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

## Guidance for Industry

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

**May 2022  
User Fees**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
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# Assessing User Fees Under the Generic Drug User Fee Amendments of 2017 Guidance for Industry<sup>1</sup>

This guidance represents 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.<sup>2</sup> 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 for each fiscal year,<sup>3</sup> nor does it address FDA's implementation of other user fee programs (e.g., under the Prescription Drug User Fee Act (PDUFA) or Biosimilar User Fee Act (BSUFA)). Throughout this guidance, references to *user fees* or the *user fee program* indicate generic drug user fees assessed and collected under section 744B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

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<sup>1</sup> This guidance has been prepared by the Division of User Fee Management, Office of Management, in the Center for Drug Evaluation and Research at the Food and Drug Administration.

<sup>2</sup> FDA Reauthorization Act of 2017 (Public Law 115-52).

<sup>3</sup> 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 (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)). On July 26, 2019, FDA published FY 2020 rates for GDUFA fees (84 FR 36101 (July 26, 2019)). On August 3, 2020, FDA published FY 2021 rates for GDUFA fees (85 FR 46662 (August 3, 2020)). On July 28, 2021, FDA published FY 2022 rates for GDUFA fees (86 FR 40582 (July 28, 2021)).

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The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance 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.<sup>4</sup>

## **II. BACKGROUND**

The Generic Drug User Fee Amendments of 2012 (GDUFA I) added sections 744A<sup>5</sup> and 744B to the FD&C Act, authorizing FDA to assess and 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 have played an important role in bringing greater predictability and timeliness to the review of generic drug applications. 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 assess and collect user fees for FY 2018 through FY 2022 and revises the fees that the Agency collects and how it collects some fees.

## **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)), an abbreviated application submitted under former section 507 of the FD&C Act (now repealed), or an abbreviated new drug application submitted 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.<sup>6</sup>
- 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

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<sup>4</sup> FDA's fiscal year begins on October 1 and ends on September 30.

<sup>5</sup> 21 U.S.C. 379j-41

<sup>6</sup> See section 744A(1) of the FD&C Act.

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become a substance or mixture as described above.<sup>7</sup>

- 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.<sup>8</sup>
- 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.<sup>9</sup>
- 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.<sup>10</sup>
- 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).<sup>11</sup>
- The term ***generic drug submission*** means an ANDA, an amendment to an ANDA, or a prior approval supplement to an ANDA.<sup>12</sup>
- The term ***person*** includes an individual, partnership, corporation, and association.<sup>13</sup>
- 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.<sup>14</sup>

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<sup>7</sup> See section 744A(2) of the FD&C Act.

<sup>8</sup> See section 744A(4) of the FD&C Act.

<sup>9</sup> See section 744A(5) of the FD&C Act; see Section IV (Changes to the Structure of the GDUFA User Fee Program) and Section VIII (Facility Fees) for more information.

<sup>10</sup> See section 744A(6) of the FD&C Act. The FDA Establishment Identifier (FEI) is used to identify unique facilities.

<sup>11</sup> See section 744A(7) of the FD&C Act.

<sup>12</sup> See section 744A(8) of the FD&C Act.

<sup>13</sup> See section 201(e) of the FD&C Act.

<sup>14</sup> See section 744A(10) of the FD&C Act; see section 201(ii) of the FD&C Act (21 U.S.C. 321(ii)).



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- 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.<sup>15</sup>
- 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.<sup>16</sup>

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

Five types of fees are authorized under GDUFA II: (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.<sup>17</sup> Under GDUFA II, applications submitted by State and/or Federal government entities for drugs that are not distributed commercially do not incur fees.<sup>18</sup>

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.<sup>19</sup>

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.<sup>20</sup>

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<sup>15</sup> See section 744A(11) of the FD&C Act.

<sup>16</sup> See section 744A(13) of the FD&C Act.

<sup>17</sup> 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.

<sup>18</sup> Such applications are not considered ANDAs for GDUFA purposes; see section 744A(1)(B)(ii) of the FD&C Act.

<sup>19</sup> See section 744B(b)(2)(C) of the FD&C Act.

<sup>20</sup> See section 744B(a) of the FD&C Act.

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### **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 such application.<sup>21</sup>

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 the application.<sup>22</sup> 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 API 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.<sup>23</sup>

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<sup>24</sup>

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

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<sup>21</sup> 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).

<sup>22</sup> Receipt of an ANDA means that FDA has made a threshold determination that the ANDA is substantially complete (21 CFR 314.101(b)(1)).

