
INSTRUCTIONS FOR FILLING OUT FORM FDA3971 – SMALL BUSINESS WAIVER AND REFUND REQUEST

(The field numbers below correspond to the numbered boxes on Form FDA 3971)

Complete and e-mail Form FDA 3971 to CDERCollections@fda.hhs.gov to request a small business waiver and refund of the application fees assessed under sections 735, 736, and 744 of the Federal Food, Drug, and Cosmetic Act (FD & C Act or the Act) for drugs, including biological and biosimilar drug products. For information on user fee waivers please refer to the *Guidance for Industry: User Fee Waivers, Reductions, and Refunds for Drug and Biological Products*. If you have questions about this form contact the Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov or at (301) 796-7900.

Section I: Applicant Information

1. **Applicant Name:** The term *applicant* refers to the owner, holder, or sponsor of a new drug application (NDA) or biologics license application (BLA) that is requesting the small business waiver or refund of the application fee for a human drug or biosimilar biological product application assessed under sections 735, 736, and 744 of the Act. Provide the full legal name of the applicant.
 - If the applicant 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 applicant's business is a sole proprietorship owned entirely by one individual, provide the name used when filing Federal, State, or other taxes.

Former Names (If applicable): List all names previously used by the applicant. This includes those changed due to transfer of ownership, change in business structure, or other reasons.
2. **Telephone Number (Including area and country codes):** This is the telephone number of the applicant's physical location. Provide the area code and telephone number for applicants located within the United States of America (U.S.) or its territories. Applicants located outside of the U.S. must also include the country code.
3. **Fax Number (Including area and country codes):** This is the fax number of the applicant's physical location. Provide the area code and telephone fax number for applicants located within the United States of America (U.S.) or its territories. Applicants located outside of the U.S. must also include the country code.
4. **Address (No P.O. Boxes allowed):** This is the address where the business is physically located. No Post Office (P.O.) Boxes are allowed. Provide the following elements of the applicant's physical address:
 - *Address 1* - Provide the physical street address where the applicant is located.
 - *Address 2* - Provide additional information such as a suite number or building number, if applicable.
 - *City* - Provide the city in which the applicant is located.
 - *State/Province/ Region* - Provide a two letter state identifier or the province or territory in which the applicant is located.
 - *Country* - Provide the country where the applicant is located.
 - *ZIP or Postal Code* - Provide the United States postal service zip code or international postal code where the applicant is located.
5. **Federal Tax ID Number (Required for all U.S. Applicants):** This is the unique identifying number issued to a business by the country's government or taxing authority. Without this entry this request cannot be processed.

