# 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***DRAFT GUIDANCE***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 2019**
**User Fees**

**Revision 1**

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

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# Assessing User Fees Under the Generic Drug User Fee Amendments of 2017
# Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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.[2] 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).[3] Throughout this guidance, references to *user fees* or the *user-fee program* indicate generic drug user fees collected under section 744B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance revises and replaces FDA's draft guidance for industry *Assessing User Fees Under the Generic Drug User Fee Amendments of 2017*, published in October 2017.

[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 Reauthorization Act of 2017 (Public Law 115-52).

[3] FDA will publish in the *Federal Register* the fee revenue and fee amounts for each fiscal year not more than 60 days before the start of each fiscal year (section 744B(d)(1) of the FD&C Act (21 U.S.C 379j-42)). On August 29, 2017, FDA published FY 2018 rates for GDUFA fees (82 FR 41026 (Aug. 29, 2017)). On July 27, 2018, FDA published FY 2019 rates for GDUFA fees (83 FR 35649 (July 27, 2018).

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.

Changes to statutory provisions described in this guidance are effective with respect to fees assessed beginning on the first day of fiscal year (FY) 2018.[4]

## 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 five-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. Under the FDA Reauthorization Act of 2017, enacted on August 18, 2017, GDUFA I was reauthorized for a five-year period (GDUFA II) beginning on October 1, 2017.

GDUFA II extends FDA's authority to collect user fees for FY 2018 through FY 2022 and revises 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(j) of the FD&C Act (21 U.S.C. 355(j)), under former section 507 of the FD&C 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.[5]

- 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

[4] FDA's fiscal year begins on October 1 and ends on September 30.

[5] See section 744A(1) of the FD&C Act.

crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture as described above.[6]

- 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.[7]

- 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.[8]

- 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.[9]

- 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).[10]

- The term ***generic drug submission*** means an ANDA, an amendment to an ANDA, or a prior approval supplement to an ANDA.[11]

- 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

[6] See section 744A(2) of the FD&C Act.

[7] See section 744A(4) of the FD&C Act.

[8] 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.

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

[10] See section 744A(7) of the FD&C Act.

[11] See section 744A(8) of the FD&C Act.

preparation of such a drug.[12]

- 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 ANDA 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.[13]

- 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 FDA 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.[14]

## 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.[15] 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 backlog fees, DMF fees, ANDA and prior approval supplement (PAS) fees, and 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.[16]

[12] See section 744A(10) of the FD&C Act; see section 201(ii) of the FD&C Act (21 U.S.C. 321(ii)).

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

[14] See section 744A(13) of the FD&C Act.

[15] 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.

[16] 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.[17]

## 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.[18]

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 (77 FR 65199 (October 25, 2012), 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.[19] See *Federal Register*: "Notice of Opportunity to Withdraw Abbreviated New Drug Applications to Avoid Backlog Fee Obligations" for additional details (77 FR 51816 (August 27, 2012), 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.[20]

The DMF fee is due on the earlier of the following:

- 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
- The date the DMF holder requests the initial completeness assessment[21]

[17] See section 744B(a) of the FD&C Act.

[18] 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).

[19] Receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete (21 CFR § 314.101(b)(1)).

[20] See section 744B(a)(2)(A) of the FD&C Act.

[21] 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 by ANDA applicants. FDA strongly encourages the DMF holder to submit a complete DMF and pay the DMF fee at least 6 months prior to the submission of an ANDA or PAS that will rely on the DMF. The DMF will then undergo an initial completeness assessment using factors articulated in FDA's guidance for industry *Completeness Assessments for Type II API DMFs Under GDUFA*.[22] DMFs for which the fee has been paid and which have not been found incomplete in accordance with the completeness assessment will be identified on FDA's Type II Drug Master Files – Available for Reference List,[23] as available, for reference in support of a generic drug submission.

