submitted a premarket application, your application does *not* qualify for the fee waiver, and you must pay the fee that would otherwise apply.

II. 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 III., Guidance for Foreign Businesses.

If you believe you qualify as a small business and want to pay reduced or waived fees, you should submit an FY 2009 MDUFMA Small Business Qualification Certification, Form FDA 3602 (for FY 2009), with your Federal income tax return for the most recent tax year, and the Federal income tax returns of each of your affiliates for the most recent tax year. FDA will review your Certification and Federal income tax returns within 60 days and will send you our decision that you are, or are not, a small business eligible for reduced or waived fees for submissions you make during FY 2009 (submissions received by FDA from October 1, 2008 through September 30, 2009). If we decide you are a small business, our decision letter will assign you a Small Business Decision number. You should provide this number to FDA each time your want to receive a small business fee discount for a premarket submission or when you want to obtain a fee waiver for your first premarket application.

What is an affiliate? This term is defined by section 737(12) of the Federal Food, Drug, and Cosmetic Act. 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 Medical Device User Fee Small Business Qualification Certification. See sections 738(d)(2)(A) and 738(e)(2)(A) of the Act.

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 Federal Food, Drug, and Cosmetic 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 income tax returns (and returns of all affiliates). A consequence of this requirement is that you cannot qualify as a small business under MDUFMA if you have not submitted a Federal income tax return. Until you file a Federal income tax return, you can not 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 the most recent tax year? The most recent tax year will be 2008, except —

- If you submit your FY 2009 MDUFMA Small Business Qualification *before* April 15, 2009 and you have not yet filed your return for 2008, you may use tax year 2007.
- If you submit your FY 2009 MDUFMA Small Business Qualification *after* April 15, 2009 and you have not yet filed your 2008 return because you obtained an extension, you may use your most-recent return filed prior to the extension.

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 Federal Food, Drug, and Cosmetic Act does not exempt you from medical device user fees or grant you automatic small business status simply because you are exempt from Federal 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."

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 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 MDUFMA. See sections 738(d)(2)(B) and 738(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act. If you have a foreign affiliate, you should submit a separate FY 2009 Foreign Small Business Qualification Certification (which includes a National Taxing Authority Certification) for that affiliate; see section III for guidance concerning foreign businesses.

Where can I obtain a copy of the *FY 2009 Medical Device User Fee Small Business Qualification Certification* form? A copy is included in the Appendix of this guidance. The form is not available as a separate document. You may print the pages that include the form, and then complete it by hand or by typewriter. If you download the PDF (portable document format) version of this guidance, you can fill in the form using your PC and then print it. The PDF version of this guidance is available on the Internet at —

www.fda.gov/cdrh/mdufma/guidance/2009.pdf

The information you enter on the PDF version of the Certification form is not saved on your PC 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 will need to print the form*, sign it, date it, and send in to FDA with your supporting Federal income tax returns.

Where do I send my completed *FY 2009 MDUFMA Small Business Qualification Certification* and supporting materials?

Send your completed Certification and all supporting documentation to:

FY 2009 MDUFMA Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

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

III. 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 II, Guidance for U.S. Businesses.

If you are a Foreign business, you should complete Sections I and II of an FY 2009 MDUFMA Foreign Small Business Qualification Certification and you should then submit your Certification and supporting evidence of qualification to your National Taxing Authority (the equivalent of the United States Internal Revenue Service). Your National Taxing Authority should complete Section III, National Taxing Authority Certification, and should return your completed FY 2009 MDUFMA Foreign Small Business Qualification Certification to you. You should then send the completed Certification to FDA.

FDA will review your Certification and supporting evidence within 60 days and will send you our decision that you are, or are not, a small business eligible for reduced or waived fees for submissions you make during FY 2009 (submissions received by FDA from October 1, 2008 through September 30, 2009). If we decide you are a small business, our decision letter will assign you a Small Business Decision number. You will need to provide this number to FDA each time your want to receive a small business fee discount for a premarket submission or when you want to obtain a fee waiver for your first premarket application.