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- For applicants headquartered in the United States (U.S.) or a U.S. territory, provide the Tax ID Number issued by the Internal Revenue Service.
 - For applicants headquartered outside the U.S. or a U.S. territory, provide the Tax ID Number issued by the taxing authority where the headquarters is located.
6. **DUNS Number:** The DUNS Number is a unique nine-digit identifier issued to an entity by Dun and Bradstreet (D&B). To establish a DUNS number at no charge, visit <https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm>. Provide the unique nine-digit identification number for the applicant's physical location. Without this entry this request cannot be processed.
7. **Number of employees:** Provide the number of people employed by the applicant at the time of the waiver request. This number includes all individuals employed on a full-time, part-time, or other basis, including employees obtained from a temporary staffing agency or other staffing contractor. FDA will consider the totality of the circumstances, including criteria used by the IRS for Federal income tax purposes, in determining whether individuals are employees of an entity.
8. **Select User Fee Program for which action is requested:** Check the box to indicate which user fee program this small business waiver is intended for. For applications under the Prescription Drug User Fee Act, select PDUFA. For applications under the Biosimilar User Fee Act, select BsUFA.
9. **Human Drug/Biosimilar Biological Product Applications:** A human drug application is an application for (1) approval of a new drug submitted under section 505(b) of the Act, or (2) licensure of a biological drug product under subsection (a) of section 351 of the Public Health Service Act (PHS Act). A biosimilar biological product application is an application for licensure of a biological product under subsection (k) of section 351 of the PHS Act.
- *Product Name* - Provide the drug product's proprietary and/or established name. Use the following format: PROPRIETARY NAME (established name).
 - *A proprietary name* refers to the exclusive name of a drug substance or drug product, proposed by the applicant, regardless of its registration status with the United States Patent and Trademark Office.
 - *An established name* refers to the applicable official name designated pursuant to section 508 of the Act, or if there is no such official name, the title of any related official United States Pharmacopeia drug product or drug substance (ingredient) monograph, or, if neither applies, the drug product's or ingredient's common or usual name.
 - *Application Number* - If the applicant has already submitted the human drug or biosimilar biological product application to the FDA, provide its six-digit application number. Application numbers less than six-digits should be preceded with zeros (i.e., for NDA 12345 enter 012345). If the application has not yet been submitted, enter "N/A".
 - *Submission Date* - Provide the date applicant submitted the human drug or biosimilar biological product application to the FDA.
 - *Application Status* - Select appropriate response:
 - Submitted refers to an application that has been sent to the FDA.
 - Withdrawn refers to an application that has been voluntarily removed from the FDA's consideration by the applicant.
 - Accepted-for-filing refers to an application that the FDA has deemed sufficiently complete to permit a substantive review.
 - Refuse-to-file refers to an application that the FDA has deemed is not sufficiently complete to permit a substantive review.
 - Not submitted refers to an application that has not yet been submitted to the FDA for consideration.

- **Is this the first application the applicant has submitted to the FDA for review?** Select the appropriate response relevant to the user fee program for which you are requesting a small business waiver (i.e. if PDUFA, only consider all submitted human drug applications; if BsUFA, only consider all submitted biosimilar biological product applications).
 - If 'YES', proceed to Field 11.
 - If 'NO', Provide the application number and submission date for each additional product held by the applicant; List the application numbers for ALL human drug and biosimilar applications submitted for the user fee program for which you are requesting a small business waiver (i.e. If PDUFA, list all prior human drug applications; if BsUFA, list all biosimilar biological product applications **AND** human drug applications). Proceed to Field 10.

10. **Human Drug/Biosimilar Biological Products:** Human drug and biosimilar biological products are drug products approved under a human drug or biosimilar biological product application. List all FDA-approved human and biosimilar biological drug products owned or sponsored by the applicant.

- **Has the Applicant ever had drug product(s) approved under a human drug or biosimilar biological product application by the FDA that have been introduced or delivered for introduction into interstate commerce?** Select appropriate response.
 - If 'YES', list ALL drug products and the approval date for each FDA-approved human drug or biosimilar biological product introduced or delivered for introduction into interstate commerce. Provide the FDA-issued six-digit NDA or BLA application number. Proceed to Field 11.
 - If 'NO', proceed to Field 11.

11. **Small Business Waiver:** Applicants granted small business waivers for their first application for human drug or biosimilar biological drug products are not required to pay application fees assessed in accordance with FD & C Act, Sections 735, 736, and 744.

- **Has the Applicant previously received a Small Business waiver for a human drug or biosimilar biological product?** Select appropriate response.
 - If 'YES', select the appropriate user fee program and provide the accompanying data elements:
 - *Small Business Waiver Number* – Provide the FDA-issued small business waiver number assigned to the applicant's request.
 - *Waiver Approval Date* - Enter the waiver decision date as listed on the FDA-issued small business approval letter.
 - *Has the waiver been redeemed?* - Select appropriate response.
 - 'YES' - The applicant redeemed a waiver for application fees assessed under FD & C Act, sections 735, 736, or 744.
 - 'NO' - The applicant did not redeem a waiver for application fees assessed under FD & C Act, sections 735, 736, or 744.

Section II: 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."

Fill out this section if the applicant has any affiliates. If the applicant does not have any affiliates, check the box located after 'The Applicant does NOT have any affiliates' and proceed to Section III.