<sup>23</sup> See section 744B(a)(2)(A) of the FD&C Act.

<sup>24</sup> See section 744B(a)(2)(E)(i) of the FD&C Act.

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industry *Completeness Assessments for Type II API DMFs Under GDUFA* (October 2017).<sup>25</sup> 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,<sup>26</sup> as available, for reference in support of a generic drug submission.

### **VII. ABBREVIATED NEW DRUG APPLICATION FILING FEES**

GDUFA II authorizes the assessment of 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 PAS filing fee, which was required under GDUFA I, is no longer required under GDUFA II.

ANDA fees are due no later than the date of submission of the application.<sup>27</sup>

#### **A. Refunds or “Transfers” for Refusal to Receive, 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 be refunded to the applicant without requiring the applicant to submit a written refund request. 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.<sup>28</sup>

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 considered received, the ANDA will be refused for receipt. In this situation, FDA will refund 100 percent of the fee paid for that ANDA.<sup>29</sup>

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](mailto: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>.

Applicants should include the Federal Tax Identification Number (TIN), also known as the Employer Identification Number (EIN) (for all domestic companies) or Data Universal Numbering System (DUNS) number (for all foreign companies) and the address where the refund should be sent.<sup>30</sup> This information is necessary for FDA to process a refund, and FDA cannot process a refund without it. If an applicant is entitled to a refund and does not submit a

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<sup>25</sup> FDA updates guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>26</sup> Available at <https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs>.

<sup>27</sup> See section 744B(a)(3)(C) of the FD&C Act.

<sup>28</sup> See section 744B(a)(3)(D)(i) of the FD&C Act.

<sup>29</sup> See section 744B(a)(3)(D)(ii) of the FD&C Act.

<sup>30</sup> See GDUFA Cover Sheet Clarifications: Facility, available at <https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm393190.htm>.

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refund request, FDA may initiate a refund during its periodic review of outstanding refunds (see Section XII.D. below).

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.<sup>31</sup>

In either circumstance, if an applicant plans to resubmit the application in the near future, FDA no longer permits the administrative action of applying a previously paid GDUFA fee (also referred to as a “transfer”) from a closed-out fiscal year cover sheet to a different fiscal year cover sheet.

For additional information regarding refund and “transfer” requests, please see Section XII.D.

### **B. Resubmissions**

A resubmission of an ANDA is a formal response to a refuse-to-accept determination and is submitted to the ANDA that was refused for receipt.<sup>32</sup> Accordingly, a full ANDA filing fee is due upon resubmission of the ANDA that FDA had refused to receive. Submission of a dispute of a refuse-to-accept 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.

FDA no longer permits the administrative action of applying a previously paid GDUFA fee (also referred to as a “transfer”) from a closed-out fiscal year cover sheet to a different fiscal year cover sheet. For additional information regarding “transfer” requests, please see Section VII.D.

### **C. Exemptions to the Application Filing Fee**

An applicant will not incur an ANDA filing fee under the following circumstances:<sup>33</sup>

- 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

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

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

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<sup>31</sup> See section 744B(a)(3)(E) of the FD&C Act.

<sup>32</sup> 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.

<sup>33</sup> See sections 744A(1)(B) and 744B(1) of the FD&C Act.

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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.

Under GDUFA II, 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*.

<b>Product</b>	<b>API</b>	<b>API Manufacturing Facility</b>
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.<sup>34</sup> However, these “serial submissions” with such paragraph IV certifications are not permitted under FDA regulations.<sup>35</sup> ANDA applicants must not submit a paragraph IV certification earlier

<sup>34</sup> 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.

<sup>35</sup> See 81 FR 69580, 69610 (Oct. 6, 2016), citing 21 CFR 314.94(a)(12)(viii)(C)(1)(ii) and 21 CFR 314.95(b)(2).

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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.<sup>36</sup> The regulations reflect 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 applicants. 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, the application filing fee should be remitted 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 percent refund of the ANDA filing fee.

## **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.<sup>37</sup>

See Section VIII.J 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.

Note that under the statute, an entity meeting the two criteria above will incur a facility fee liability regardless of whether it is actually manufacturing or processing the API or FDF for which the facility is referenced in the approved generic drug submission. For example, if a facility is referenced in an approved ANDA and at the time of fee assessment it is manufacturing *any* API or FDF, including only brand-name FDF (or only API used in a brand-name FDF), it will be assessed a facility fee under GDUFA II.<sup>38</sup>

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<sup>36</sup> 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.").

