
Instructions for Completing Form FDA 3794 (Generic Drug User Fee Cover Sheet)

Form FDA 3794 is to be completed on-line at https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp for each 1) abbreviated new drug application (ANDA) or applicable amendment, 2) annual program fee for a generic drug applicant, 3) type II active pharmaceutical ingredient (API) drug master file (DMF) prior to initial reference by a generic drug submission submitted to the Agency on or after October 1, 2012, unless specifically exempted below, and 4) annual fee for a facility referenced in at least one approved generic drug submission for producing generic drugs (API, finished dosage form (FDF), or both). A copy of the completed form FDA 3794 must be included in the first volume with Form 356(h) for an ANDA submission, or with the cover letter for the DMF submission to the FDA to which it applies. If you need assistance in completing the form, call 301-796-7200 or email: userfees@fda.gov.

GENERAL INFORMATION

- 1. APPLICANT, HOLDER, OR OWNER:** This is the legal person or entity that owns, controls, or represents the subject of the submission (i.e., the application, Generic Drug Applicant Program, the DMF, or the facility). This field is intended to reflect the name and address of record for the applicant, holder, or owner. Note that it is not intended to reflect the physical location of a facility, unless the applicant, holder, or owner is physically located in that facility.
- 2. REPRESENTATIVE OR U.S. AGENT:** This provides the FDA with a person that is authorized to respond to questions on this user fee cover sheet. If this is a foreign applicant, holder, or owner, the contact person must be a U.S. agent. This field is intended to reflect the name, title, telephone number, and e-mail address of the representative or U.S. agent.
- 3. FISCAL YEAR:** Indicate the U.S. government's fiscal year (*October 1 – September 30*) to which this payment applies. Note that each fiscal year starts on October 1 of the previous calendar year (*i.e., October 1, 2012 is the beginning of Fiscal Year 2013*).
- 4. GENERIC DRUG USER FEE TYPE:** Check the box to indicate the type of generic drug user fee this cover sheet references.
 - **ANDA** (*Original submission or amendment*) - Refer to instructions for item 5.
 - **GENERIC DRUG APPLICANT PROGRAM** - Refer to instructions for item 17.
 - **TYPE II API DRUG MASTER FILE** - Refer to instructions for item 19.
 - **FACILITY** - Refer to instructions on items 23 to 25.

ANDA INFORMATION

- 5. APPLICATION NUMBER FOR ANDA:** Please provide the six-digit application number for the ANDA. If the application number has fewer than six digits, please include one or more leading zeroes until the number has six digits. Further information is available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/default.htm>.
- 6. ESTABLISHMENT NAME OF PRODUCT:** The name of the product as referenced by the application will be a validation check if and when questions arise about application of payments or for other purposes.
- 7. AMENDING ANDA:** Indicate whether you are amending an ANDA that has been submitted to the FDA but on which a final official action has not yet been taken.
- 8. API MANUFACTURING INFORMATION INCLUDED:** Some ANDA submissions contain API manufacturing information that does not reference a Type II API Drug Master File. GDUFA requires that such applications pay the Section 744B(a)(3)(F) fee which relates to API and facility combinations. For more information, see Section 744B(a)(3)(F) of the Federal Food, Drug, and Cosmetic Act.
- 9. PROVIDE THE QUANTITY OF APIs INCLUDED IN THE APPLICABLE ANDA SUBMISSION:** Enter the quantity of APIs contained in the applicable ANDA submission upon which the ANDA relies and which are not also contained in Type II API Drug Master Files. For original ANDA submissions, this would include all APIs stated in the submission that are manufactured by the applicant. For ANDA amendments, this would include only the change and/or addition to APIs manufactured by the applicant that are stated in the applicable submission and would exclude the APIs previously stated in a prior ANDA submission. See Section 744B(a)(3)(F) of the Federal Food, Drug, and Cosmetic Act.
- 10. NAME OF DRUG SUBSTANCE FOR EACH API:** For each API mentioned in question 9, provide the name of the drug substance.

