Guidance for Industry

Guidance for Industry and FDA: FY 2003 MDUFMA Small Business Qualification Worksheet and Certification

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For questions regarding this document, contact Thomas E. Cardamone at (301) 443-0806, ext. 115 or by e-mail to tec@cdrh.fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Biologics Evaluation and Research
Center for Devices and Radiological Health

Contains Nonbinding Recommendations

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket No. 03D-0063. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at —

www.fda.gov/oc/mdufma

Copies are also available from the CDRH Facts-on-Demand system. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1204) followed by the pound symbol (#). Follow the remaining voice prompts to complete your request.

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 the information requested in the guidance is not relevant to the decision-making process or 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 —

http://www.fda.gov/cdrh/ombudsman/

Contains Nonbinding Recommendations

Guidance for Industry

Guidance for Industry and FDA: FY 2003 MDUFMA Small Business Qualification Worksheet and Certification

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.

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.

Who qualifies as a small business under MDUFMA? For FY 2003, you qualify as a small business within the meaning of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) if you reported *gross receipts or sales* of no more than $30 million on your Federal income tax return for the most recent tax year. The law requires that, if you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours and the *total* must be no more than $30 million. If you qualify as a MDUFMA small business, you are eligible for reduced or waived medical device user fees.

You may use the *Small Business Qualification Worksheet* (a copy is included with this guidance) to help you determine whether you are a MDUFMA small business. FDA does not require you to use this worksheet, and you will not submit the completed worksheet to FDA.

What are the benefits of qualifying as a MDUFMA small business? If you qualify as a MDUFMA small business, you will be eligible to pay reduced fees for your medical device applications that are subject to a user fee. You will also be able to obtain FDA review of your *first* premarket application (PMA, PMR, PDP, or BLA) without paying any fee (the law requires that you must count premarket applications made by any of your affiliates, partners, or parent

firms when determining whether your premarket application is your "first." If an affiliate, partner, or parent firm previously submitted a premarket application, your application is *not* your "first" in this context.).

What are the standard and small business fees for FY 2003? Fees for FY 2003 are shown in the accompanying table. If your submission is subject to a fee, the law requires you to pay the standard fee unless FDA decides you qualify as a small business. If you qualify as a small business, you are eligible to pay a reduced fee, and no fee is required for your first (ever) premarket application.

FY 2003 Medical Device Review User Fees

Application	Standard Fee	Small Business
Premarket application (PMA, PDP, BLA)	$154,000	$58,520
Premarket report (premarket application for a reprocessed single-use device)	$154,000	$58,520
First premarket application *by a small business*	Not applicable	Fee is waived
Panel-track supplement	$154,000	$58,520
Efficacy supplement	$154,000	$58,520
180-day supplement	$33,100	$12,582
Real-time supplement	$11,088	$4,213
510(k)	$2,187	$2,187⊥

⊥ During FY 2003, all 510(k) applicants will pay the standard fee. A reduced small business fee will be available beginning FY 2004.

How can I obtain an FDA decision that I am a small business for FY 2003? If you believe you qualify as a small business and want to pay reduced or waived fees, you should submit an *FY 2003 MDUFMA Small Business Qualification Certification* (a copy is included with this guidance), your Federal income tax return for the most recent tax year, and the Federal income tax returns of each of your affiliates, partners, and parent firms 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 2003 (submissions received by FDA from October 1, 2002 through September 30, 2003). If we decide you are a small business, our decision letter will assign you a Small Business Decision number.

Why does FDA require me to submit Federal 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, partners, and parent firms). 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 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.

What is the purpose of a Small Business Decision number? You will use your Small Business Decision number to demonstrate that you have qualified as a small business for FY 2003. For example, whenever you submit a Medical Device User Fee Cover Sheet (Form FDA 3601), you will 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? *For FY 2003 only*, if FDA determines that you qualify, you will be eligible to pay reduced or waived small business fees for all medical device applications you submit or have submitted from October 1, 2002 through September 30, 2003. (Although FDA has not yet established procedures for FY 2004 and future years, we expect that, beginning FY 2004, 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.

When will my status as a small business expire? Your status as a small business *will expire September 30, 2003.*

Do I need to requalify as a small business for FY 2004 and future years? Yes. 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.
- FDA may adjust the qualification threshold each year (it may not always be $30 million).
- We will always need a copy of your most recent Federal income tax return.

FDA will publish the criteria for FY 2004 in the *Federal Register* by August 2, 2003, and will announce the new criteria on our Internet site at —

www.fda.gov/oc/mdufma

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.

If I have a question, who can I call? If you need additional information about qualifying as a MDUFMA small business, contact FDA's Division of Small Manufacturers, International, and Consumer Assistance at 800-638-2041 or 301-443-6597.

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FY 2003 MDUFMA Small Business Qualification Worksheet

1. Did you file a United States Federal income tax return for the most recent tax year?

   ☐ Yes — Go on to Question 2

   ☐ No — *Stop*. You do not qualify as a small business for FY 2003 medical device user fees.