What is an affiliate? This term is defined by section 737(12) of the Federal Food, Drug, and Cosmetic Act. 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 Medical Device User Fee Small Business Qualification Certification.

How do I contact my National Taxing Authority? You should contact the government agency that collects your national income tax. FDA does not have a complete list of every National Taxing Authority, but as we obtain authoritative information from foreign governments, we will post contact information on our MDUFMA web site at www.fda.gov/cdrh/mdufma. If we have not posted contact information for your National Taxing Authority, it is your responsibility to identify the appropriate point of contact.

May a foreign applicant file a Federal (U.S.) income tax return in order to qualify as a small business under MDUFMA? FDA expects nearly all foreign businesses will not submit a

Federal income tax return, but will instead submit an FY 2009 Foreign Small Business Qualification Certification, a National Taxing Authority Certification. Although the law does not prohibit a foreign business from submitting a Federal income tax return, filing a Federal income tax return may have significant tax and other legal consequences beyond simply making you eligible as a small business under MDUFMA. FDA cannot provide advice concerning whether you should or should not file a Federal income tax return. If you are in doubt as to whether it is advisable for you to file a Federal income tax return, you should consider consulting with qualified legal and tax professionals. Additional information on Federal income taxation is available from the United States Internal Revenue Service (www.irs.gov).

Where can I obtain a copy of the FY 2009 MDUFMA Foreign Small Business Qualification Certification form? A copy is included in the Appendix of this guidance. The form is not available as a separate document. You may print the pages that include the form, and then complete it by hand or by typewriter. If you download the PDF (portable document format) version of this guidance, you can fill in the form using your PC and then print it. The PDF version of this guidance is available on the Internet at —

www.fda.gov/cdrh/mdufma/guidance/2009.pdf

The information you enter on the PDF version of the Certification form is not saved on your PC 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*, sign it, date it, and send it to your National Taxing Authority with any additional information or materials required by the National Taxing Authority.

Your National Taxing Authority should complete Section III, National Taxing Authority Certification, and you should then send your completed FY 2009 MDUFMA Foreign Small Business Qualification Certification and supporting evidence to FDA.

Where do I send my completed FY 2009 MDUFMA Foreign Small Business Qualification Certification and supporting materials?

After your National Taxing Authority has completed Section III and returned the completed Certification to you, you should send your FY 2009 MDUFMA Foreign Small Business Qualification Certification and all supporting documentation to:

FY 2009 MDUFMA Foreign Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850
United States of America

IV. Guidance for Foreign Governments — Preparation of a National Taxing Authority Certification

Qualification as a MDUFMA 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. Prior to enactment of the Medical Device User Fee Amendments of 2007, very few foreign businesses could qualify as a small business under MDUFMA 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 MDUFMA 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 Act.

The FY 2009 MDUFMA Foreign Small Business Qualification Certification, Form FDA 3602A (for FY 2009), 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 Federal Food, Drug, and Cosmetic Act require the certification to be in English.

What are "gross receipts or sales"? If you are unsure how "gross receipts or sales" relates 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 provide an FY 2009 MDUFMA Foreign Small Business Qualification Certification, with Section I and II 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 Federal Food, Drug, and Cosmetic Act require the National Taxing Authority Certification to bear the official seal of the National Taxing Authority.

V. Frequently-asked Questions

What is the purpose of a Small Business Decision number? You should use your Small Business Decision number to demonstrate that you have qualified as a small business for FY 2009. For example, whenever you submit a Medical Device User Fee Cover Sheet (Form FDA 3601), you should provide your Small Business Decision number. This will allow FDA to quickly confirm that you are entitled to a reduced or waived fee.

When will my status as a small business begin? Your status as a small business will begin as of the date of FDA's decision letter finding that you qualify as a small business. FDA expects to make its decision within 60 days of receiving your Certification and supporting materials.