<sup>37</sup> See section 744B(a)(4)(A) of the FD&C Act; see section 744A(6) of the FD&C Act.

<sup>38</sup> As described in section 744B(a)(4)(A) of the FD&C Act, this provision imposes fees on facilities identified in at least one generic drug submission that is approved to produce one or more FDF or API of a human generic drug (or identified in a Type II API drug master file referenced in at least one such generic drug submission).

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Facility fees are due on the later of (i) the first business day on or after October 1 of each fiscal year, or (ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of GDUFA fees for such year.<sup>39</sup>

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.<sup>40</sup>

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.<sup>41</sup>

### **B. Exceptions to Facility Fees**

The following entities will not incur facility fees under GDUFA II:<sup>42</sup>

- 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.
- A business or other entity 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.<sup>43</sup> This differs from the treatment under GDUFA I, which required that such facilities pay both API and FDF fees.

### **D. Contract Manufacturing Organizations**

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<sup>39</sup> See section 744B(a)(4)(D) of the FD&C Act.

<sup>40</sup> See section 744B(a)(4)(A)(ii) of the FD&C Act.

<sup>41</sup> See section 744B(a)(4)(A)(i) of the FD&C Act.

<sup>42</sup> See section 744B(l) of the FD&C Act (exempting facilities that solely produce PET drugs from GDUFA facility fees), section 744A(1)(B) of the FD&C Act (excluding certain applications from the definition of "ANDA"), and section 744A(6)(A)(ii) of the FD&C Act (excluding certain entities from the definition of "facility").

<sup>43</sup> See section 744B(a)(4)(A)(iii).

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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.<sup>44</sup> 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.<sup>45</sup> 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. For example, a facility that is referenced in one or more ANDAs as both an API and FDF manufacturer (i.e., a dual operation facility) may qualify as a CMO, for purposes of an approved ANDA held by the facility owner or affiliate, so long as that ANDA does not reference the facility as an FDF manufacturer.

### **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.<sup>46</sup> 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<sup>47</sup> 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 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 produces 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

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<sup>44</sup> See section 744A(5) of the FD&C Act.

<sup>45</sup> Id.; see section 744B(b)(2)(C) of the FD&C Act.

<sup>46</sup> See section 744B(b)(2)(C) of the FD&C Act.

<sup>47</sup> For a description of post-approval notifications, see FDA's guidance for industry *Changes to an Approved NDA or ANDA* (Apr. 2004, rev. 1).



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approved application. For example, a facility that currently manufactures APIs or FDFs for only non-generic drugs, or only drugs for the non-U.S. market, would have to pay a facility fee if it is referenced in an approved ANDA. 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.<sup>48</sup> 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.<sup>49</sup>

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 a 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 ANDA 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 ANDA 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<sup>50</sup> for any approved ANDA that would incur a fee
- Copies of the facility’s communications to the ANDA holder(s) or DMF holder(s)
- A list of all known, approved generic drug submissions and DMFs that reference the facility which has communicated with the ANDA 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 after the facility fee due date, 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 ANDA holder, the facility will be considered withdrawn for user fee

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<sup>48</sup> 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.

<sup>49</sup> See section 744B(g)(4) of the FD&C Act.

<sup>50</sup> See the definition of "manufacture" in 21 CFR 207.1; see also section 744A(6)(A)(ii), which excludes from the definition of "facility" an entity whose only manufacturing or processing activities consist of repackaging, relabeling, or testing.

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purposes for the next fiscal year.<sup>51</sup> For purposes of this section and in addition to the actions outlined above, FDA considers a good faith effort by a facility requesting to be withdrawn from an ANDA to include the facility's submission of this letter to FDA no earlier than 30 calendar days following the facility's initial withdrawal request to the ANDA holder, but before the October 1 facility fee due date. Facility owners who fail to submit this letter to the FDA prior to the facility fee due date will be assessed a facility fee for that fiscal year.

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](mailto: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.<sup>52</sup> 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 Section VIII.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 labeling for 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 of approved labeling. 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 a manufacturer if it receives product in a container/closure specified in the "How Supplied" section of labeling for an approved ANDA and applies the FDA-approved prescription package labeling to that product for the first time.

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<sup>51</sup> The applicant is still expected to report the change to the approved application in a manner consistent with 21 CFR 314.70.

<sup>52</sup> See footnote 49, *supra*.

