Assessing User Fees Under the Generic Drug User Fee Amendments of 2017

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Office of Management, Division of User Fee Management and Budget Formulation, Phone: 301-786-7900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

October 2017
User Fees

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides stakeholders information regarding FDA's implementation of the Generic Drug User Fee Amendments of 2017 (GDUFA II) under Title III of the FDA Reauthorization Act of 2017. Because GDUFA II created changes to the user fee program, this guidance serves to provide an explanation about the new fee structure and types of fees for which entities are responsible.

This guidance describes the types of user fees authorized by GDUFA II, the process for submitting payments to FDA, the consequences for failing to pay generic drug user fees, and the process for requesting a reconsideration of a user fee assessment. This guidance also describes how FDA determines affiliation for purposes of assessing generic drug user fees. FDA will issue separate guidance documents regarding GDUFA II non-user fee requirements and processes. This guidance does not address how FDA determines and adjusts fees each fiscal year; nor does it address FDA's implementation of other user fee programs (e.g. Prescription Drug User Fee Amendments, Biosimilar Biological User Fee Amendments).[2] Throughout this guidance, references to *user fees* or the *user-fee program* are to generic drug user fees collected under section 744B of the Federal Food Drug and Cosmetic Act (FD&C Act).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Division of User Fee Management and Budget Formulation, Office of Management, in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] FDA will publish in the *Federal Register* the fee revenue and fee amounts for each fiscal year not later than 60 days before the start of each fiscal year. Section 744B(d)(1) of the FD&C Act.

Changes to statutory provisions that are described in this guidance are effective with respect to fees assessed beginning on the first day of fiscal year (FY) 2018.

II. BACKGROUND

The Generic Drug User Fee Amendments of 2012 (GDUFA I) added sections 744A and 744B to the FD&C Act, authorizing FDA to collect user fees for a 5-year period from persons that submit certain abbreviated new drug applications (ANDAs) for review, or that are referenced in certain ANDAs. Fees authorized by this legislation help fund the process for the review of generic drug applications and have played an important role in expediting the drug review and approval process. GDUFA was reauthorized for a five-year period in 2017 (GDUFA II) under the FDA Reauthorization Act of 2017, enacted on August 18, 2017.

GDUFA II extends FDA's authority to collect user fees for FY[3] 2018 to FY 2022 and revised the fees that the Agency collects and how it collects some fees. Discussions about the further reauthorization of GDUFA are expected to begin before or during FY 2022, the final fiscal year of GDUFA II.

III. DEFINITIONS

For purposes of this guidance:

- The term ***abbreviated new drug application*** means an application submitted under section 505 of the FD&C Act (21 U.S.C. § 355(j)), under former section 507 of the Act (now repealed), or pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984. The term does not include an application for a positron emission tomography drug and does not include an application submitted by a State or Federal Government entity for a drug that is not distributed commercially.[4]

- The term ***active pharmaceutical ingredient*** means a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended (A) to be used as a component of a drug; and (B) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture as described above.[5]

[3] FDA's fiscal year begins on October 1 and ends on September 30.
[4] See Section 744A(1) of the FD&C Act.
[5] See Section 744A(2) of the FD&C Act.

- The term ***affiliate*** means 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.[6]

- The term ***facility*** means 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. The term facility 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.[7]

- The term ***finished dosage form*** means (A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application; (B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or (C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).[8]

- The term ***generic drug submission*** means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.[9]

- The term ***positron emission tomography drug*** means a drug that exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images, and includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.[10]

- The term ***prior approval supplement*** means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.[11]

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[6] See Section 744A(4) of the FD&C Act.

[7] See Section 744A(6) of the FD&C Act. The FDA Establishment Identifier (FEI) is used to identify unique facilities.

[8] See Section 744A(7) of the FD&C Act.

[9] See Section 744A(8) of the FD&C Act.

[10] See Section 744A(10) of the FD&C Act; See Section 201(ii) of the FD&C Act.

[11] See Section 744A(11) of the FD&C Act.

- The term ***Type II active pharmaceutical ingredient drug master file*** means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.[12]

- The term ***contract manufacturing organization facility*** means a manufacturing facility of a finished dosage form of a drug approved pursuant to an ANDA which is not identified in an ANDA held by the owner of that facility or its affiliates.[13]

IV. CHANGES TO THE STRUCTURE OF THE GDUFA USER FEE PROGRAM

GDUFA II authorizes the collection of five types of fees: (1) backlog fees; (2) drug master file (DMF) fees; (3) ANDA filing fees; (4) active pharmaceutical ingredient (API) and finished dosage form (FDF) facility fees; and (5) generic drug applicant program fees (GDUFA Program Fees). The statute directs FDA to set annual fee amounts for each fiscal year so that DMF fees will account for 5 percent, ANDA fees 33 percent, API facility fees 7 percent, FDF facility fees 20 percent, and GDUFA Program Fees 35 percent of the total revenue amount determined for a fiscal year.[14] Under GDUFA II, applications submitted by State and/or Federal government entities for drugs that are not distributed commercially also do not incur fees.

Previously, section 744B of the FD&C Act authorized FDA to collect (1) backlog fees; (2) DMF fees; (3) ANDA and prior approval supplement (PAS) fees; and (4) API and FDF facility fees. GDUFA II establishes a new fee structure that eliminates PAS fees and adds GDUFA Program Fees.

Additionally, facilities that manufacture both APIs and FDFs will only incur FDF fees instead of owing both API and FDF facility fees. A facility no longer incurs a fee if it is only referenced in pending generic drug submissions because the facility fee obligation now applies only to facilities referenced in approved generic drug submissions. Facilities that qualify as contract manufacturing organizations (CMOs) pay one-third the amount of the facility fee incurred by FDF facilities that do not qualify as CMOs.[15]

[12] See Section 744A(13) of the FD&C Act.

[13] See Section 744A(5) of the FD&C Act; See Section IV (Changes to the Structure of the GDUFA User Fee Program) and Section VII (Facility Fees) for more information.

[14] See Section 744B(b) of the FD&C Act. While in almost all cases applicants that owed backlog fees have now paid those fees, this obligation remains part of the statute.

[15] See Section 744B(b)(2)(C) of the FD&C Act.

The Agency will continue to establish generic drug user fees for each fiscal year based on revenue amounts set forth in the statute, and will publish the fees and fee revenue amounts for a fiscal year in the Federal Register not later than 60 days before the start of that year.[16]

V. BACKLOG FEES

Under GDUFA II, each person that owns an ANDA that was pending on October 1, 2012, and that has not received a tentative approval prior to that date, owes a backlog fee for each such application.[17]

The backlog fee was due no later than November 26, 2012. The final backlog fee is $17,434. See *Federal Register* notice: "Generic Drug User Fee – Backlog Fee Rate for Fiscal Year 2013" for additional details (available at https://www.gpo.gov/fdsys/pkg/FR-2012-10-25/pdf/2012-26257.pdf).