What is the *most recent* tax year?
Your most recent tax year will be 2002 *unless* you submit your FY 2003 MDUFMA Small Business Qualification prior to
April 15, 2003 *and* have not yet filed a return for 2002, in which case you may use tax year 2001.

2. Does the line for *gross receipts or sales* on your Federal income tax return for the most recent tax year show $30 million or less?

   ☐ Yes — Go on to Question 3

   ☐ No — *Stop*. You do not qualify as a small business for FY 2003 medical device user fees.

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
Any other form	*Please contact FDA*

3. Do you have any affiliates, parents, or partner firms?

   ☐ Yes — Go on to Question 4

   ☐ No — *Stop*. You appear to qualify as a small business for FY 2003 medical device user fees. To receive small business fees and waivers for your FY 2003 medical device submissions, please send the following documents to FDA:

What is an *affiliate*? This term is defined by § 737(8) 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.

   1. A complete, signed FY 2003 MDUFMA Small Business Certification (a copy is attached for your use), and

   2. A copy of your Federal income tax return for the most recent tax year.

Send these materials to:

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

FDA will review your materials within 60 days and will inform you of our decision that you are, or are not, a small business for FY 2003.

4. Do the amounts on the lines for *gross receipts or sales* on the Federal income tax return for the most recent tax year, for your firm and all of its affiliates, partners, and parent firms, *when added together*, total $30 million or less?

☐ Yes — *Stop*. You appear to qualify as a small business for medical device user fees.

To receive small business fees and waivers for your FY 2003 medical device submissions, please send the following documents to FDA:

1. A complete, signed FY 2003 MDUFMA Small Business Qualification Certification (a copy is attached for your use), and

2. Copies of the Federal income tax returns of your firm and all of its affiliates, partners, and parent firms for the most recent tax year.

Send these materials to:

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

FDA will review your materials within 60 days and will inform you of our decision that you are, or are not, a small business for FY 2003.

☐ No — You do not qualify as a small business for medical device user fees.

FY 2003 MDUFMA Small Business Qualification Certification

Form Approved: [Pending]
Expiration Date: October 1, 2003
OMB Statement: See Instructions

Section I — Information about Yourself

1. Name of entity claiming MDUFMA Small Business status:

2. Entity's Federal Employer Identification Number (EIN):

3. Name of person making this Certification:

4. Your telephone number:
(_____) _____
Area Code **Telephone Number**

5. Your mailing address:

6. Your e-mail address:

7. What is your relation to the entity claiming MDUFMA Small Business status?

8. Have you listed all of the entity's affiliates, partners, and parent firms on the back of this form?

Check (✓) *one* response: ☐ Yes ☐ The entity identified in item 1 has no affiliates, partners, or parent firms

9. Complete, sign, and date the following certification:

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

(Check *one* response:)

☐ Has no affiliates, partners, or parent firms.

☐ Has only the affiliates, partners, and parent firms listed on the back of this form

(Check *one* response:)

☐ Reported "gross receipts or sales" of no more than $30,000,000 on its most recent Federal income tax return. I have attached a true and accurate copy of the entity's most recent Federal income tax return.

☐ Together with the affiliates, partners, and parent firms listed on the back of this form, reported total "gross receipts or sales" of no more than $30,000,000 on their Federal income tax returns. 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 of each of the entity's affiliates, partners, and parent firms.

I further certify that, to the best of my knowledge, the information I have provided in this MDUFMA Small Business Qualification 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: _
Date of this Certification:

Section II — Information about Your Affiliates, Partners, and Parent Firms

a. Name of Entity	b. Federal Employer Identification Number (EIN)	c. Relation to Entity Making this Certification (Check (✓) *One* Response)			d. Gross Receipts or Sales for Most-Recent Tax Year
		Affiliate	Partner	Parent	
1					$
2					$
3					$
4					$
5					$
6					$
7					$
8					$
9					$
10					$
11					$
12					$
13					$
14 Total Gross Receipts and Sales of all Affiliates, Partners, and Parent Firms (Sum of lines 1 - 13)					$
15 Gross Receipts and Sales of the Entity Making this Certification					$
16 Total Gross Receipts and Sales Used to Determine Qualification as a MDUFMA Small Business (Sum of lines 14 and 15)					$

Mail your completed FY 2003 MDUFMA Small Business Qualification Certification and copies of your latest Federal income tax returns (including the latest returns of your affiliate, partner, and parent firms) to —

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

(FDA Use Only)

Review: ☐ **Information verified**

☐ **Information not verified**
(Decision must be "Does not qualify")

Decision: ☐ **Qualifies as a Small Business**

SBD-03-_____

☐ **Does not qualify**

Instructions for Completing Your
FY 2003 MDUFMA Small Business Qualification Certification
Form FDA 3602

You should complete and submit a FY 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602) in order to determine whether you are eligible for reduced or waived fees for medical device submissions you make during FY 2003 (submissions received by FDA from October 1, 2002 through September 30, 2003). Under the law, you must also submit a copy of your most recent Federal income tax return, and a copy of the most recent Federal income tax returns of each of your affiliate, partner, or parent firms. FDA will use these materials to decide whether you qualify as a "small business" within the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

Mail your FY 2003 MDUFMA Small Business Qualification Certification, and copies of the Federal income tax returns that support your Certification, to FDA at this address —

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

For further assistance, please contact the Center for Devices and Radiological Health's (CDRH) Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at 800-638-2041 or 301-443-6597 or the Center for Biologics Evaluation and Research's (CBER) Regulatory Information Management Staff (RIMS) at (301) 827-3503.