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Repackagers are not required to pay facility fees under GDUFA II.<sup>53</sup> 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.<sup>54</sup>

### **H. API-Excipient Mixtures**

Generally, manufacturers of API-excipient mixtures are required to pay the annual FDF facility fee.<sup>55</sup> However, GDUFA II provides one exception, for fee-paying purposes only, to the definition of FDF as inclusive of in-process materials. GDUFA II defines an API-excipient mixture as an API when the mixture is produced because the API is unstable or cannot be transported on its own.<sup>56</sup> In such cases, mixing the API with one or more excipients may prevent the loss of one or more critical quality attributes that allow the API to be made into a finished dosage form. Examples include an API mixed with an antioxidant for chemical stability when the API is prone to oxidative degradation or a highly potent API mixed with a polymer to facilitate safe handling. Additional examples include an API-excipient mixture for physical stability to maintain the API's amorphous form or an API mixed with a lubricant to prevent agglomeration or solidification of a powder. When claiming this exception, the rationale should be clearly stated and accompanied by supporting information in the DMF or application, as appropriate, for each excipient added for stability purposes. APIs mixed with one or more excipients for commercial convenience only are not considered to fall under this exception to characterization as FDF.

### **I. Atypical APIs**

Some ingredients are used as APIs in certain generic drug submissions 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 and manufacturers or processes *any* FDF or API, 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 covered API or FDF. See Section VIII.F for a description of how a facility can ensure that it is no longer identified in an ANDA.

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<sup>53</sup> See section 744A(6)(A)(ii) of the FD&C Act, relating to the definition of "facility".

<sup>54</sup> See *SPL Industry Technical Specification Information: Electronic Self-Identification of Generic Drug Facilities or Sites* (Aug. 2017) at 7.

<sup>55</sup> See sections 744A(7)(C) and 744B(a)(4)(A)(i) of the FD&C Act.

<sup>56</sup> See section 744A(2)(A) of the FD&C Act.

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The facility will cease to incur facility fees if (1) it is no longer identified in any approved generic drug submission or (2) it has stopped manufacturing or processing *all* human APIs and FDFs (including both generic and non-generic FDFs) and the facility or applicant has documented its ceasing of such operations to FDA by following the procedures outlined in Section VIII.F above by the date that the fee is due. If an entity has ceased manufacturing or processing all human APIs and FDFs, the entity no longer qualifies as a facility under GDUFA II (see the definition of *facility* in Section III above)<sup>57</sup>. Any outstanding fee obligations will, however, remain due.

A facility that ceases such manufacturing or processing should follow the steps outlined in Section VIII.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 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;
- Under the supervision of the same local management; and
- Capable of being inspected by FDA during a single inspection.<sup>58</sup>

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.<sup>59</sup>

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](mailto: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.

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<sup>57</sup> See section 744A(6)(A)(i) of the FD&C Act.

<sup>58</sup> 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.

<sup>59</sup> See FDA's guidance for industry *Self-Identification of Generic Drug Facilities, Sites, and Organizations* (Sept. 2016).

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### **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.<sup>60</sup> An ANDA applicant 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.<sup>61</sup>

#### **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 6 to 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 approved 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 approved 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 approved ANDAs on the GDUFA Program Fee due date, the person and its affiliates will be assessed a large-size operation GDUFA Program Fee.<sup>62</sup>

See FDA's GDUFA website ([www.fda.gov/GDUFA](http://www.fda.gov/GDUFA)) for the current fiscal year's fee amounts.

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<sup>60</sup> See section 744B(b)(2)(E)(i) of the FD&C Act.

<sup>61</sup> See section 744B(a)(5) of the FD&C Act.

<sup>62</sup> See section 744B(b)(2)(E) of the FD&C Act.

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### **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.<sup>63</sup> 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 (or a designated affiliate of such person) shall submit to the Secretary, on behalf of the person and the affiliates of such person, a list of (A) all approved ANDAs owned by such person; and (B) if any affiliate of such person also owns an ANDA, all affiliates that own any such ANDA and all approved ANDAs owned by any such affiliate.<sup>64</sup> Please see FDA’s GDUFA website section discussing the GDUFA Program Fee ([www.fda.gov/GDUFA](http://www.fda.gov/GDUFA)) for more information on the format and method for submission of a list of all owned ANDAs.

### **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.<sup>65</sup> 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 GDUFA Program Fee 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 assessment.

## **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

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<sup>63</sup> Id.