An original ANDA was considered to be pending and subject to the backlog fee, if, as of September 28, 2012, FDA had not tentatively approved, approved, or refused to receive (RTR) the application.[18] See *Federal Register*: "Notice of Opportunity to Withdraw Abbreviated New Drug Applications to Avoid Backlog Fee Obligations" for additional details (available at https://www.gpo.gov/fdsys/pkg/FR-2012-08-27/html/2012-20947.htm).

VI. DRUG MASTER FILE FEES

Each person that owns a Type II active pharmaceutical ingredient DMF that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization is assessed a one-time DMF fee under GDUFA II.[19]

The DMF fee is due on whichever of the following dates occurs earlier:

- The date on which the first generic drug submission is submitted that references the associated Type II API DMF by an initial letter of authorization; or
- The date the DMF holder requests the initial completeness assessment.[20]

[16] Section 744B(a) of the FD&C Act.
[17] See Section 744B(a)(1)(A) of the FD&C Act; GDUFA II contains a sunset provision of October 1, 2022, for backlog fees; See Section 744B(a)(1)(E) of the FD&C Act.
[18] Receipt of an ANDA means that FDA has made a threshold determination that the ANDA is sufficiently complete to permit a substantive review. 21 CFR § 314.101(b)(1).
[19] See Section 744B(a)(2)(A) of the FD&C Act.
[20] See Section 744B(a)(2)(E)(i) of the FD&C Act.

For a DMF referenced in an ANDA prior to GDUFA I implementation, the one-time DMF fee must be paid if the DMF is newly referenced in a generic drug submission on or after October 1, 2012.

Type II API DMF holders do not need to wait for a new ANDA applicant to request a letter of authorization before the DMF is assessed to be available for reference. DMF holders can pay the fee before a letter of authorization is requested. The DMF will then undergo an initial completeness assessment, using factors articulated in the final guidance *Completeness Assessments for Type II API DMFs Under GDUFA* (available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf). If the DMF passes the initial completeness assessment, FDA will include the DMF on the Type II Drug Master Files – Available for Reference List (available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM332875.xls).

VII. ABBREVIATED NEW DRUG APPLICATION FILING FEES

GDUFA II levies a user fee on certain human generic drug applications. A fee is assessed for each ANDA submitted to FDA after October 1, 2012. A prior approval supplement filing fee, which was required under GDUFA I, is no longer required under GDUFA II.[21]

ANDA fees are due on the date of submission of the application.[22]

A. Refund for Refusal to Receive and Withdrawals and Inappropriate Receipts

If FDA refuses to receive an ANDA for reasons not related to failure to pay fees, then 75 percent of the filing fee paid will automatically be refunded to the applicant. Under GDUFA II, a 75 percent refund of the application filing fee paid will also be remitted for an application that has been withdrawn prior to being received within the meaning of section 355(j)(5)(A) of the FD&C Act.[23]

If FDA initially receives an ANDA and subsequently determines that exclusivity should have prevented that receipt so that the ANDA is no longer considered received, FDA will refund 100% of the fee paid for that ANDA.[24]

[21] Unpaid fees for supplements submitted under GDUFA I will not automatically be considered met once GDUFA II takes effect in FY 2018. These supplements will continue to be considered as refused to receive by the Agency. The ANDA applicant may submit a new supplement in FY 2018 under GDUFA II, which will not incur a supplement fee.

[22] See Section 744B(a)(3)(C)(i) of the FD&C Act.

[23] See Section 744B(a)(3)(D)(i) of the FD&C Act.

[24] See Section 744B(a)(3)(D)(ii) of the FD&C Act.

Although certain GDUFA refunds are automatic, FDA encourages applicants to submit refund requests as soon as possible to expedite the refund process. To request a refund, applicants should fill out Form FDA 3913 and email the form to CDERCollections@fda.hhs.gov. Form FDA 3913 is attached as Appendix 1, and available on the internet at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf.

Include the Tax ID number (required for all domestic companies) or DUNS number (required for all foreign companies), and the address where the refund should be sent. This information is required, and FDA cannot process a refund without it. If an applicant does not submit a refund request, FDA will initiate a refund during its periodic review of outstanding refunds.

If an application that FDA previously refused to receive is resubmitted, the applicant will be required to pay the full fee at the time of resubmission. Similarly, an applicant who withdraws an application before it is received and then submits a new ANDA for that product must pay the full fee upon submission. If the applicant notifies FDA that it plans to resubmit the application in the near future, the Agency may hold the refund and initiate a transfer of the funds to the resubmission upon the request of the applicant. To request a transfer, applicants should fill out Form FDA 3914 and email the form to CDERCollections@fda.hhs.gov. Form FDA 3914 is attached as Appendix 2, and available on the internet at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492195.pdf.

B. Resubmissions

A resubmission of an ANDA attempts to remedy deficiencies (major, minor, Electronic Common Technical Document) indicated in a RTR letter. A full ANDA filing fee is due upon resubmission of the ANDA that FDA refused to receive. Dispute of a RTR decision without attempting to remedy the deficiencies is not considered a resubmission and is therefore not subject to a new ANDA filing fee.

C. Exemptions to the Application Filing Fee

An applicant will not incur an ANDA filing fee under the following circumstances:

- The application is for a positron emission tomography (PET) drug;
- The application is submitted by a State or Federal Government entity for a drug that is not distributed commercially; or
- The submitted application is a serial submission (see subsection E. below).

Approved applications of the types described in this subsection will also not be considered in determination of GDUFA Program Fees (see section IX below).

D. Fee for API Information Not Included by Reference to DMF - (a)(3)(F) Fee

An applicant is required to pay an API information fee for a generic drug submission:

- That contains information concerning the manufacture of an API at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical DMF; and
- For which a fee in the amount equal to the DMF fee has not been previously paid.

Similar to the DMF fee, this fee is paid only once.[25]

GDUFA II specifies that an additional API information fee must be paid for each manufacture of an API by one facility described in an application, when such a fee has not already been paid for the manufacture of that API by that facility. Therefore, the total amount of the API information fees for a particular application is a function of the number of APIs referenced in the application and the number of facilities in which those APIs are manufactured. The API information fee must be paid for each manufacture of an API by a particular API facility, provided a DMF or API information fee has not already been paid for the manufacture of the same API by the same facility.

Because the calculation is potentially confusing, please see the following two examples:

Example One:

An applicant (XYZ Corp.) submits an ANDA that, rather than referencing a DMF, describes the manufacture of three APIs at one or more facilities. No previous API information or DMF fee has been paid for the manufacturing of the APIs by these facilities.

Product	**API**	**Facility that has not paid API fee**
Drug X	Alpha	1, 2, 3
	Beta	1, 2
	Gamma	1

In this example, XYZ Corp. owes the following API information fee:

Fee = (APIs (Alpha + Beta + Gamma) + extra facilities (Alpha 2 + Alpha 3 + Beta 2)) x DMF Fee Amount

= (3 APIs + 3 extra facilities) x DMF Fee Amount

= 6 x DMF Fee Amount

[25] See Section 744B(a)(3)(F) of the FD&C Act.