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 determined you qualify 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.*

When will my status as a small business expire? Your status as a small business will expire on September 30, 2009. You should submit a new MDUFMA Small Business Qualification 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 income tax return (if your are a U.S. business) or your most recent certification of income from your national taxing authority (if you are a foreign business).

Can I be certain FDA will protect my income tax returns and other financial information? Yes. Your income tax returns and other financial information are "confidential commercial information" and will not be released to the public.

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, who can I call? If you need additional information about becoming a MDUFMA small business, contact FDA's Division of Small Manufacturers, International, and Consumer Assistance at 800-638-2041 or 240-276-3150.

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Appendix — Forms and Instructions

This appendix provides a copy of —

- **FY 2009 MDUFMA Small Business Qualification Certification**, Form FDA 3602 (for FY 2009). You should use this form if your business is headquartered in the United States. Instructions are provided immediately after the form.

- **FY 2009 MDUFMA Foreign Small Business Qualification Certification**, Form FDA 3602A (for FY 2009). You should use this form if your business is headquartered outside the United States. Instructions are provided immediately after the form.

You may print whichever form you need, and then complete it by hand or by typewriter. If you download the PDF (portable document format) version of this guidance, you can fill in the form using your PC and then print it. The PDF version of this guidance is available on the Internet at —

www.fda.gov/cdrh/mdufma/guidance/2009.pdf

The information you enter on the PDF version of the Certification form is not saved on your PC 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*, sign it, date it, and send in to FDA with your supporting Federal income tax returns.

FY 2009 MDUFMA Small Business Qualification Certification

For a Business Headquartered in the United States

OMB No. 0910-0508
Expiration Date: December 31, 2010
OMB Statement: See last page.

Section I — Information about the Business Requesting Small Business Status

1. Name of business claiming MDUFMA Small Business status:

2. Federal Employer Identification Number:

3. Address where business is physically located:

4. Name of person making this Certification:

5. Your telephone number:

(_____) _____
Area Code Telephone Number

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

7. Your e-mail address:

8. What is your relation to the business claiming MDUFMA 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 income tax return. I have attached a true and accurate copy of the business's most recent Federal 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 income tax return, and a true and accurate copy of the most recent Federal income tax return, or an FY 2009 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: _____
Signature (must be signed by the person identified in item 4)

Date of this Certification: _____

Section II — Information about 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			$
17			$
18			$
19			$
20			$
21	*Total Gross Receipts and Sales of All Affiliates* (sum of lines 1 through 20)		$
22	*Gross Receipts and Sales of the Business Making this Certification*		$
23	*Total Gross Receipts and Sales Used to Determine Qualification as a Small Business* (sum of lines 21 and 22)		$

Mail your completed FY 2009 Small Business Qualification Certification and copies of your latest Federal income tax return to the address below. You must also send a separate FY 2009 Small Business Qualification Certification or U.S. Federal income tax return or for of each of your affiliates. Send all materials to —

FY 2009 Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

(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

SBD09_____

□ Does not qualify

OMB Statement. The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration
Forms Comments, HFZ-20
2098 Gaither Road
Rockville, MD 20850
United States of America

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 Office of Management and Budget (OMB) control number.

Instructions for Completing Your FY 2009 MDUFMA Small Business Qualification Certification

For a Business Headquartered in the United States

Form FDA 3602

You should complete and submit an FY 2009 MDUFMA Small Business Qualification Certification (Form FDA 3602) if you wish to be eligible for reduced or waived fees for medical device submissions you make during FY 2009 (submissions received by FDA from October 1, 2008 through September 30, 2009). 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 income tax return of *each* of your domestic (U.S.) affiliates, *and*
  - a copy of an FY 2009 MDUFMA Foreign Small Business Qualification Certification for *each* of your foreign affiliates.

See sections 738(d)(2) and 738(e)(2) of the Act.