ANDA/PAS INFORMATION cont.

- 11. FOR EACH FACILITY, PROVIDE ADDRESS, FDA ESTABLISHMENT IDENTIFIER (FEI), AND FACILITY DUNS:** Indicate the official name of the facility and the facility's physical address. The FDA Establishment Identifier (FEI) number is a unique identifier issued by the FDA's Office of Regulatory Affairs. More information is available at <http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061432.htm>. If you have questions about obtaining an FDA Establishment Identifier (FEI) number, please contact FDAGDUFAFEIRequest@fda.hhs.gov. The DUNS number is issued by Dun & Bradstreet, Inc. and widely used for firm identification; see <http://www.dnb.com/duns-number.html> for more information. Please be sure to use the DUNS number associated with the physical location of the facility (also known as the 'establishment DUNS' as distinguished from the 'registrant DUNS').
- 12. IDENTIFY THE APIs THAT ARE MANUFACTURED BY EACH FACILITY:** For each facility, identify which of the APIs mentioned in question 10 are manufactured at that facility.
- 13. HAS FEE REQUIRED BY SECTION 744B(a)(3)(F) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT ALREADY BEEN PAID?** Indicate whether the Section 744B(a)(3)(F) fee has already been paid for any of the API/facility combinations through a previously submitted cover sheet or Form FDA 3794. For applications including API manufacturing information other than by reference to a DMF, GDUFA requires that such applications pay the Section 744B(a)(3)(F) fee which relates to API and facility combinations. For more information see Section 744B(a)(3)(F) of the Federal Food, Drug, and Cosmetic Act.
- 14. FOR EACH API/FACILITY COMBINATION, PROVIDE USER FEE PAYMENT I.D. NUMBER IN WHICH THE SECTION 744B (a)(3)(F) FEE WAS PAID:** Provide the User Fee Payment I.D. Number given at the completion of the cover sheet in which the fee required by Section 744B(a)(3)(F) of the Federal Food, Drug, and Cosmetic Act was paid. This will prevent double payments.
- 15. PET DRUG:** Positron Emission Tomography (PET) drugs are exempt from paying any generic drug user fees. If this application deals only with PET drugs under an ANDA, the fee does not apply. This will be reflected in Field 27 "User Fee Payment Amount for This Submission" upon checkout.
- 16. NON-COMMERCIAL/GOVERNMENT ENTITY:** Identify whether the application is submitted by a State or Federal Government entity for a drug that is not distributed commercially. For the purposes of the State and Federal exemption from user fees under the Act, "distributed commercially" means any distribution in exchange for financial reimbursement, goods, or services, whether or not the amount of the charge covers the full costs associated with the product. Any recovery by the applicant of all or part of the costs of manufacture or distribution of a product makes the distribution commercial.

GENERIC DRUG APPLICANT PROGRAM INFORMATION

- 17. PARENT COMPANY NAME:** Provide the name of the parent company. A parent company is the entity that owns and controls its subsidiaries.
- 18. PARENT COMPANY TIER:** According to FDA records of approved ANDAs, this is the program fee tier of the generic drug applicant program fee. See: www.fda.gov/gdufa.

DRUG MASTER FILE INFORMATION

- 19. TYPE II API DRUG MASTER FILE NUMBER:** This applies to a Type II API drug master file (DMF) where the owner intends to authorize the FDA to reference the information to support approval of a generic drug submission without the application holder having to disclose the information to the generic drug submission applicant. Please provide the number of the applicable Type II API DMF, which should be available from the DMF holder. See: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073164.htm> for further information or contact the FDA at dmfquestion@fda.hhs.gov.
- 20. NAME OF DRUG SUBSTANCE:** Provide the name of the substance covered by the Type II API DMF.
- 21. PET DRUG:** Positron Emission Tomography (PET) drugs are exempt from paying any generic drug user fees. If this Type II API DMF relates only to a PET drug, the fee does not apply. This will be reflected in Field 27 "User Fee Payment Amount for This Submission" upon checkout.
- 22. NON-COMMERCIAL/GOVERNMENT ENTITY:** Identify whether the DMF is referenced in only ANDAs that are submitted by a State or Federal Government entity for drugs that are not distributed commercially. For the purposes of the State and Federal exemption from user fees under the Act, "distributed commercially" means any distribution in exchange for financial reimbursement, goods, or services, whether or not the amount of the charge covers the full costs associated with the product. Any recovery by the applicant of all or part of the costs of manufacture or distribution of a product makes the distribution commercial.