Example Two:

XYZ Corp. then submits a new application for a second product with the following information about API manufacture other than by reference to a DMF:

Product	**API**	**Facility**
Drug Y	Alpha	1, 2, 3
	Beta	1, 2
	Gamma	1, 2
	Delta	1

The one-time fee has already been paid for the description of the manufacture of API Alpha at Facility 1, 2, and 3; API Beta at Facility 1 and 2; and API Gamma at Facility 1, so no additional fee is due with respect to these facilities.

The applicant owes an API information fee for the following:

Fee = (additional API Delta + manufacture of API Gamma at Facility 2 x DMF Fee Amount

= (1 API + 1 extra facility) x DMF Fee Amount

= 2 x DMF Fee Amount

The fees, referenced in the above calculations, for each API manufacturing facility that manufactures a particular API included in an application is meant to replicate the applicable DMF fee if the information had been submitted in a DMF. Annual API facility fees are discussed below and are required for each facility that is identified in an ANDA or a DMF.

E. Serially Submitted ANDAs

In some circumstances, ANDA applicants choose to serially submit complete ANDAs containing "paragraph IV certifications" in anticipation of a patent being listed for a reference listed drug.[26] Note that under 21 CFR § 314.94, serial submissions are prohibited: "for a paragraph IV certification, the certification must not be submitted earlier than the first working day after the day the patent is published" in FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly known as the Orange Book. The regulation reflects FDA's judgment that permitting serial submissions of amendments and multiple notices of paragraph IV

[26] For a description of ANDA patent certifications see draft guidance for industry *180-day Exclusivity: Questions and Answers* (Jan 2017) available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536725.pdf.

certifications is overly burdensome to FDA and NDA holders.[27] Applications submitted prior to the time specified in the cited regulation are not considered to be in the possession of the Agency. However, applicants who nonetheless choose to serially submit complete ANDAs in anticipation of a new patent being listed in the Orange Book should remit their application filing fee on the first working day after the day the relevant patent is listed in the Orange Book or, if the application is not submitted on that date, on the date the application is submitted.

F. Withdrawn ANDAs

Once a fee is incurred, it must be paid notwithstanding what happens to the application. Accordingly, an ANDA that is withdrawn still owes the fee. However, if an application is withdrawn before being received, the applicant is eligible for a 75% refund.

VIII. FACILITY FEES

Under GDUFA II, the owner of a facility incurs a fee when both of the following conditions are met on the facility fee due date:

- The facility is referenced in an *approved* generic drug submission; and
- The facility is engaged in manufacturing or processing an API or FDF.[28]

A facility does not incur a fee for being referenced only in *pending* generic drug submissions in GDUFA II.

Note that an entity meeting the two criteria above will incur a facility fee liability regardless of whether it is manufacturing or producing generic *or* non-generic human drugs. For example, if a facility is referenced in an approved ANDA and is manufacturing only brand-name drugs, it will be assessed a facility fee under GDUFA II.

Facility fees are due on the later of the first business day on or after October 1 of each fiscal year, or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year.[29]

If a facility is first identified in an approved generic drug submission after the due date for payment of the facility fee for a fiscal year, the facility is not required to pay the fee for that fiscal year.

[27] See 81 FR 69580, 69610.
[28] See Section 744B(a)(4)(A) of the FD&C Act; See Section 744A(5) of the FD&C Act.
[29] See Section 744B(a)(4)(D) of the FD&C Act.

A. API and FDF Facility Fees

Each person that owns a facility will incur an API facility fee when the facility is identified in:

- At least one generic drug submission in which the facility is approved to produce one or more APIs, or
- A Type II API DMF referenced in an approved generic drug submission.[30]

Each person that owns a facility will incur an FDF facility fee when the facility is identified in at least one generic drug submission that is approved to produce one or more FDFs.[31]

B. Exceptions to Facility Fees

The following entities will not incur facility fees under GDUFA II:

- Facilities that solely produce PET drugs.
- Facilities that are only listed in applications submitted by State and/or Federal government entities for drugs that are not distributed commercially.
- Facilities whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

C. Dual Operation Facilities Only Incur FDF Facility Fees

If a facility is identified in one or more approved generic drug submissions to produce both APIs and FDFs, the facility will only incur an FDF fee.[32] This differs from the treatment under GDUFA I, which required that such facilities pay both API and FDF fees.

D. Contract Manufacturing Organizations

CMOs are independent firms with no ownership stake (either directly or through affiliates) in the ANDAs for the drug products they manufacture. An FDF manufacturer facility that is not identified in an approved ANDA held by the owner of that facility or its affiliates is considered a CMO for GDUFA user fee purposes.[33]

For example, if the FDF facility is referenced in an ANDA held by its owner, that FDF facility would not be a CMO. However, even if the owner of the FDF facility holds an ANDA, so long as the facility is not referenced in its owner's or its owner's affiliates' ANDAs, then it qualifies as a CMO and pays one-third the amount of the FDF facility fee if referenced in another

[30] See Section 744B(a)(4)(A)(ii) of the FD&C Act.
[31] See Section 744B(a)(4)(A)(iii) of the FD&C Act.
[32] *Id.*
[33] See Section 744A(5) of the FD&C Act.

ANDA.[34] Similarly, if an FDF facility owner is affiliated with Company X, and Company X references that FDF facility in its ANDA, the FDF facility is not a CMO.

A facility's qualification as a CMO depends only on the FDF manufacturing activities of that facility. A facility that is referenced in one or more ANDAs as both an API and FDF manufacturer may qualify as a CMO even if it is referenced as an API manufacturer in its own or its affiliates' ANDA. As long as a dual facility is not referenced as an FDF manufacturer in its own or its affiliates' ANDAs, it may qualify as a CMO.

E. Foreign-Facility Fee Differential

GDUFA II specifies that the amount of the fee for a facility located outside the United States and its territories and possessions is $15,000 higher than the amount of the fee for a domestic facility. For example, a foreign facility will pay one-third the FDF facility fee plus $15,000.[35] The $15,000 differential applies to all facilities that incur a fee under GDUFA II, including those facilities defined as CMOs. The differential amount is designed to reflect the higher costs of foreign inspections funded, in part, through GDUFA II.

F. Withdrawal of Facility From Reference

If an ANDA sponsor determines that a manufacturing facility no longer manufactures its API or FDF and the ANDA sponsor no longer seeks to retain the facility as an approved manufacturer of the API or FDF, the ANDA sponsor should submit an appropriate notification to remove the manufacturing facility from the ANDA. The supplement should provide a justification if the site being removed is not considered redundant (i.e., the particular facility's manufacturing role is not replaced by another appropriate site to continue the approved function). If approval of another facility is desired, the notification to remove the prior facility may be included in the supplement to add the new facility to the ANDA. If a facility identified in an ANDA wishes to be removed from that ANDA, the Agency encourages the owner of the facility to contact the ANDA sponsor and/or DMF holder and work together to effect the facility's removal from the application.