## 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 on or after October 1, 2012. A prior approval supplement filing fee, which was required under GDUFA I, is no longer required under GDUFA II.[24]

ANDA fees are due no later than the date of submission of the application.[25]

### 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 (i.e., FDA determines that the ANDA is not substantially complete), then 75 percent of the filing fee paid will automatically be refunded to the applicant. Under GDUFA II, 75 percent of the application filing fee paid will also be refunded for an application that has been withdrawn prior to being received within the meaning of section 505(j)(5)(A) of the FD&C Act.[26]

If FDA initially receives an ANDA and subsequently determines that a period of exclusivity for the reference listed drug should have prevented that receipt so that the ANDA is no longer

[22] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[23] Available at https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.

[24] Unpaid fees for prior approval supplements submitted under GDUFA I are not automatically considered to have met under GDUFA II when GDUFA II took effect in FY 2018. The unpaid fees will continue to be a basis for the Agency to refuse to receive those supplements. However, an applicant may submit a new prior approval supplement under GDUFA II which will not incur a prior approval supplement fee.

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

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

considered received, the ANDA will be refused for receipt. In this situation, FDA will refund 100% of the fee paid for that ANDA.[27]

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 is available 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.[28] This information is required, and FDA cannot process a refund without it. If an applicant is entitled to a refund and does not submit a refund request, FDA may initiate a refund during its periodic review of outstanding refunds.

If an applicant resubmits an application that FDA previously refused to receive, 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 for substantive technical review and then submits a new ANDA for that product must pay the full fee upon submission of the new ANDA. In either circumstance, 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 applicant's request. 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 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492195.pdf.

### B. Resubmissions

A resubmission of an ANDA is a formal response to a refuse-to-receive (RTR) determination and is submitted to the ANDA that was refused for receipt.[29] Accordingly, a full ANDA filing fee is due upon resubmission of the ANDA that FDA had refused to receive. Submission of a dispute of an RTR determination without attempting to remedy the deficiencies (i.e., without resubmitting the ANDA) 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

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

[28] See GDUFA Cover Sheet Clarifications: Facility, available at https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm393190.htm.

[29] See FDA's draft guidance for industry *ANDA Submissions – Refuse-to-Receive Standards: Questions and Answers* (Oct. 2017). When final, this guidance will represent the FDA's current thinking on this topic.

- The application is submitted by a State or Federal Government entity for a drug that is not distributed commercially
- 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 additional fee, also known as the (a)(3)(F) fee (because this fee is referenced in section 744B(a)(3)(F) of the FD&C Act), 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 API DMF.

GDUFA II specifies that this (a)(3)(F) fee must be paid for each combination of API and the API's manufacturing facility, provided that a DMF fee or (a)(3)(F) fee has not already been paid for the manufacture of the same API by the same facility. The (a)(3)(F) fee amount for each API and facility combination is equal to the DMF fee and is paid only once.

***Example***:

An applicant (XYZ Corp.) submits an ANDA that, rather than referencing a DMF, describes the manufacture of three APIs at one or more facilities. The (a)(3)(F) fee has been paid for the combination of *API Beta manufactured at Facility 2*.

| **Product** | **API** | **API Manufacturing Facility** |
|---|---|---|
| Drug X | Alpha | 1, 2, 3 |
| | Beta | 1, 2 |
| | Gamma | 1 |

In this example, the calculation for the (a)(3)(F) fee that XYZ Corp. owes is as follows:

**(a)(3)(F) Fee API-Facility combinations:**

(Alpha-Facility 1) + (Alpha-Facility 2) + (Alpha-Facility 3) + (Beta-Facility 1) + (Gamma-Facility 1) = 5 unpaid API-Facility combinations*

**Note: The Beta-Facility 2 combination has been paid and is, therefore, not included.*

**(a)(3)(F) fee amount** = (5 API-Facility combinations) x DMF fee amount

= 5 x DMF fee amount

This information must be listed correctly in the Generic Drug User Fee Cover Sheet (Form FDA 3794) for the generic drug submission.

