## FY 2008 MDUFMA Foreign Small Business Qualification Certification

For a Business Headquartered Outside the United States

OMB No. [Pending]

Expiration Date: [Pending]

OMB Statement: See last page.

Section I — Information about the Busines.	s Requesti	ing Small Busin	ess 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:		5. Your telephone number:			
Check (✓) one response: □ Head of Firm □ Chief Financial Officer					
6. Your mailing address: □ Check (✔) if same a	as item 3.	7. Your e-mail address:			
Section II — Information al	bout 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	\$				
12. Gross Receipts and Sales of the Busine	\$				
13. Total Gross Receipts and Sales Used to Determine Qualif	Small Business lines 11 and 12)	\$			
14. Have you attached a separate FY 2008 MDUFMA Foreign Small Business Qualification Certification or a U.S. Federal income tax return for each of your affiliates?					
Check ( $\checkmark$ ) one response: $\Box$ Yes $\Box$ $\Box$	Γhis business	s 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:)					
<ul> <li>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.</li> <li>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.</li> </ul>					
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 3)					

This Certification Must be Completed by the National Taxing Authority					
1. Name of business:					
2. This business is: C	heck (✓) one response				
_	nesting small business s usiness requesting sma			ust be completed.) 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:			4. Does the National Taxing Authority know of any affiliate(s) of the business		
	Currency Unit	Amount Repor	ted	requesting small business status, other than those listed in Section II?	
a. Local currency:				Check (✓) one response:	
b. U.S. currency:	U.S. Dollars	\$		□ No (or not applicable).	
c. Exchange rate (per	U.S. Dollar):			☐ Yes. An explanation is attached.	
5. Period during which	n reported receipts or s	sales were collected	:		
a. Starting date: b. Ending date:					
Month-Day-Year				Month-Day-Year	
6. a. Name of Nationa this Certification	•	cial making	7.	Your telephone number:	
b. Your title:			8.	8. Your e-mail address:	
9. Name of this Natio	nal Taxing Authority:		·		
10. Sign and date the following certification:  Affix Official Seal of National Taxing Authority has the seal of National Taxing Authority Authority has the seal of National Taxing Authority					
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 5)  Date of this Certification:					
The business seeking small business status should mail its completed FY 2008 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 2008 Small Business Qualification Certification or U.S. Federal income tax return for each affiliate. Send all materials to —		Review:	☐ Information not complete.		
FY 2008 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		and fee waiver for first premarket application.  SBD08 □ Does not qualify.			

Section III — National Taxing Authority Certification

 $\label{lem:omb_statement} \textbf{OMB Statement}. \ \ \textbf{The public reporting burden for this collection of information is estimated}$ 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:

Forms Comments, HFZ-20 2098 Gaither Road Rockville, MD 20850 United States of America

U.S. Food and Drug Administration 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.