In the rare situation when the ANDA sponsor or DMF holder does not file a notification to remove an approved manufacturing facility for its API or FDF, a facility may remove itself from reference in all ANDAs to prevent incurring future user fees through the process described in the following paragraphs.

An ANDA sponsor can identify a facility that it does not own in its application only if the owner of that facility has provided the ANDA sponsor permission to refer to the facility. If the owner of the facility submits a notification to FDA to withdraw that permission—and thus no longer be approved for use by the ANDA applicant—FDA will consider the facility to be no longer identified in the application as of the date FDA receives notice of the withdrawal via the process

[34] See Section 744B(b)(2)(C) of the FD&C Act.

[35] *Id.*

described below. The facility will no longer be approved for manufacture of the FDF, or the API, for that application.

Since a facility continues to incur facility fees until FDA is notified of the facility's withdrawal, the Agency encourages the owner of the facility identified in an ANDA to take the following steps prior to the fiscal year fee due date:

- Notify the ANDA sponsor and/or DMF holder in writing that it is withdrawing its permission to reference the facility in its ANDA and/or DMF.

- Send a copy of this letter to the standard application submission methods for ANDAs and DMFs via FDA electronic gateway or by mail to the ANDA archival file at the following address:

  Office of Generic Drugs (HFD-600)
  Center for Drug Evaluation and Research
  Food and Drug Administration
  Document Control Room
  Metro Park North VII
  7620 Standish Pl.
  Rockville, MD 20855

- If the facility owner is also a DMF holder, update the DMF with this change. See FDA's DMF website for more information (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm).

- In addition, email a copy of the withdrawal letter to the Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov.

An entity will incur facility fees if it manufactures any human drugs and is referenced in an approved generic drug submission on the facility fee due date, regardless of whether it manufactures only non-generic APIs or FDFs. Similarly, a facility owner will have to pay a facility fee if the facility is referenced in an approved generic drug submission, even if it is only manufacturing drugs for the non-US market. For example, a facility that is only manufacturing one non-generic drug for a non-US market and is referenced in an approved ANDA as an API manufacturer on the facility fee due date will incur an API facility fee.

Self-identification does not, in and of itself, trigger a liability to pay GDUFA facility fees. Many—but not all—facilities that self-identify are required to pay an annual facility user fee. Those that do incur the fee include facilities manufacturing API of human generic drugs and/or FDF human generic drugs. Other sites and organizations must self-identify but are not required to pay the annual facility user fee. These include facilities that solely manufacture PET

drugs, or sites and organizations that only perform testing, repackaging, or relabeling operations. While repackagers are not required to pay user fees, packagers are, in most cases, FDF or CMO FDF manufacturers and subject to facility fees. Removal of a facility from self-identification will not prevent the facility from incurring facility fees.

For more information on self-identification, please visit http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm, and see the final guidance *Self-Identification of Generic Drug Facilities, Sites, and Organizations* (https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm316672.pdf).

If a facility is identified in an approved generic drug submission on the due date, and that reference to the facility or the drug submission is later withdrawn, the fee will not be refunded. Accordingly, withdrawal of all reference to facilities in generic drug submissions after the due date will not absolve the facility owner from the requirement to pay previously incurred facility fees.

G. Packagers and Repackagers

Packagers are considered to be manufacturers, regardless of whether that packaging is done pursuant to a contract or by the applicant itself. Such facilities are required to pay annual FDF facility fees. A packaging facility may incur only one-third of the FDF facility fee if it qualifies as a CMO (see definitions section above).

A facility is considered a packager for the purposes of GDUFA II if it receives product prior to the point in the manufacturing process in which the drug is first packaged in a container/closure system specified in the "How Supplied" section of an approved ANDA and packages that product into such a container/closure system for the first time. Every ANDA specifies the forms or configuration in which the approved drug product may be packaged and distributed in the "How Supplied" section. For example, if a facility receives bulk drugs and packages them into the containers in which they are marketed, it is a packager.

A facility is also considered to be a manufacturer if it receives product in a container/closure specified in the "How Supplied" section of an approved ANDA and applies the FDA-approved prescription package labeling to that product for the first time.

Repackagers are not required to pay facility fees under GDUFA II. Repackagers include facilities that remove a drug from a primary container/closure system and subdivide the contents into a different primary container/closure system. For example, a facility that takes tablets out of a plastic bottle and packages the tablets into blister packaging is considered a repackager.[36]

[36] See guidance for industry *SPL Industry Technical Specification Information: Electronic Self-Identification of Generic Drug Facilities or Sites* (2017) at 7, available at https://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM329269.pdf.

H. API and Excipient Mixtures

Generally, manufacturers of API mixtures are required to pay the annual FDF facility fee. However, GDUFA II provides one exception, for fee-paying purposes only, to the definition of in-process mixtures as FDF. GDUFA II defines an API and excipient mixture as an API when it is produced because the API is unstable and cannot be transported on its own. Examples include an API mixed with an antioxidant for chemical stability when the API is prone to oxidative degradation or an API excipient mixture for physical stability to maintain its amorphous form.

I. Atypical APIs

Facilities that process raw materials used to manufacture human generic drugs are generally required to pay annual facility fees if they supply a product that qualifies as an API as defined in GDUFA II. For example, if a facility manufactures an ingredient which is used as a component of a drug and furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, and the ingredient is referenced in an approved ANDA, that facility may incur a facility fee.

J. Facilities That Cease Manufacturing

A facility incurs annual facility fees as long as it is so identified, even if the facility has not started commercial-scale production of the API or FDF covered by that submission, or if the facility has stopped, temporarily or permanently, the production of that API or FDF. See above for a description of how a facility can ensure that it is no longer identified in an ANDA.

The facility will cease to incur additional fees if it is no longer identified in any generic drug submission or has stopped manufacturing *all* APIs and FDFs (including both generic and non-generic APIs and FDFs) by the date that the fee is due. In the latter case, the entity no longer qualifies as a facility under GDUFA II – see the definition of facility in Section III above. Any outstanding fee obligations will, however, remain due.

A facility is encouraged to contact its ANDA holder to withdraw its permission to be referenced in an ANDA or follow the steps outlined in the "Withdrawal of Facility from Reference" section to remove itself from all ANDA references. If a facility goes out of business, it should contact FDA to notify the Agency of its status.

K. Fees for Multiple Locations of the Same Company

If a company's two locations manufacture a U.S. generic product and they are in different geographic locations, each has to pay an annual facility fee. However, 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;
- They are under the supervision of the same local management; and
- They are capable of being inspected by FDA during a single inspection.[37]

These are the same criteria used by the FDA's Office of Regulatory Affairs to evaluate whether separate FDA Facility Establishment Identifiers **(**FEIs) are necessary for multiple facilities (see final guidance *Self-Identification of Generic Drug Facilities, Sites, and Organizations*, available at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm316672.pdf).