<sup>64</sup> See section 744B(o) of the FD&C Act.

<sup>65</sup> See section 744B(b)(2)(E)(ii) of the FD&C Act.

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- A breakdown of entities that may directly or indirectly exert control or influence over the applicant
- A breakdown of entities over which the applicant directly or indirectly exerts control or influence
- Identification of persons in leadership and management positions of the applicant as well as affiliated businesses

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 entities 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 satisfied. 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 [www.fda.gov/GDUFA](http://www.fda.gov/GDUFA). FDA will not receive—within the meaning of section 505(j)(5)(A) of the FD&C Act<sup>66</sup>—a new ANDA or supplement submitted by that person, or any affiliate of that person, until the outstanding fee is paid.<sup>67</sup>

#### **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, the generic drug submission referencing the DMF will not be received.<sup>68</sup>

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<sup>66</sup> 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).

<sup>67</sup> See section 744B(g)(1) of the FD&C Act.

<sup>68</sup> See section 744B(g)(2) of the FD&C Act.

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### **C. ANDA Filing Fees**

If an applicant does not submit payment within 20 calendar days of the due date, its application will be deemed incomplete on the date of submission and will not be received.<sup>69</sup> So long as FDA finds that none of the disqualifications outlined in 21 CFR 314.101(d) and (e) apply (i.e., the ANDA is otherwise substantially complete), the application will be considered submitted as of the date all user fee obligations are satisfied in full.

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

If a generic drug applicant submission 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, and a fee equal to the DMF fee has not been previously paid with respect to such submission, then the applicant shall pay a fee in the amount described in section VII.D, in addition to the applicable ANDA filing fee.<sup>70</sup> If these fees are not submitted within 20 calendar days of the due date then the submission will not be received.<sup>71</sup> So long as FDA finds that none of the disqualifications outlined in 21 CFR 314.101(d) and (e) apply (i.e., the ANDA is otherwise substantially complete), the application will be considered submitted as of the date all user fee obligations are satisfied in full.

### **E. Facility Fees**

Failure to pay the facility fee within 20 calendar days of the due date will result in the following penalties:<sup>72</sup>

- No new ANDA or supplement submitted by the person responsible for paying the fee or that person's affiliates will be received
- 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
- 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.<sup>73</sup> 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.

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<sup>69</sup> See section 744B(g)(3) of the FD&C Act.

<sup>70</sup> See section 744B(a)(3)(F) of the FD&C Act.

<sup>71</sup> See section 744B(g)(3) of the FD&C Act.

<sup>72</sup> See section 744B(g)(4) of the FD&C Act.

<sup>73</sup> Id.



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### **F. 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 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.<sup>74</sup> 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.

However, if an application or supplement was already received by FDA prior to the applicant being placed in arrears, FDA will continue the review of and accept amendments to those applications.

### **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<sup>75</sup> 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 identification number (PIN) to assist in tracking payment

Cover sheets for ANDA filing fees should be submitted with ANDA submissions. The Generic Drug User Fee Cover Sheet and additional payment information is available on the GDUFA website ([www.fda.gov/GDUFA](http://www.fda.gov/GDUFA)).

#### **B. Acceptable Forms of Payment**

Payment must be made in U.S. currency drawn on a U.S. bank.<sup>76</sup> 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.

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<sup>74</sup> See section 744B(g)(5) of the FD&C Act.

<sup>75</sup> <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments>

<sup>76</sup> <https://www.govinfo.gov/content/pkg/FR-2021-07-28/pdf/2021-16039.pdf>

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### **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 and "Transfer" Requests**

Other than as described in section VII.A, 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.<sup>77</sup> 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>.

A Form FDA 3913 written refund request should be submitted to the Division of User Fee Management at [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov).

FDA no longer permits the administrative action of applying a previously paid GDUFA fee (also referred to as a "transfer") from a closed-out fiscal year cover sheet to a different fiscal year cover sheet.<sup>78</sup> Instead, payments from closed-out fiscal year cover sheets will only be processed as refunds to the original payors, provided that the request is made within 180 calendar days from when the original payment was made.

Requests for the "transfer" of payments within the same fiscal year or open fiscal year may be permitted for the same fee type and for a fee obligation of the same payor, provided that the request is made within 180 calendar days from the original payment date. For example, a request to "transfer" a fee payment from a FY 2021 cover sheet to another FY 2021 cover sheet within the same fee type (perhaps due to an incorrect FEI) by the same payor will be processed, provided the request is made within 180 calendar days of the original payment date.