### E. Serially Submitted ANDAs

In the past, some ANDA applicants chose to serially submit complete ANDAs containing "paragraph IV certifications" in anticipation of a newly listed patent for a reference listed drug.[30] ANDA applicants must not submit a paragraph IV certification earlier than the first working day after the day the patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book.[31] The regulation reflects FDA's judgment that permitting serial submissions of amendments and multiple notices of paragraph IV certifications is overly burdensome to FDA and new drug application (NDA) applicants.[32] In this situation, applicants should remit their application filing fee with their ANDA 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.[33]

See subsection J of this section for further discussion of when fees may be incurred.

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

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[30] For a description of ANDA patent certifications, see FDA's draft guidance for industry *180-day Exclusivity: Questions and Answers* (Jan. 2017). When final, this guidance will represent FDA's current thinking on this topic.

[31] Available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book. See 21 CFR 314.94(a)(12)(viii)(C)(1)(*ii*) ("An applicant must submit an appropriate patent certification or statement under paragraph (a)(12)(i) and/or (iii) of this section if, after submission of the ANDA, a new patent is issued by the U.S. Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or that claims an approved use for such reference listed drug and for which information is required to be filed under section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act and § 314.53. 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 the list.").

[32] See 81 FR 69580, 69610 (Oct. 6, 2016).

[33] See section 744B(a)(4)(A) of the FD&C Act; see section 744A(5) of the FD&C Act.

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 it 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.[34]

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.

### 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 that is approved to produce one or more APIs, or
- A Type II API DMF referenced in at least one such generic drug submission.[35]

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.[36]

### 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.[37] This differs from the treatment under GDUFA I, which required that such facilities pay both API and FDF fees.

[34] See section 744B(a)(4)(D) of the FD&C Act.

[35] See section 744B(a)(4)(A)(ii) of the FD&C Act.

[36] See section 744B(a)(4)(A)(i) of the FD&C Act.

[37] See section 744B(a)(4)(A)(iii).

### D. Contract Manufacturing Organizations

CMOs are independent entities 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.[38] In general, CMOs pay a reduced facility fee of one-third the amount of the FDF facility fee.

For example, if the FDF facility is referenced in an ANDA held by the facility's owner, that FDF facility would not be a CMO. However, 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 when referenced in another ANDA.[39] 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 on the FDF manufacturing activities of that facility and not on its manufacturing activities related to an API. 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.

### 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. The $15,000 differential applies to all facilities that incur a fee under GDUFA II, including those facilities defined as CMOs. For example, a foreign CMO facility will pay one-third the FDF facility fee plus $15,000.[40] 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 applicant or holder does not want to retain a manufacturing facility subject to GDUFA user fees in its application, the ANDA applicant or holder should submit an amendment (for a pending application) or "post-approval notification" (for an approved application) to remove the manufacturing facility from the ANDA. A post-approval notification is described in 21 CFR 314.70 and relevant guidance[41] and includes supplements, annual reports, or similar submissions. The amendment or post-approval notification should provide an explanation for the removal of the facility. If the amendment or post-approval notification is seeking to replace the

[38] See section 744A(5) of the FD&C Act.

[39] Id.; see section 744B(b)(2)(C) of the FD&C Act.

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

[41] For a description of post-approval notifications, see FDA's guidance for industry *Changes to an Approved NDA or ANDA* (Apr. 2004, rev. 1).

facility, the request to remove the prior facility and to add the new facility may be included in the same amendment or post-approval notification.

The owner of a facility will incur facility fees if that facility is approved to produce any APIs or FDFs and is referenced in an approved generic drug submission on the facility fee due date, regardless of whether the facility is actually performing the manufacturing operations referenced in the approved application. For example, a facility that currently manufactures only non-generic APIs or FDFs, or drugs for the non-US market, would have to pay a facility fee if it is referenced in an approved ANDA. Similarly, a facility that has ceased manufacturing an API previously used to manufacture a drug product in an approved ANDA and is still named as an API manufacturer in the ANDA on the facility fee due date will incur an API facility fee. The facility is ultimately responsible for the assessed fee once incurred. If the fee is not paid, all FDFs or APIs manufactured in the non-paying facility and all FDFs containing APIs manufactured in such a facility will be deemed misbranded.[42] Furthermore, any new generic drug submission that is submitted by or references the facility or its affiliates will not be "received" until the fee is paid.[43]

To prevent a facility that is not manufacturing for an approved ANDA from incurring a facility fee, the ANDA holder should submit a post-approval notification prior to the fiscal year due date. If a facility identified in an approved ANDA wants to be removed from that ANDA, the facility should work with the ANDA holder to remove itself from the application prior to the facility fee due date. It is the ANDA holder's responsibility to maintain an accurate and complete application, including an updated list of manufacturing facilities.