If a firm believes that multiple FEIs have been assigned in error or that its separate facilities qualify for a single FEI, the firm may request consolidation of the FEIs. Once a facility fee is incurred, the fee remains outstanding regardless of whether FDA later agrees to consolidation of FEI numbers. Domestic firms should submit the request to the appropriate FDA District office. Contact information is available at http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123522.pdf. Foreign firms should contact FDAGDUFAFEIRequest@fda.hhs.gov.

IX. GENERIC DRUG APPLICANT PROGRAM FEE

Under GDUFA II, a GDUFA Program Fee will be assessed annually based on the number of approved applications that an entity and its affiliates own. Affiliated companies will be grouped together and counted as a single entity for purposes of assessing the GDUFA Program Fee.[38] An ANDA sponsor and its affiliates cannot choose to pay multiple smaller fees to avoid paying the fee associated with larger tiers.

GDUFA Program Fees are due on the later of the first business day on or after October 1 of each fiscal year, or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year.[39]

A. GDUFA Program Fee Structure

The GDUFA Program Fee will be allocated among three tiers of application holders:

- Small (companies with 5 or fewer approved ANDAs).
- Medium (companies with between 6 and 19 approved ANDAs).

[37] See Section 744A(5) of the FD&C Act. The statute further states that if a business or other entity would meet the definition of a facility but for being under multiple management, the business or entity is deemed to constitute multiple facilities, one per management entity.
[38] See Federal Register Notice, 82 FR 2381.
[39] See Section 744B(a)(5) of the FD&C Act.

- Large (companies with 20 or more approved ANDAs).

If a person and its affiliates own at least one but not more than five ANDAs on the GDUFA Program Fee due date, the person and its affiliates shall owe a small size operation GDUFA Program Fee equal to one-tenth of the large size operation GDUFA Program Fee.

If a person and its affiliates own at least six but not more than 19 ANDAs on the GDUFA Program Fee due date, the person and its affiliates shall owe a medium size operation GDUFA Program Fee equal to two-fifths of the large size operation GDUFA Program Fee.

If a person and its affiliates own at least twenty ANDAs on the GDUFA Program Fee due date, the person and its affiliates shall owe a large size operation GDUFA Program Fee.[40]

See FDA's GDUFA website for the current fiscal year's fee amounts (https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm).

B. Single Fee for Applicant and its Affiliates

An applicant and its affiliates together will only incur one GDUFA Program Fee per year. GDUFA II mandates that a "single fee shall be assessed" for an ANDA sponsor and its affiliates.[41] The ANDA sponsor who is responsible for submitting the affiliate information on behalf of the company and its affiliates must submit complete information so that FDA will assess one GDUFA Program Fee for the sponsor. If FDA finds an affiliation that was not reported to the Agency, FDA will re-assess the fees for both the affiliate and parent company, potentially resulting in an invoice if FDA finds that the firm should have paid a higher amount.

C. Submitting Information to FDA

Each person that owns an ANDA shall submit to the Secretary, by April 1 of each year, a list of all ANDAs held by such person; except that, if an affiliate of such person also owns ANDAs, the person or its affiliate must submit, on behalf of the person and its affiliates, a list identifying all affiliates that own such applications and the ANDAs owned by the person and its affiliates. Please see FDA's GDUFA website (https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm) for more information.

[40] See Section 744B(b)(2)(E) of the FD&C Act.
[41] *Id.*

D. Timing for Withdrawal of ANDAs

An ANDA shall be deemed not to be approved for purposes of the GDUFA Program Fee if the applicant has submitted a written request for withdrawal of approval of such ANDA by April 1 of the previous fiscal year. If such a request to withdraw an ANDA is made after April 1st, FDA may not be able to withdraw the approved ANDA by the October 1 due date for that fee and the applicant should expect that that ANDA will be counted as approved when determining which tier an applicant and its affiliates are placed.

X. DETERMINING AFFILIATION

When determining whether parties are affiliated, the critical factor is whether one party controls or has the power to control another entity, or if a third party has the power to control both entities.

FDA may contact the applicant to request additional information and clarification of the information asserted by the applicant. Examples of requested information include, but are not limited to the following:

- A copy of the applicant's Articles of Incorporation and Bylaws;
- The applicant's last annual statement to shareholders;
- A breakdown of entities that maintain ownership of the applicant's company; and
- Identification of persons in leadership and management positions at the applicant's company.

Occasionally, FDA finds entities affiliated with the applicant that the applicant did not identify as one of its affiliates. In such cases, FDA recommends that the applicant submit any agreements between an applicant and the other entities that demonstrate the nature of the relationship the applicant has with the entity.

FDA recognizes that some information provided by companies may be confidential. FDA will treat confidential commercial or financial information consistent with applicable federal laws and regulations.

XI. FAILURE TO PAY FEES

Failure to remit payment for user fees incurred pursuant to GDUFA II will result in certain penalties based on the type of fee. Outstanding user fees are an obligation to the U.S. government and the failure to pay fees may lead to collection activities by the government pursuant to applicable laws.

A. Backlog Fees

Any person who owned an original ANDA that failed to pay the backlog fee was placed on a publicly available arrears list available at https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm. FDA will not receive—within the meaning of section 505(j)(5)(A) of the FD&C Act (21 U.S.C. § 355(j)(5)(A))[42]—a new ANDA or supplement submitted by that person, or any affiliate of that person, until the outstanding fee is paid.[43]

B. DMF Fees

Unless the DMF fee is paid in full, the DMF will not be deemed available for reference. No generic drug submission referencing the DMF will be received unless the fee is paid and the DMF is deemed available for reference.

ANDA applicants that reference a DMF for which a fee is due but has not been paid will be provided notification of the DMF holder's failure to satisfy the user fee obligation. If the DMF fee is not paid within 20 calendar days after notification, any generic drug submission referencing the DMF will not be received for user fee reasons and no refund of the fee will be allowed.[44]

C. ANDA Filing Fees

If an applicant does not submit payment within 20 calendar days of the due date, its application or supplement to an application will be deemed incomplete on the date of submission and will not be received. So long as FDA finds that none of the disqualifications outlined in 21 CFR 314.101(d) and (e) apply, the application will be considered submitted as of the date all obligations are satisfied and the payments are received in full.[45]

D. Facility Fees

There are several consequences for failure to pay a facility fee:

- No new ANDA or supplement submitted by the person responsible for paying the fee or that person's affiliates will be received.

[42] This provision references the "receipt" of ANDAs by FDA. The agency does an initial review of the application to determine whether it may be received. Receipt represents a threshold determination that the ANDA is sufficiently complete to permit a substantive review. 21 CFR 314.101(b). An application that is not received will not be reviewed substantively and will not be approved. References to receiving applications in this section of the guidance refer to receipt under this process.

[43] See Section 744B(g)(1) of the FD&C Act.

[44] See Section 744B(g)(2) of the FD&C Act.

[45] See Section 744B(g)(3) of the FD&C Act.

- No new generic drug submission referencing the facility will be received until the fee is paid.
- The facility will be placed on a publicly available arrears list if the fee is not fully paid within 20 days of the due date.
- FDA will notify the referencing ANDA applicant of the facility's failure to satisfy its user fee obligations.

