

Outsourcing Facilities for Human Drug Compounding Small Business Establishment Fee Reduction Request

Form Approved: OMB No. xxxx-xxxx
Expiration Date: XXXXXXXX xx, 201x
See PRA Statement below.

Instructions for Filling Out Form FDA 3908: Outsourcing Facilities for Human Drug Compounding – Small Business Establishment Fee Reduction Request

General Instructions

To qualify for a small business fee reduction for a fiscal year, the Outsourcing Facility's Gross Annual Sales, **both compounding and non-compounding related**, including the sales of all affiliates, must total \$1,000,000 or less for the 12 months ending April 1st of the previous fiscal year. An Outsourcing Facility must complete and return the Small Business Establishment Fee Reduction Request form to the FDA for review by April 30th to receive a fee reduction for the next fiscal year.

Section 1: Company Information

1(a) Company Name: Provide the full legal name of the company.

1(b) Address: Provide the street address of the physical location. Do not include P.O. Box.

1(c) Address: Provide additional information such as a suite number or building number, if applicable.

1(d) City: Provide the city in which the company is located.

1(e) State: Provide the two letter state identifier for which the company is located.

1(f) Zip Code: Provide the United States Postal Service zip code where the company is located.

1(g) DUNS Numbers: Dun and Bradstreet (D&B) provides a DUNS Number. It is a unique nine digit identification number for each physical location of your business. Provide the unique nine digit DUNS number issued by Dun and Bradstreet. To establish a DUNS number, click on the link provided: <https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm>

1(h) Federal Tax ID Number: A Taxpayer Identification Number (TIN) is an identification number used by the Internal Revenue Service (IRS) in the administration of tax laws. Provide the company's federal tax ID number.

1(i) Contact Person: The contact person should be an officer or employee of the outsourcing facility with authority to speak on behalf of the facility and bind it legally.

1(j) Telephone Number: Provide a telephone number (include area code). The telephone number is the number where the contact is usually available during normal work hours.

1(k) Email Address: Provide an email address of the person identified in field 1(i).

Section 2: Affiliate Information

Affiliate is defined as 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." If the company has affiliates, provide for each affiliate (domestic and foreign) associated with the company; the name of the affiliate(s), the address, the responsible point of contact's name, phone number and email address.

If the company does not have any affiliates, check the box located in part 2 of this form.

Section 3: Gross Annual Sales

Gross Annual Sales means the total worldwide gross annual sales, in United States dollars, **of the outsourcing facility's compounding and non-compounding related activities**, including the sales of all domestic and foreign affiliates.

Section 4: Signature

Provide a signature of an officer or employee of the outsourcing facility with authority to speak on behalf of the facility and bind it legally. Print the name and provide the date of signature.

How can I contact the FDA if I have questions?

Email address:

CDERCollections@fda.hhs.gov

Telephone number:

1-301-796-7900

For physical mail:

Department of Health and Human Services
Food and Drug Administration
10001 New Hampshire Ave, Mail Stop 2163
Silver Spring, MD 20903

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

**DO NOT SEND YOUR COMPLETED FORM
TO THIS PRA STAFF EMAIL ADDRESS.**

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page i.

Section 1. Company Information

a. Company Name

b. Address 1 (Street Address)

g. DUNS Number

h. Federal Tax ID Number

c. Address 2 (Suite, unit building, floor etc.)

i. Contact Person

d. City

j. Telephone Number (Include area code)

e. State

f. ZIP Code

k. Email Address

Section 2. Affiliate Information

List of Outsourcing Facility's Affiliates as defined in §§ 744J(1) and 735(11) of the FD&C Act. Please include name and address of all domestic and foreign facility affiliates, the name, phone number, and email address for a responsible point of contact for each affiliate. Please click the provided button for additional affiliates.

Check box only if facility has NO affiliates:

Name of Affiliate

Address of Affiliate

Point of Contact Name

Point of Contact Telephone Number (Include area code)

Point of Contact Email Address

As needed, you may click this button to add a new affiliate. This may be repeated multiple times. Each affiliate set will consist of the 5 items shown in the first set above.

Add New Affiliate

Section 3. Total Gross Annual Sales

Gross Annual Sales (as defined in § 744J(2) of the FD&C Act) **both compounding and non-compounding related**, of the entity and its affiliates for the twelve months ending April 1st of the current fiscal year.

Section 4. Signature

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

Signature

Printed Name and Position

Date Signed (mm/dd/yyyy)

Send Completed Form via electronic
mail (preferred) to:
CDERCollections@fda.hhs.gov

For physical mail: Department of Health and Human Services
Food and Drug Administration
10001 New Hampshire Ave, Mail Stop 2163
Silver Spring, MD 20903

For FDA Use Only

Date Received: _____

Approved

Denied

Privacy Act Notice: This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. § 353b, 379j-62 and 371. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online: [Privacy Act](#) and [Website Policies](#).

Draft
Sample overflow page
header and footer
(non-functional)