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

You should mail your FY 2009 MDUFMA Small Business Qualification Certification, and copies of the Federal income tax returns that support your Certification, to FDA at this address —

FY 2009 MDUFMA Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850

If you need assistance, please contact the Division of Small Manufacturers, International and Consumer Assistance at 800-638-2041 or 240-276-3150.

Section I — Information about the Business Requesting Small Business Status

1. *Name of business claiming MDUFMA 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 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.

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).

5. *Your telephone number*. This is the telephone number where FDA can reach you if we have a question concerning your FY 2009 MDUFMA Small Business Qualification 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 2009 MDUFMA Small Business Qualification Certification.

8. *What is your relation to the business claiming MDUFMA 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 2009 MDUFMA Small Business Qualification Certification 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.").

10. *Complete, sign, and date the following certification*. In this certification, should provide the following information:

- The name of the business that is claiming MDUFMA 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.

- 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 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 income tax return.

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	*Please contact FDA.*

What is the *most recent* tax year?
The most recent tax year will be **2008**, except —

- If you submit your FY 2009 MDUFMA Small Business Qualification *before* April 15, 2009 *and* you have not yet filed your return for 2008, you may use tax year 2007 .
- If you submit your FY 2009 MDUFMA Small Business Qualification *on or after* April 15, 2008 *and* have not yet filed your 2008 return because you obtained an extension, you may submit your most-recent return filed prior to the extension.

- Check the second box if the business *and* all of its affiliates *together* reported "gross receipts or sales" of no more than $30 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 income tax return *and* a true and accurate copy of each affiliate's most recent Federal income tax return.

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.

- 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 Your Affiliates

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

Lines 1 through 20 —

List each affiliate on a separate line. For each, you should provide the following information —

a. *Name of Affiliate*. Provide the full legal name of the affiliate –

- 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 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 income tax return for the affiliate. See the instruction for item 9 to learn where you will find this information on a Federal 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.

21. *Total Gross Receipts and Sales of All Affiliates*. This is the sum of the Gross Receipts or Sales shown in column c. of lines 1 through 20.

22. *Gross Receipts and Sales of the Business Making this Certification*. This is the gross receipts or sales of the business identified in Section I, item 1.

23. *Total Gross Receipts and Sales Used to Determine Qualification as a Small Business*. This is the sum of lines 21 and 22. To qualify as a MDUFMA 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 Act.

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FY 2009 MDUFMA Foreign Small Business Qualification Certification

For a Business Headquartered Outside the United States

OMB No. 0910-0613
Expiration Date: May 31, 2011
OMB Statement: See last page.

Section I — Information about the Business Requesting Small Business Status

1. Name of business requesting MDUFMA Small Business status:	2. Taxpayer Identification Number:
3. Address where business is physically located:	
4. Name of person making this Certification: Check (✓) *one* response: ☐ Head of Firm ☐ Chief Financial Officer	5. Your telephone number:
6. Your mailing address: ☐ Check (✓) if same as item 3.	7. Your e-mail address:

Section II — Information about 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. *Total Gross Receipts and Sales of All Affiliates* (sum of lines 1 through 10)		$
12. *Gross Receipts and Sales of the Business Making this Certification*		$
13. *Total Gross Receipts and Sales Used to Determine Qualification as a Small Business* (sum of lines 11 and 12)		$

14. Have you attached a separate FY 2009 MDUFMA Foreign Small Business Qualification Certification *or* a U.S. Federal income tax return for *each* of your affiliates?

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

15. 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)

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: _____ (Month-Day-Year) b. Ending date: _____ (Month-Day-Year)

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

b. Your title:

7. Your telephone number:

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:

The business seeking small business status should mail its completed FY 2009 Small Business Qualification Certification to FDA at the address below. Your Certification is not complete and will not be accepted unless Section III has been completed by your National Taxing Authority. If your business has any affiliates, you must also send a separate FY 2009 Small Business Qualification Certification or U.S. Federal income tax return for each affiliate. Send all materials to —

FY 2009 Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
U.S. Food and Drug Administration
1350 Piccard Dr.
Rockville, MD 20850
United States of America

(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.