Furthermore, all FDFs or APIs manufactured in the non-paying facility and all FDFs containing APIs manufactured in such a facility will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products deemed misbranded are subject to being denied entry into the United States.[46]

Additionally, goal dates may not apply to applications that have already been received but that reference facilities for which facility fees are owed.

E. GDUFA Program Fees

Failure to pay the GDUFA Program Fee within 20 calendar days of the GDUFA Program Fee due date will result in the following penalties:

- Applicants that have not paid the GDUFA Program Fee will be placed on a publicly available arrears list.
- Any ANDAs submitted by the applicant or an affiliate of that applicant will not be received.
- All drugs marketed pursuant to ANDAs held by such applicant or an affiliate of that applicant will be deemed misbranded.[47]

These penalties apply until the GDUFA Program Fee is paid.

XII. PAYMENT INFORMATION AND PROCEDURES

The payment process for GDUFA II is similar to the previous iteration of the program and other FDA user fees. The FDA website contains instructions for paying the fees.

A. Payment Procedures for GDUFA Fees

- Those responsible for payment of fees enter required information on FDA's User Fee System to generate a GDUFA cover sheet.
- The cover sheet is designed to provide the minimum necessary information to determine

[46] See Section 744B(g)(4) of the FD&C Act.
[47] See Section 744B(g)(5) of the FD&C Act.

if a person has satisfied all relevant user fee obligations.

- The cover sheet is submitted to FDA electronically generating a user fee payment identification number (PIN) to assist in tracking payment.

Cover sheets should be submitted with generic drug submissions and DMFs. The Generic Drug User Fee Cover Sheet and additional payment information is available on the GDUFA website (https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm).

B. Acceptable Forms of Payment

Payment must be made in U.S. currency drawn on a U.S. bank. Fee payers may pay online by credit card or Automated Clearing House (ACH) electronic check or send payment by check, bank draft, U.S. postal money order, or wire transfer.

C. Timely Payment of Fees

FDA's expectation is for full and timely payment of all GDUFA fees. Penalties associated with non-payment, including, but not limited to, refusal to receive a generic drug submission and failure of a DMF to be placed on a publicly available reference list, will apply until such obligations are satisfied in full.

One entity may pay GDUFA fees on behalf of another entity. Those paying fees are responsible for determining all financial institution transaction fees that may be deducted from a company's authorized amount for payment to FDA. These include wire transfer and foreign exchange fees.

D. Refund Requests

FDA will only refund payments of fees made in error. If a fee was properly incurred, there will be no refund of the payment.

To qualify for the return of a fee claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid. The format for submitting refund requests is Form FDA 3913, attached as Appendix 1. Form FDA 3913 is available on the internet at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf.

FDA will not permit a refund if a written request is made past 180 calendar days from the date of payment.

A written refund request should be submitted to the Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov.

E. Non-Payment of GDUFA Fees

Delinquent companies will receive an invoice from FDA detailing information on the user fee incurred, the due date, and payment instructions.

If full payment is not received by the date specified on the invoice, interest will be charged at a rate set by the U.S. Department of the Treasury. In addition, delinquent invoices will have a $20 administrative fee assessed for each 30-day period that the invoice remains outstanding. A penalty of 6 percent per year will be assessed on any invoices delinquent for more than 90 days, in accordance with 45 CFR 30.18.

F. Cover Sheet for PET Manufacturers and Non-Commercial Government Entities

PET drug manufacturers and State or Federal Government entities which sponsor or manufacture drugs but do not distribute them commercially are excluded from payment of GDUFA fees. However, FDA requests that all drug manufacturers, including generic PET manufacturers and non-commercial government entities, complete a facility user fee coversheet in the user fee system.

G. Waivers of and Reductions to GDUFA Fees

Waiver and reductions to GDUFA fees are generally not available. However, facilities that qualify as CMOs only incur one-third of the facility FDF fee.

H. Arrears Lists

The backlog arrears list, GDUFA Program Fee arrears list, facility arrears list, and outstanding facility fees—not on arrears list are available on the GDUFA website (https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm) and are updated regularly.

FDA cannot receive generic drug submissions from sponsors or their affiliates until the sponsor and its affiliates satisfy all outstanding user fee obligations. See the Definitions section (Section III) above regarding affiliates for more information.

FDA will not notify sponsors before refusing to receive a submission.[48] Companies are in the best position to monitor their business affiliates for compliance with GDUFA II. It is an applicant's responsibility to ensure that its user fee obligations, as well as those of its affiliates, are satisfied before submitting a new generic drug submission.

[48] See Section 744B(g) of the FD&C Act.

If a company believes that its appearance on the arrears list is in error, it should contact the Division of User Fee Management and Budget Formulation at CDERCollections@fda.hhs.gov. A concise rationale for why the facility should not be included on the arrears list should be provided.

I. Submitting Generic Drug Submissions

A generic drug submission or Type II API DMF is deemed to be submitted to FDA on the calendar day when the electronic submission arrives at FDA's electronic gateway, except when a submission is made on a weekend, Federal holiday, or a day when the FDA office that will review the submission is not otherwise open for business. In those cases, the submission will be deemed to be submitted on the next day that office is open for business.

For a generic drug submission or Type II API DMF that is submitted in physical media form, the date of submission will be the day it arrives at the appropriate designated FDA document room, except when a submission arrives on a weekend or a day when the FDA office is not otherwise open for business. In those cases, the submission will be deemed to be submitted on the next day that office is open for business.

When a government-wide shutdown or closing of the relevant FDA office because of inclement weather occurs, FDA is considered not open for business and will not receive generic drug submissions until the next day that FDA is open for business.[49]

XIII. APPEALS PROCESS

A. Reconsideration Request

If FDA fully or partially denies a request for a refund or reduction of user fees, the entity may request reconsideration of that decision. A request for reconsideration should be made within 30 calendar days of the issuance of FDA's decision to fully or partially deny a request for a refund or reduction of user fees.

FDA recommends that requests for reconsideration state the entity's reasons for believing that the decision is in error and include any additional information, including updated financial information, that is relevant to the entity's position. The Agency will issue a response upon reconsideration, setting forth the basis for the decision.

[49] See guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*, available at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm333969.pdf.

All requests for reconsiderations should be submitted via email to CDERCollections@fda.hhs.gov and should be addressed to the following:

Division of User Fee Management and Budget Formulation
Attention: Division Director
Center for Drug Evaluation and Research

Alternatively, the entity can mail the request to FDA via the carrier of its choice. For the most updated mailing address, visit the following FDA website: http://www.fda.gov/forindustry/userfees/genericdruguserfees/default.htm.

B. Appeal Request

If a request is denied upon reconsideration, the entity may choose to appeal the denial. A request for an appeal should be made within 30 calendar days of the issuance of FDA's decision to affirm its denial of a request for a refund or reduction of user fees. The following information should be included in the appeal:

- The original request
- The denial of the request
- The reconsideration request
- The denial of the reconsideration request; and
- A statement of the entity's belief that the prior conclusions were in error.