FACILITY INFORMATION

- 23. U.S. FACILITY:** Please indicate if the facility for which this fee is being paid is located in the United States, its territories, or possessions. This information is required to determine the correct fee due, which will be reflected in Field 27 "User Fee Payment Amount for This Submission" upon checkout.
- 24. PROVIDE FACILITY NAME, ADDRESS, FDA ESTABLISHMENT IDENTIFIER (FEI), AND FACILITY DUNS NUMBER:** Indicate the official name of the facility and the facility's physical address. The FDA Establishment Identifier (FEI) is a unique identifier issued by FDA's Office of Regulatory Affairs. More information is available at <http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061432.htm>. If you have questions about obtaining an FDA Establishment Identifier (FEI) number, please contact FDAGDUFAFEIRequest@fda.hhs.gov. The DUNS Number is issued by Dun & Bradstreet, Inc. and widely used for firm identification; see <http://www.dnb.com/duns-number.html> for more information. Please be sure to use the DUNS Number associated with the physical location of the facility (also known as the 'establishment DUNS' as distinguished from the 'registrant DUNS').
- 25. TYPE OF FACILITY:** A facility is a business or other entity under one management, either direct or indirect, and at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form. This term does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing. Separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are closely related to the same business enterprise, are under the supervision of the same local management, and can be inspected by the FDA during a single inspection. Indicate whether the facility for which this fee is being paid is engaged in manufacturing one or more APIs, one or more FDFs, or both for at least one approved generic submission. If the API facility produces ONLY Positron Emission Tomography (PET) drugs, user is exempt from paying any API user fees, but may require FDF fees if applicable. If the FDF facility produces ONLY PET drugs, user is exempt from paying any FDF user fees, but may require API fees if applicable. Similarly, the user is exempt from facility user fees if all APIs and FDFs produced at the facility are for ANDAs submitted by State or Federal Government entities for drugs that are not distributed commercially. Lastly, identify if the facility is a contract manufacturing organization (CMO). An FDF facility which is not identified in an ANDA owned by the owner of that facility or its affiliates is considered a CMO for GDUFA user fee purposes. Check all that are applicable.

USER FEE PAYMENT INFORMATION

- 26. USER FEE PAYMENT I.D. NUMBER (PIN):** This number is automatically generated by the User Fee System. When submitting your payment, please include the PIN on your check, bank draft, or postal money order or reference the PIN on your wire transfer payment.
- 27. USER FEE PAYMENT AMOUNT FOR THIS SUBMISSION:** This amount is automatically calculated by the User Fee System based on the information provided in the cover sheet. If you are remitting this payment by wire transfer, please be sure to include any additional charges imposed by your financial institution (e.g., wire transfer fee).

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. 744B. 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 detect or 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 details regarding FDA's use of information is available online: <http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/>.

This section applies only to the requirements for the Paperwork Reduction Act of 1995

DO NOT SEND YOUR COMPLETED FORM OR USER FEE PAYMENT TO THIS PRA STAFF ADDRESS

Public reporting burden for this collection of information is estimated to average 30 minutes 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 any other aspect of this collection of information, including suggestions for reducing this burden, to the address to the right:

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Food and Drug Administration
Office of Information Management (HFA-710)
Paperwork Reduction Act (PRA) Staff
8455 Colesville Road, COLE-14-14253
Silver Spring, MD 20993-0002

"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 control number."