12. **Affiliate Name:** Provide the full legal name of the affiliate. If the affiliate 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 affiliate's business is a sole proprietorship owned entirely by one individual, provide the name used when filing Federal, State, or other taxes.

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13. **Affiliate Address: Provide the address where the business affiliate is physically located. No P.O. Boxes allowed.** Include the physical street address, city, state/province/region, country, zip code/ international postal code. Foreign entries must include the name of the country. See field 4 for full description.
14. **DUNS Number:** Provide the unique nine-digit identification number for the affiliate's physical location.
15. **Number of employees:** Provide the number of people employed by the affiliate at the time of the waiver request. See Field 7 for a detailed description of employees.
16. **Name of Affiliate's Point of Contact:** Enter the name of the affiliate's point of contact (POC).
17. **E-mail Address:** Enter the affiliate POC's e-mail address.
18. **Telephone number:** List the affiliate POC's telephone number. This includes area and country codes if applicable.
19. **Has the Affiliate previously received a small business waiver for any human drug or biosimilar biological product application?** Select appropriate response.
- If 'YES', provide the following data elements:
 - *Small Business Waiver Number* - Provide the FDA-issued small business waiver number assigned to the affiliate.
 - *Waiver Approval Date* – Enter the waiver approval date listed on the FDA-issued small business waiver approval letter.
 - *Has the waiver been redeemed?* - Select appropriate response.
 - 'YES' - The applicant redeemed a waiver for application fees assessed under FD & C Act, sections 735, 736, or 744.
 - 'NO' - The applicant did not redeem a waiver for application fees assessed under FD & C Act, sections 735, 736, or 744.
20. **Has the Affiliate ever submitted a human drug or biosimilar biological product application?** Select appropriate response.
- If 'YES', list the application numbers and FDA submission date for ALL human drug or biosimilar biological product applications submitted by the affiliate. Then proceed to Section III.
 - If 'NO', proceed to Section III.

If the applicant has more than one affiliate, click the 'Add New Affiliate' button and enter data for each affiliated entity

Section III: Refund

21. **Did the Applicant pay a fee for this application prior to requesting this small business waiver?** Check the appropriate box to disclose if the applicant paid the application fee for the human drug or biosimilar biological product application for which the waiver is requested.
- If 'YES', provide the following data elements:
 - *NDA or BLA Number* - Provide the number of the human drug or biosimilar biological product application.
 - *Payment Amount* - Provide the amount paid for the submitted application.

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- *PIN/Invoice Number* - Provide the payment identification number (PIN) or invoice number where payment was applied.
 - *Payment Reference Number* - Provide the payment reference number. If payment was remitted via check, money order, or bank draft, enter the check or money order number; if made electronically via Automated Clearing House (ACH) or credit card, enter the confirmation number; if made via wire transfer, enter the trace or Input Message Accountability Data (IMAD) number.
 - *Refund Amount Requested* - Provide the amount requested for the refund.
- If 'NO', proceed to Section IV.

Section IV: Certification

Review the certification in its entirety. Verify that the Applicant Name matches entry in Field 1 then sign and date the statement.

22. **Name of the Applicant's Responsible Official:** This is the Responsible Official authorized to conduct legally binding transactions on behalf of the applicant. This person is responsible for the completeness and accuracy of the information provided in this form, and will serve as FDA's point of contact for all communications regarding this request.

23. **Title:** Enter Responsible Official's title or position within the company.

24. **Telephone Number:** Provide the Responsible Official's telephone number.

25. **E-mail Address:** Enter the Responsible Official's email address. This address will be used for correspondence regarding the request, including the final determination documentation.

26. **Responsible Official's Address:** Provide the address where the Responsible Official is physically located. *No P.O. Boxes allowed.* Include the physical street address, city, state/province/region, country, zip code/international postal code. Foreign entries must include the name of the country. See field 4 for full description.

27. **Signature:** The Responsible Official must sign this request. **Without this signature, the request will not be processed.**

28. **Date:** Enter the date the Responsible Official signed the certification.

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