No new information or analyses should be presented in the appeal request. If new information or analyses are presented in the appeal request, the appeal will not be accepted and the matter will be referred back to the original deciding authority to consider the new information or analyses.

All requests for appeals should be submitted to the Director of CDER's Office of Management via CDERCollections@fda.hhs.gov and a copy should be submitted to the CDER Formal Dispute Resolution Project Manager. The contact information can be found on the CDER Formal Dispute Resolution Web page.[50] Alternatively, the entity can mail the request to FDA via the carrier of its choice. For the most updated mailing address, visit the following FDA website: http://www.fda.gov/forindustry/userfees/genericdruguserfees/default.htm.

After FDA reviews the information submitted in the appeal request, the Director of CDER's Office of Management will issue a written decision on the entity's request.

[50] See https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/ucm444092.htm.

If the entity's appeal is denied at one management level, the entity can appeal the same matter to the next higher management level in the center chain of command. A new request should be submitted for each appeal to the next management level and should follow the process provided in this guidance. If the sponsor has exhausted the center's management levels and remains unsatisfied with the decision, the sponsor may request review of the matter by the Commissioner of Food and Drugs (Commissioner) under 21 CFR 10.75(c). Requests for review by the Commissioner should be submitted to FDA's Ombudsman, with copies provided to the centers. Review of such matters by the Commissioner is discretionary.[51]

XIV. OTHER RESOURCES

The following guidance documents may be helpful:

- *Completeness Assessments for Type II API DMFs Under GDUFA* (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321884.pdf)
- *Self-Identification of Generic Drug Facilities, Sites, and Organizations* (https://www.fda.gov/downloads/drugs/guidances/ucm316672.pdf)
- *Formal Dispute Resolution: Appeals Above the Division Level,* Revision 2 (September 2015) (https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm343101.pdf)

Additional information is also available on the FDA User Fees web page. For any questions, please email the GDUFA User Fee staff at CDERCollections@fda.hhs.gov or call 301-796-7900.

[51] See 40 FR 40682, 40693 (September 3, 1975); See 21 CFR 10.75.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

User Fee Payment Refund Request

Form Approved: OMB No. 0910-0805
Expiration Date: November 30, 2018
See PRA Statement on page 4.

Section A: Organization Information

1. Date of Request *(mm/dd/yyyy)*

2. Organization Name

3. Organization Address

Address 1 *(Street address. No P.O. Boxes allowed)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

4. Type of Vendor *(Select applicable)*

☐ U.S. vendor ☐ Foreign vendor

6. DUNS *(Nine-digit number required for **all** foreign vendors. See instructions for additional information.) Without this entry, refund cannot be processed.*

5. TIN/EIN *(Nine-digit number required for **all** U.S. vendors.) Without this entry, refund cannot be processed.*

***Information for U.S. vendors:** To facilitate your request, visit https://www.sam.gov/portal/public/SAM/ and register with Central Contractor Registration (CCR). CCR electronically validates registrant information and shares the encrypted data securely with the FDA. For questions about CCR, call (334) 206-7828.*

Section B: Contact Information

7. Contact Name | 8. Contact Title/Position

9. Contact Phone Number *(Include area code)* | 10. Contact Email Address

Section C: Payment Information

11. Payment Amount | 12. Payment Reference Number

13. PIN or Invoice Number | 14. Refund Amount

15. Is this a FURLS refund request? *(See instructions for more information.)* ☐ Yes ☐ No *(Proceed to field 16)*

(a) FURLS Request Type

☐ Used PIN ☐ Unused PIN *(Proceed to field 16)*

(b) Registration or Owner/Operator Number

(c) Why did your facility originally pay the fee?

(d) Why do you believe your facility is not required to pay the fee?

(e) List all activities performed at your facility

(Section C continued, next page)

***Section C: Payment Information** (Continued)*

15. Is this a FURLS refund request? *(Continued)*

(f) List all products manufactured at your facility

16. Reason for Request *(Please explain)*

17. **ACKNOWLEDGEMENT: By signing this document I acknowledge that I am the official listed on this form, authorized to execute this request on behalf of my organization. Any questions regarding this request can be directed to me via the contact information provided.**

18. Signature	Date of Signature *(mm/dd/yyyy)*
To enable the signature field, please fill out all prior required fields. For a list of required fields which have not yet been filled out, please click here.	

Section D: FDA Acknowledgement

19. FDA Received Date *(mm/dd/yyyy)*	20. Center Decision ☐ Approved ☐ Denied
21. If Denied, State Reason	
22. Decision Date *(mm/dd/yyyy)*	23. Center Contact Name

OFM Use Only

24. Request Executed? ☐ Yes ☐ No	25. If No, State Reason	
26. Final Action ☐ Completed – Refunded ☐ Completed – Not Refunded		27. Date of Final Action *(mm/dd/yyyy)*
28. OFM Contact Name		

Instructions for Completing User Fee Payment Refund Request – Form FDA 3913

Form FDA 3913 is to be completed online at http://www.fda.gov/forindustry/userfees/default.htm and is to be used when requesting the transfer of user fee payments received by the FDA. If you need assistance in completing this form contact the User Fee Helpdesk via phone at (301) 796-7200 or email userfees@fda.gov.

Section A: Payment Information

1. **Date of Request:** Enter calendar date the form is being completed.
2. **Organization Name:** This is name of the organization submitting the request.
3. **Organization Address:** Enter the following elements of the organization's address.

Address 1 – Enter organization's physical street address where the refund is to be sent. *No P.O. Boxes are allowed.*

Address 2 – As needed, enter apartment, suite, unit, building, floor, etc.

City – Enter the city where organization is located.

State/Province/Region – Enter the state, province or region where organization is located.

Country – Enter country where organization is located.

ZIP or Postal Code – Enter zip code or postal code of the organization's location.

4. **Type of Vendor:** Select the appropriate box to indicate whether the organization is a U.S. or foreign vendor.
5. **TIN/EIN:** *(U.S. vendor only)* Enter organization's nine-digit federal Taxpayer Identification Number (TIN) or Employer Identification Number (EIN). *Without this entry, the refund request cannot be processed.*
6. ***DUNS:*** *(Foreign vendor only)* Enter organization's nine-digit Dun & Bradstreet Data Universal Numbering System (DUNS) number. If you do not know your DUNS number or need to request one, visit *www.dnb.com* or call (800) 234-3867. *Without this entry the refund cannot be processed.*

Section B: Contact Information

7. **Contact Name:** Enter the name of the person requesting the refund.
8. **Contact Title/Position:** Enter the position/title of the person requesting the refund.
9. **Contact Phone Number:** Enter the phone number of the person requesting the refund.
10. **Contact Email Address:** Enter the email address of the person requesting the refund.