For user fee purposes only, FDA will no longer consider the facility to be identified in the application as of the date FDA receives notice of the withdrawal from the ANDA holder via a post-approval notification, or if the facility follows the instructions below.

An API or FDF facility seeking to be removed from an approved ANDA to avoid an unwarranted fee should contact the applicant well in advance of the facility fee due date. On rare occasions, if timely good faith efforts and communications requesting removal from the ANDA have been made and the facility has reason to believe the holder will not act in time to prevent a facility fee from being incurred, the facility owner may submit a letter to FDA, copying the holder, requesting that the facility be removed from the approved ANDA. The letter to the FDA should contain:

- A statement that the facility is not involved in manufacturing activities[44] for any approved ANDA that would incur a fee
- Copies of the facility's communications to the ANDA holder(s) or DMF holder(s)

[42] Section 744B(g)(4)(A)(iii) of the FD&C Act. It is a violation of federal law to ship products misbranded into 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.

[43] See section 744B(g)(4) of the FD&C Act.

[44] See 21 C.F.R. 205.3(d): "*Manufacturer* means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug."

- A list of all known, approved generic drug submissions and DMFs that reference the facility for which the facility has communicated with the holder(s) and DMF holder(s) (as applicable), but for which there is reason to believe the facility will remain named in the application on October 1st

If the facility owner submits this letter and if FDA agrees that a good faith effort has been made by the facility to work with the ANDA holder to withdraw itself without response by the holder, the facility will be considered withdrawn for user fee purposes for the next fiscal year.[45]

Letters should be submitted by July 1 or as far in advance of October 1 as possible. Letters received after July 1 may not be processed before October 1, in which case facilities will incur the fee if the ANDA holder still has not submitted a post-approval notification before October 1. The letter should be sent to the following address with a copy to CDERCollections@fda.hhs.gov:

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room
5901B Ammendale Road
Beltsville, MD 20705

If a facility is identified in an approved generic drug submission on October 1 and the facility is subsequently withdrawn, the fee will not be waived or refunded. Accordingly, withdrawal of a facility from generic drug submissions will not remove the requirement of the facility to pay previously incurred facility fees.

### G. Packagers and Repackagers

Packagers are considered 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 and subsection D 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.

[45] The applicant is still expected to report the change to the approved application in a manner consistent with 21 CFR 314.70.

A facility is also considered 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.[46]

### H. API-Excipient Mixtures

Generally, manufacturers of API-excipient 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-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

Under GDUFA II, facilities that manufacture APIs generally pay annual API facility fees. However, some ingredients may be intended for use as APIs in certain contexts but are more commonly used as inactive pharmaceutical ingredients (excipients) or as ingredients in non-drug products such as foods. Facilities that manufacture these atypical APIs are subject to API facility fees when the ingredient is intended for use 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.

### J. Facilities That Cease Manufacturing

A facility incurs annual facility fees as long as it is identified in an approved ANDA, 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* human APIs and FDFs (including both generic and non-generic APIs and FDFs) and the facility or applicant has followed the procedures outlined in section F above 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 the definitions section above). Any outstanding fee obligations will, however, remain due.

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

A facility that ceases manufacturing should follow the steps outlined in section F so it will be removed from all ANDA references. If a facility goes out of business, it should contact the applicants, DMF holder (if applicable), and FDA to notify the Agency of its status.