FIELD DEFINITIONS

Section I — Information about Yourself

1. Name of entity claiming MDUFMA Small Business status. Provide the full legal name of the entity –

- If the entity is a corporation, limited liability company, partnership, or other legal entity, 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 entity is a sole proprietorship (that is, the firm is owned by an individual), the name used when filing Federal, State, or other taxes.

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

3. 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 signs the Certification (see item 9).

4. Your telephone number. This is the telephone number where FDA can reach you if we have a question concerning your FY 2003 MDUFMA Small Business Qualification Certification.

5. 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.

6. Your e-mail address. This is the e-mail address where FDA can reach you if we have a question concerning your FY 2003 MDUFMA Small Business Qualification Certification.

7. What is your relation to the entity claiming MDUFMA Small Business status? Briefly explain your position within the entity (*e.g.*, Chief Financial Officer; Vice President; Chief Counsel; or other relationship that gives you authority to provide an FY 2003 MDUFMA Small Business Qualification Certification on behalf of the entity).

8. Have you listed all of the entity's affiliates, partners, and parent firms on the back of this form? If you have any affiliates, partners, or parent firms, check the first box ("Yes") *and list them on the back of the form*. If the entity has no affiliates, partners, or parent firms, check the second box ("The entity has no affiliates, partners, or parent firms").

9. Complete, sign, and date the following certification. In this certification, please provide the following information:

- The name of the entity that is claiming MDUFMA small business status. This should be identical to your response to item 1.
- Check *one* response to indicate whether the entity has any affiliates, partners, or parent firms —
    - Check the first box if the entity has no affiliates, partners, or parent firms.
    - Check the second box if the entity has only the affiliates, partners, or parent firms you listed on the back of the form.
- Check *one* response to indicate how the entity determined it met the requirement that it have "gross receipts or sales" of no more than $30 million —
    - Check the first box if the entity reported "gross receipts or sales" of no more than $30 million on its most recent Federal income tax return. Attach a true and accurate copy (a complete and unaltered copy) of the entity's most recent Federal 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
Any other form	*Please contact FDA*

What is the *most recent* tax year? Your most recent tax year will be 2002 *unless* you submit your FY 2003 MDUFMA Small Business Qualification prior to April 15, 2003 *and* have not yet filed a return for 2002, in which case you may use tax year 2001.

- Check the second box if the entity *and* all of its affiliates, partners, or parent firms *together* reported "gross receipts or sales" of no more than $30 million on their most recent Federal income tax returns. 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, partner's, or parent firm's most recent Federal income tax return.

What is an *affiliate*? This term is defined by § 737(8) 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.

- The person identified in item 3 ("Name of person making this Certification") should sign the certification.
- Date the Certification (this is the date you signed the certification).

Section II — Information about Your Affiliates, Partners, and Parent Firms

The back of the form provides space for listing up to 13 affiliate, partner, or parent firms. If you have more than 13 affiliate, partner, or parent firms, you may provide the additional information on the back of one or more additional copies of the form (you do not need to complete the front of those additional forms).

Lines 1 through 13 —

List each affiliate, partner, or parent firm on a separate line. For each, provide the following information —

a. Name of Entity. Provide the full legal name of the affiliate, partner, or parent firm –

- if the entity 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 entity is a sole proprietorship (that is, the firm is owned by an individual), provide the name used when filing Federal, State, or other taxes.

b. Federal Employer Identification Number (EIN). This number was assigned to the affiliate, partner, or parent firm by the U.S. Internal Revenue Service and uniquely identifies each business.

c. Relation to Entity Making this Certification. Check *one* response (put a T in the appropriate column) to indicate whether the entity you are identifying is an *Affiliate*, a *Partner*, or a *Parent firm*.

d. Gross Receipts or Sales for Most-Recent Tax Year. Copy this number from the Federal income tax return for the affiliate, partner, or parent firm. See the instruction for item 9 to learn where you will find this information on a return.

Line 14 — Total Gross Receipts and Sales of all Affiliates, Partners, and Parent Firms. This is the sum of the gross receipts or sales shown in lines 1 through 17.

Line 15 — Gross Receipts and Sales of the Entity Making this Certification. This is the gross receipts or sales of the entity identified in item 1.

Line 16 — Total Gross Receipts and Sales Used to Determine Qualification as a MDUFMA Small Business. This is the sum of lines 14 and 15. To qualify as a MDUFMA small business for FY 2003, this sum must be *no more than* $30 million.

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:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

and to

Department of Health and Human Services
Food and Drug Administration
CDRH, HFZ-20
2098 Gaither Road
Rockville, MD 20850

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.