

FY 2007 MDUFMA Small Business
Qualification Certification

Form Approved: January 9, 2004
Expiration Date: December 31, 2006
OMB Statement: See following page.

Section I — Information about Yourself

1. Name of entity claiming MDUFMA Small Business status:

2. Federal Employer Identification Number:

3. Address where entity 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 entity claiming MDUFMA Small Business status?

9. Have you listed all of the entity's affiliates, partners, and parent firms on the second page (Section II) of this form?

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

10. 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 (Section II) of this form,

and

(Check *one* response:)

- 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 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 \$100,000,000 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 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 Total Gross Receipts and Sales of All Affiliates, Partners, and Parent Firms (Sum of lines 1 - 12)					\$ \$0.00
14 Gross Receipts and Sales of the Entity Making this Certification					\$
15 Total Gross Receipts and Sales Used to Determine Qualification as a MDUFMA Small Business (Sum of lines 13 and 14)					\$ \$0.00
Mail your completed FY 2007 MDUFMA Small Business Qualification Certification and copies of your latest Federal income tax returns (including the latest returns of each of your affiliate, partner, and parent firms) to — FY 2007 MDUFMA Small Business Qualification (HFZ-222) Division of Small Manufacturers, International, and Consumer Assistance 1350 Piccard Dr. Rockville, MD 20850		(FDA Use Only) Review: <input type="checkbox"/> Information verified <input type="checkbox"/> Information not verified (Decision must be "Does not qualify") Decision: <input type="checkbox"/> Qualifies for Small Business fee discounts <input type="checkbox"/> Qualifies for Small Business fee discounts and fee waiver for first premarket application SBD07 _____ <input type="checkbox"/> 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:

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.