### K. Fees for Multiple Locations of the Same Entity

If an entity has multiple sites manufacturing a product approved under a U.S. human generic drug submission and those sites are in different geographic locations, each facility is generally assessed 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.[47]

These are the same criteria used by FDA's Office of Regulatory Affairs to evaluate whether separate FDA Facility Establishment Identifiers (FEIs) are necessary for multiple facilities.[48]

If an entity believes that multiple FEIs have been assigned in error or that its separate facilities qualify for a single FEI, the entity may request consolidation of the FEIs. Domestic entities 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 entities should contact FDAGDUFAFEIRequest@fda.hhs.gov.

Once a facility fee has been incurred, the fee is not waived, reduced, or refunded if FDA subsequently agrees to consolidate FEI numbers.

## 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.[49] An ANDA applicant and its affiliates cannot choose to pay multiple smaller fees to avoid paying the fee associated with larger tiers.

[47] See section 744A(6) 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, for purposes of this paragraph.

[48] See FDA's guidance for industry *Self-Identification of Generic Drug Facilities, Sites, and Organizations* (Sept. 2016).

[49] See section 744B(b)(2)(E)(i).

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.[50]

### A. GDUFA Program Fee Structure

The GDUFA Program Fee will be allocated among three tiers of ANDA owners:

- Small (companies with 5 or fewer approved ANDAs)
- Medium (companies with between 6 and 19 approved ANDAs)
- 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 will be assessed 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 will be assessed 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 20 ANDAs on the GDUFA Program Fee due date, the person and its affiliates will be assessed a large-size operation GDUFA Program Fee.[51]

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 an ANDA Applicant and Its Affiliates

An ANDA applicant and its affiliates together will only incur one GDUFA Program Fee per year. GDUFA II mandates that a "single program fee shall be assessed" for an ANDA applicant and its affiliates.[52] The ANDA applicant 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 applicant. If FDA finds an affiliation that was not reported to the Agency, FDA will reassess the fees for both the affiliate and parent company, potentially resulting in an invoice if FDA finds that the entity should have paid a higher amount.

### C. Submitting Information to FDA

By April 1 of each year, each person that owns an ANDA shall submit to the Secretary 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, one list identifying all affiliates that own such applications and the ANDAs owned by the person and its affiliates.

[50] See section 744B(a)(5) of the FD&C Act.

[51] See section 744B(b)(2)(E) of the FD&C Act.

[52] Id.

Please see FDA's GDUFA website section discussing the GDUFA Program Fee (https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm) for more information.

### 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.[53] If such a request to withdraw an ANDA is made after April 1, 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 the tier in which an applicant and its affiliates are placed for purposes of the GDUFA Program Fee.

## 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 an ANDA applicant to request additional information and clarification of the information asserted by the applicant regarding its affiliates. Examples of requested information include, but are not limited to:

- 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
- 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 response to such a finding, 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 in full for user fees incurred pursuant to GDUFA II will result in certain penalties on an entity and/or its affiliates based on the type of fee. These penalties apply until the outstanding user fees are fully paid. Outstanding user fees are an obligation to the U.S.

[53] Section 744B(b)(2)(E)(ii) of the FD&C Act.

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[54]—a new ANDA or supplement submitted by that person, or any affiliate of that person, until the outstanding fee is paid.[55]

### B. DMF Fees

A DMF will be deemed available for reference if both the DMF fee is paid in full and the DMF has not failed an initial completeness assessment. 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.[56]

### 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 (i.e., so long as the ANDA is otherwise substantially complete), the application will be considered submitted as of the date all obligations are satisfied and the payments are received in full.[57]

### 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

[54] This provision references the "receipt" of ANDAs by FDA. The Agency evaluates an ANDA after it is submitted to determine whether it may be received. Receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete. 21 CFR 314.101(b)(1).

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

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

[57] 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

Further, all FDFs or APIs manufactured in the non-paying facility and all FDFs containing APIs manufactured in such a facility will be deemed misbranded.[58] 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.

### 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

Further, all drugs marketed pursuant to ANDAs held by such applicant or an affiliate of that applicant will be deemed misbranded.[59] 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.