As another example, during September 2021 (FY 2021), an applicant may request a "transfer" of a fee to a FY 2022 cover sheet of the same fee type because FY 2021 has not yet been closed-out. However, if an applicant requests a "transfer" of a fee from a FY 2021 cover sheet during FY 2022 (beginning October 1, 2021, through September 30, 2022), this transaction will not be permitted as FY 2021 has already been closed-out.

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<sup>77</sup> Section 744B(m) of the FD&C Act.

<sup>78</sup> FDA's fiscal year begins on October 1 and ends on September 30, with the fiscal year being designated by the calendar year in which it ends (e.g., FY 2020 begins on October 1, 2019, and ends on September 30, 2020).

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To request a “transfer,” applicants should complete Form FDA 3914 and email the form to [CDERCollections@fda.hhs.gov](mailto: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>

FDA may not issue a refund or process a “transfer” if a written request is made past 180 calendar days from the payment receipt date. For example, a payment “transfer” request submitted after 180 calendar days from the payment receipt date to correct a FEI number may not be processed. Similarly, a request to “transfer” payment from one cover sheet to another cover sheet to correct a DMF number may not be processed if it is received after 180 calendar days from the payment receipt date.

### **E. Non-Payment of GDUFA Fees**

Delinquent entities 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 cover sheet in the user fee system.

### **G. Waivers of and Reductions to GDUFA Fees**

Waivers of and reductions to GDUFA fees are not available. However, facilities that qualify as CMOs only incur one-third of the facility FDF fee. See Section VIII.D for more information on CMOs.

### **H. Arrears Lists**

The backlog arrears list, 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.

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FDA may not necessarily notify applicants before refusing to receive a submission.<sup>79</sup> Applicants 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 a GDUFA arrears list is in error, it should contact the Division of User Fee Management at [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov) and provide a rationale for why the facility should not be included on an arrears list.

### **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.<sup>80,81</sup> 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 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.<sup>82</sup>

## **XIII. APPEALS PROCESS**

### **A. Reconsideration Request**

If FDA fully or partially denies a request for a refund, 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 that is relevant to the entity's

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<sup>79</sup> See section 744B(g) of the FD&C Act.

<sup>80</sup> See section 744B(a)(6) of the FD&C Act.

<sup>81</sup> 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 section 745A(a) of the FD&C Act; see also 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).

<sup>82</sup> 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 drug applications during a lapse in appropriations is financed by carryover GDUFA funding, FDA will be able to accept submissions for which payment was made before the lapse in appropriations occurs and the received date will reflect such payment date. However, FDA 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.

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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](mailto:CDERCollections@fda.hhs.gov) and should be addressed to the following:

Division of User Fee Management  
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 [www.fda.gov/GDUFA](http://www.fda.gov/GDUFA).

### **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 original 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 Evaluation and Research's (CDER) Office of Management via [CDERCollections@fda.hhs.gov](mailto: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.<sup>83</sup> Alternatively, the entity can mail the request to FDA via the carrier of its choice. For the most updated mailing address, visit [www.fda.gov/GDUFA](http://www.fda.gov/GDUFA).

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

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<sup>83</sup> Available at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/ucm444092.htm>.

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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,<sup>84</sup> with a copy provided to CDER. Review of such matters by the Commissioner is discretionary.<sup>85</sup>

#### **XIV. OTHER RESOURCES**

The following guidance documents may be helpful:

- *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*, (Nov. 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](mailto:CDERCollections@fda.hhs.gov) or call 301-796-7900.

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<sup>84</sup> Available at <https://www.fda.gov/about-fda/office-chief-scientist/fda-ombudsman>.

<sup>85</sup> See 40 FR 40682 at 40693 (September 3, 1975); see 21 CFR 10.75.

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**Appendix 1: Form FDA 3913**

Form 3913 is available at <https://www.fda.gov/media/96650/download>.

If you are experiencing difficulties accessing the form, please contact the FDA forms manager at [FormsManager@OC.FDA.GOV](mailto:FormsManager@OC.FDA.GOV) for assistance.

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**Appendix 2: Form FDA 3914**

Form 3914 is available at <https://www.fda.gov/media/96658/download>.

If you are experiencing difficulties accessing the form, please contact the FDA forms manager at [FormsManager@OC.FDA.GOV](mailto:FormsManager@OC.FDA.GOV) for assistance.