INSTRUCTIONS FOR FILLING OUT FORM FDA 4068 – Prescription Drug User Fee Act (PDUFA) Waiver, Refund, and Exemption Request

(The field numbers below correspond to the numbered boxes on Form FDA 4068)

Complete and email Form FDA 4068 to the Food and Drug Administration (FDA or the Agency) at CDERCollections@fda.hhs.gov to request an orphan exemption, waiver or refund of application or program fees assessed under section's 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for prescription drugs, including biological products. For information on PDUFA user fee exemptions, waivers and refunds, please refer to guidance for industry *Prescription Drug User Fee Act 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 Holder 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 exemption, waiver or refund. 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. **Contact Name:** 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.

3. **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.

4. **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 U.S. or its territories. Applicants located outside of the U.S. must also include the country code.

5. **Contact Email Address:** Enter the Responsible Official's email address. This email address will be used for correspondence regarding the request, including the final determination documentation.

6. **Address (*No P.O. Boxes allowed*):** This is the address where the business is physically located. Provide the following elements of the applicant's physical address:

   - *Address 1(Street address)* - Provide the physical street address where the applicant is located.
   - *Address 2 (Apartment, suite, unit, building, floor, etc.)*- 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 U.S. postal service zip code or international postal code where the applicant is located.

7. **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 the request cannot be processed for U.S. applicants.

   - For applicants headquartered in the U.S. or its territories, provide the Tax ID Number issued by the Internal Revenue Service.

   - For foreign applications (outside of the U.S. or its territories), provide a DUNS number (see field 8 below for information on DUNS number).

8. **DUNS Number:** The DUNS Number is a unique nine-digit identifier issued to an entity by Dun and Bradstreet. 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.

Section II: Authorized Contact Information (*Complete if different than Section I above*)

9. **Contact Name:** This is the Responsible Official authorized to conduct legally binding transactions on behalf of the applicant if different than the Responsible Official authorized personnel listed in Section I. 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.

10. **Email Address:** Enter the Point of Contact (POC)'s email address.

11. **Telephone Number (*Including area and country codes*):** This is the telephone number of the applicant's POC. Provide the area code and telephone number for POC located within

the U.S. or its territories. POC located outside of the U.S. must also include the country code.

12. **Fax Number (*Including area and country codes*)**: This is the fax number of the POC's physical location. Provide the area code and telephone fax number for POC located within the U.S. or its territories. POC located outside of the U.S. must also include the country code.

13. **Address (*No P.O. Boxes allowed*)**: This is the address where the POC is physically located. Provide the following elements of the POC's physical address:

    - *Address 1 (Street address)* - Provide the physical street address where the POC is located.
    - *Address 2 (Apartment, suite, unit, building, floor, etc.)* - Provide additional information such as a suite number or building number, if applicable.
    - *City* - Provide the city in which the POC is located.
    - *State/Province/Region* - Provide a two-letter state identifier or the province or territory in which the POC is located.
    - *Country* - Provide the country where the POC is located.
    - *ZIP or Postal Code* - Provide the U.S. postal service zip code or international postal code where the POC is located.

Section III: Request Information

Please note that your initial request for a waiver, reduction, or refund will NOT qualify for consideration unless it is submitted not later than 180 days after such fee is due in accordance with FD&C Act, Section 736(j).

14. **Select Request Type:** Select "Initial Request" if this is your first time submitting a request. Select "Reconsideration Request" if this is a request for FDA to reconsider a previous decision.

15. **Select Request Subtype:** Check only one box. Each request must be accompanied by a separate form. For example, if the applicant is submitting a waiver request of an application fee under the Barrier-to-Innovation and the Public Health waiver provisions for the same application, the applicant must submit a separate form for each waiver request.

    For a Small Business Waiver, please use Form FDA 3971 (Small Business Waiver and Refund Request), available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM584476.pdf

    For PEPFAR waiver, please select Barrier-to-Innovation waiver. For more information on which user fee waiver provision, refund or exemption the applicant may qualify, please refer to the guidance for industry *Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.*

    Other Refund Requests: Examples of requests based on exceptions would be situations where a program fee should not have been assessed (e.g., a large volume parental product (LVP), a product that was moved to the discontinued section, etc.).

Please Note: If payment was made after the submission of an initial or reconsideration of a waiver or exemption request and before a determination was made on the request, the waiver or exemption request will qualify as a refund request.

16. **Select Fee Type:** Check the appropriate box to disclose if the request is for an application fee or annual program fee.

17. **Specify the fiscal year (FY) of the user fee:** The Agency's FY runs from October 1 of a calendar year through September 30 of the following calendar year. For example, if you are requesting a waiver of an application fee and plan to submit your application after September 30, 2018, please enter FY 2019. If you are unsure when an application will be submitted to the Agency, please provide the best estimated FY for your request.

18. **Human Drug Product Application:** A human drug application is an application for (1) approval of a new drug submitted under section 505(b) of the FD&C Act, or (2) licensure of a biological drug product under section 351(a) of the Public Health Service Act (PHS Act).

    - *Application Type* - Select appropriate response: New Drug Application (NDA) is a human drug application for approval of a new drug submitted under section 505(b) of the FD&C Act. Biologics License Application (BLA) is a human drug application for licensure of a biological drug product under section 351(a) of the PHS Act.

      NDA/BLA Application Number - If the applicant has already submitted the human drug product application to the FDA, provide the six-digit NDA or BLA application number. Application number less than six-digits should be preceded using zeros (i.e., for NDA 12345 enter 012345). If you do not have an application number, please stop here. If you do not have an application number, please obtain one.

    - *Product Name* - Provide the drug product's proprietary and/or established name. Use the following format: PROPRIETARY NAME (established name).

      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 U.S. Patent and Trademark Office.

      Established name refers to the applicable official name designated pursuant to section 508 of the FD&C Act, or if there is no such official name, the title of any related official U.S. Pharmacopeia drug product or drug substance (ingredient) monograph or, if neither applies, the drug product's or ingredient's common or usual name.

Section IV: Affiliate Information

This section is applicable for Orphan Exemption, Public Health Waiver and Barrier-to-Innovation Waiver subtypes. If the request is not one of the above subtypes, skip this section and proceed to Section V.

"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 V.

19. **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.

20. **Affiliate Address (*No P.O. Boxes allowed*): Provide the address where the business affiliate is physically located.** 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 6 for full description.

21. **DUNS Number:** Provide the unique nine-digit identification number for the affiliate's physical location. See field 8 for full description.

22. **Name of Affiliate's Point of Contact:** Enter the name of the affiliate's POC.

23. **Telephone Number:** List the affiliate POC's telephone number. This includes area and country codes if applicable.

24. **Email Address:** Enter the affiliate POC's email address.

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

Section V: Certification

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

25. **Please certify that you have followed and submitted additional documentation as specified in the guidances below:**

For information on user fee waivers please refer to the guidance for industry *Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.*

For information on Fixed-Combination Antiretroviral Drugs for President's Emergency Plan for AIDS Relief (PEPFAR), please refer to the guidance for industry *Prescription Drug User Fee*

Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief.

For information on Positron Emission Tomography (PET) drug products, please click here.

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

27. Date: Enter the date the Responsible Official signed the certification.

Once complete, email completed Form FDA 4068 with additional documentation as specified in the applicable guidance to CDERCollections@fda.hhs.gov. If you have questions, contact the Division of User Fee Management and Budget Formulation at:

Email: CDERCollections@fda.hhs.gov
Phone: (301) 796-7900