## 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 if a person has satisfied all relevant user fee obligations
- The cover sheet is submitted to FDA electronically generating a user fee payment

[58] See section 744B(g)(4) of the FD&C Act.

[59] See section 744B(g)(5) of the FD&C Act.

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, drug product deemed misbranded, 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 an entity's authorized amount for payment to FDA. These include wire transfer and foreign exchange fees.

### D. Refund Requests

FDA will only fully 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 and available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf.

FDA may not issue 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 invoice 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 do not incur 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

Waivers of 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/industry/generic-drug-user-fee-amendments/user-fee-lists) and are updated regularly.

FDA cannot receive generic drug submissions from applicants or their affiliates until those applicants and their affiliates satisfy all outstanding user fee obligations. See the definitions in section III above regarding affiliates for more information.

FDA may not notify applicants before refusing to receive a submission.[60] Companies are in the best position to monitor their business affiliates for compliance with GDUFA II. It is the 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.

If an entity 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 and provide a concise rationale for why the facility should not be included on the arrears list.

[60] See section 744B(g) of the FD&C Act.

### I. Submitting Generic Drug Submissions

A generic drug submission or Type II API DMF is deemed 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, a Federal holiday, or a day when the FDA office that will review the submission is not otherwise open for business.[61] In those cases, the submission will be deemed to be submitted on the next day that office is open for business.

When a lapse in appropriations 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.[62]

## 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 FDA's 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.

All requests for reconsideration 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 at http://www.fda.gov/forindustry/userfees/genericdruguserfees/default.htm.

[61] See guidance for industry *Providing Regulatory Submissions in Electronic Format – Receipt Dates* (Feb. 2014). All ANDAs are required to be submitted electronically as of May 5, 2017, and all DMFs must be submitted electronically by May 5, 2018. See FDA's guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (Jan. 2019, rev. 6).

[62] See FDA's guidance for industry *Providing Regulatory Submissions in Electronic Format – Receipt Dates* (Feb. 2014), at 4, note 9. Note that, in situations in which work on generic applications during a lapse in appropriations is financed by carry-over GDUFA funding, FDA will be able to accept submissions for which payment was made before the lapse in appropriations occurs, but will be considered not open for business to receive fees during the lapse and thus will not receive applications for which applicable fees were not paid before the lapse.

### 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
- A statement of the entity's reasons for believing 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 the Center for Drug Research and Evaluation's (CDER) 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.[63] Alternatively, the entity can mail the request to FDA via the carrier of its choice. For the most updated mailing address, visit https://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.

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 CDER 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 entity has exhausted CDER's management levels and remains unsatisfied with the decision, the entity 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 CDER. Review of such matters by the Commissioner is discretionary.[64]

## XIV. OTHER RESOURCES

The following guidance documents may be helpful:

[63] Available at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/ucm444092.htm.

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

- *Completeness Assessments for Type II API DMFs Under GDUFA* (Oct. 2017, rev. 1)
- *Self-Identification of Generic Drug Facilities, Sites, and Organizations* (Sept. 2016)
- *Formal Dispute Resolution: Appeals Above the Division Level*, (November 2017, rev. 1)

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.

## Appendix 1: Form FDA 3913

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration | Form Approved: OMB No. 0910-0805<br>Expiration Date: November 30, 2018 |
|---|---|

### 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<br>☐ 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: 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<br>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. | Date of Signature *(mm/dd/yyyy)* |
|---|---|

## Section D: FDA Acknowledgement

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

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

## Appendix 2: Form FDA 3914

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>Food and Drug Administration | Form Approved: OMB No. 0910-080<br>Expiration Date: November 30, 2018 |
|---|---|

**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.<br>To enable the signature field, please fill out all prior required fields. For a list of required fields | Date of Signature |
|---|---|

| **Section C: FDA** | |
|---|---|
| **Acknowledgement** | 17. Center<br>☐ Approv ☐ Denie |
| 18. If Denied, State | |
| 19. Decision Date | 20. Center Contact |