Section C: Payment Information

11. **Payment Amount:** Enter the amount (in U.S. Dollars) of the original payment issued to the FDA.
12. **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.
13. **PIN or Invoice Number:** Enter the Payment Identification Number (PIN) or invoice number where payment was applied.
14. **Refund Amount:** Enter the amount (in U.S. Dollars) that is to be refunded.
15. **Is this a FURLS refund request?** If request is for fees paid for registration within the FDA Unified Registration and Listing System (FURLS), check the appropriate box. If response is "Yes", complete fields (a) through (f). If response is "No", proceed to field 16.

    (a) FURLS Request Type – Check "Used PIN" if PIN was used to register your facility with FDA's Center for Devices and Radiological Health (CDRH). Check "Unused PIN" if PIN was not used to register, and proceed to field 16.

    (b) Registration or Owner/Operator Number – Enter FURLS registration or owner/operator number.

    (c) Why did your facility originally pay the fee? – Provide reason why the user fee was paid.

    (d) Why do you believe your facility is not required to pay the fee? – Provide reason why the facility should not be required to pay the fee.

    (e) List all activities performed at your facility – Provide list of all activities currently performed at your facility (i.e. manufacture medical device, contract sterilizer, etc.).

    (f) List all products manufactured at your facility – Provide list of all products associated with each activity.
16. **Reason for Request:** Provide a brief description of why refund is being requested.
17. **Acknowledgement:** Review acknowledgment, confirming that you are the authorized representative listed on this form and have provided valid contact information in the event that there are questions pertaining to the request.
18. **Signature**: Place signature of listed authorizing official here.

    Date of Signature – Date document is signed by authorizing official.

Section D: FDA Acknowledgement

This section is for FDA use only. An FDA representative will fill out the following items:

19. **FDA Received Date:** Enter date that request was received by FDA.
20. **Center Decision:** Check appropriate box, indicating if request was approved or denied.
21. **If Denied, State Reason:** If response to field 20 was "Denied", provide reason.
22. **Decision Date:** Enter date decision was made.
23. **Center Contact Name:** Enter name of the Center's action officer.
24. **Request Executed:** Check the appropriate box, indicating if request was executed.
25. **If No, State Reason:** If response to field 24 was "No", provide reason.

Instructions *(Continued)*

26. **Final Action:** Check the appropriate box, indicating if request was refunded or not refunded.
27. **Date of Final Action:** Enter date that final action was taken on request.
28. **OFM Contact Name:** Enter name of the OFM action officer.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.40 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:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

User Fee Payment Transfer Request

Form Approved: OMB No. 0910-0805
Expiration Date: November 30, 2018
See PRA Statement on page 3.

Section A: Payment Information

1. Date of Request *(mm/dd/yyyy)*

2. Payment Amount	3. Payment Reference Number
4. Transfer Funds From	5. Transfer Funds To
6. Transfer Amount	

7. Transfer Reason *(Please explain)*

Section B: Contact Information

8. Organization Name

9. Organization Address

Address 1 *(Street address. No P.O. Boxes allowed)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Region
Country	ZIP or Postal Code

10. Contact Name	11. Contact Title/Position
12. Contact Phone Number *(Include area code)*	13. Contact Email Address

14. **ACKNOWLEDGEMENT: By signing this document I acknowledge that I am the official listed on this form, authorized to execute this request on behalf of my organization. Any questions regarding this request can be directed to me via the contact information provided.**

15. Signature	Date of Signature *(mm/dd/yyyy)*

To enable the signature field, please fill out all prior required fields. For a list of required fields which have not yet been filled out, please click here.

Section C: FDA Acknowledgement

16. FDA Received Date *(mm/dd/yyyy)*	17. Center Decision ☐ Approved ☐ Denied
18. If Denied, State Reason	
19. Decision Date *(mm/dd/yyyy)*	20. Center Contact Name

(FDA Acknowledgement continued, next page)

***Section C: FDA Acknowledgement** (Continued)*

OFM Use Only		
21. Request Executed? ☐ Yes ☐ No	22. If No, State Reason	
23. Final Action ☐ Completed – Transferred ☐ Completed – Not Transferred		24. Date of Final Action *(mm/dd/yyyy)*
25. OFM Contact Name		

Instructions for Completing User Fee Payment Transfer Request – Form FDA 3914

Form FDA 3914 is to be completed online at http://www.fda.gov/forindustry/userfees/default.htm and is to be used when requesting the transfer of user fee payments received by the FDA. If you need assistance in completing the form contact the User Fee Helpdesk via phone at (301) 796-7200 or email userfees@fda.gov.

Section A: Payment Information

1. **Date of Request:** Enter calendar date the form is being completed.
2. **Payment Amount:** Enter the amount (in U.S. Dollars) of the original payment.
3. **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.
4. **Transfer Funds From:** Enter the Payment Identification Number (PIN) or invoice number where payment is coming from.
5. **Transfer Funds To:** Enter the PIN or invoice number where payment is to be applied.
6. **Transfer Amount:** Enter the amount (in U.S. Dollars) that is to be transferred.
7. **Transfer Reason:** Provide a brief description of why funds are being transferred.

Section B: Contact Information

8. **Organization Name:** This is name of the organization listed on the cover sheet or invoice. Entry should match both old and new cover sheets or invoices as listed in items 4 and 5.
9. **Organization Address:** Enter the following elements of the organization address.

   Address 1 – Enter organization's physical street address. *No P.O. Boxes are allowed.*

   Address 2 – As needed, enter apartment, suite, unit, building, floor, etc.

   City – Enter the city where organization is located.

   State/Province/Region – Enter the state, province or region where organization is located.

   Country – Enter country where organization is located.

   ZIP or Postal Code – Enter zip code or postal code of the organization's location.
10. **Contact Name:** Enter the name of the person requesting the transfer.
11. **Contact Title/Position:** Enter the position/title of the person requesting the transfer.
12. **Contact Phone Number:** Enter the phone number of the person requesting the transfer.
13. **Contact Email Address:** Enter the email address of the person requesting the transfer.
14. **Acknowledgement:** Review acknowledgment, confirming that you are the authorized representative listed on this form and have provided valid contact information in the event that there are questions pertaining to the request.
15. **Signature**: Place signature of listed authorizing official here.

    Date of Signature – Date document is signed by authorizing official.

Section C: FDA Acknowledgement

This section is for FDA use only. An FDA representative will fill out the following items:

16. **FDA Received Date:** Enter date that request was received by FDA.

Instructions *(Continued)*

17. **Center Decision:** Check appropriate box, indicating if request was approved or denied.
18. **If Denied, State Reason:** If response to field 17 was “Denied”, provide reason.
19. **Decision Date:** Enter date decision was made.
20. **Center Contact Name:** Enter name of the Center’s action officer.
21. **Request Executed:** Check the appropriate box, indicating if request was executed.
22. **If No, State Reason:** If response to field 21 was “No”, provide reason.
23. **Final Action:** Check the appropriate box, indicating if request was transferred or not transferred.
24. **Date of Final Action:** Enter date that final action was taken on request.
25. **OFM Contact Name:** Enter name of the OFM action officer.

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

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Food and Drug Administration
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