SBD09_____

□ Does not qualify.

OMB Statement. The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration
Forms Comments, HFZ-20
2098 Gaither Road
Rockville, MD 20850
United States of America

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 Office of Management and Budget (OMB) control number.

Instructions for Completing Your FY 2009 MDUFMA Foreign Small Business Qualification Certification For a Business Headquartered Outside the United States Form FDA 3602A

You should complete and submit an FY 2009 MDUFMA Foreign Small Business Qualification Certification, Form FDA 3602A (for FY 2009), if you wish to be eligible for reduced or waived fees for medical device submissions you make during FY 2009 (submissions received by FDA from October 1, 2008 through September 30, 2009). 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 2009 MDUFMA Foreign Small Business Qualification 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 MDUFMA.

You should mail your FY 2009 MDUFMA Foreign Small Business Qualification Certification and all supporting documentation to FDA at this address —

FY 2009 MDUFMA Foreign Small Business Qualification (HFZ-222)
Division of Small Manufacturers, International, and Consumer Assistance
1350 Piccard Dr.
Rockville, MD 20850
United States of America

If you need assistance, please contact the Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or 1-240-276-3150.

Section I — Information about the Business Requesting Small Business Status

1. *Name of business claiming MDUFMA Small Business status*. You should 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 15). 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 Act.

5. *Your telephone number*. This is the telephone number where FDA can reach you if we have a question concerning your FY 2009 MDUFMA Small Business Qualification 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 2009 MDUFMA Small Business Qualification Certification.

Section II — Information about Your Affiliates

Section II of the form provides space for listing up to 10 affiliates; if you have more than 10 affiliates, you may provide the additional information on one or more additional copies of Section II.

Lines 1 through 10 —

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 Nation, State, or other government under whose laws the firm was created.

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 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.

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	*Please contact FDA.*

What is the *most recent* tax year of an affiliate headquartered in the United States? The most recent tax year will be **2008**, except —

- If you submit your FY 2009 MDUFMA Small Business Qualification *before* April 15, 2009 *and* your affiliate has not yet filed its return for 2008, you may use tax year 2007.
- If you submit your FY 2009 MDUFMA Small Business Qualification *on or after* April 15, 2008 *and* your affiliate has not yet filed your 2008 return because it obtained an extension, you may submit its most-recent return filed prior to the extension.

11. *Total Gross Receipts and Sales of All Affiliates*. This is the sum of the Gross Receipts or Sales shown in column c. of lines 1 through 10.

12. *Gross Receipts and 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.

13. *Total Gross Receipts and Sales Used to Determine Qualification as a Small Business*. This is the sum of items 11 and 12. To qualify as a MDUFMA 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 Act.

14. *Have you attached a separate FY 2009 MDUFMA Foreign Small Business Qualification 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.").

15. *Complete, sign, and date the following certification*. In this certification, you should provide the following information:

- The name of the business that is claiming MDUFMA 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 2009 MDUFMA Foreign Small Business Qualification 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. If a National Taxing Authority provides FDA with contact information, we will post it on our Internet site at www.fda.gov/cdrh/mdufma. 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 2009 MDUFMA Foreign Small Business Qualification Certification to you. You are responsible for sending your completed FY 2009 MDUFMA Foreign Small Business Qualification Certification and all required supporting documentation to FDA.

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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:

U.S. Food and Drug Administration
Forms Comments, HFZ-20
2098 Gaither Road
Rockville, MD 20850
United States of America

The guidance refers to approved collections of information under sections 738(d) and 738(e) of the Federal Food, Drug, and Cosmetic Act. The collections of information in Form FDA 3602 have been approved under OMB Control Number 0910-0508 (expires December 31, 2010). The collections of information in Form FDA 3602A have been approved under OMB Control Number 0910-0613 (expires May 31, 2011).

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.