May 5, 2023

Dear Colleague:

The FDA User Fee Reauthorization Act of 2022, which includes the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing the Food and Drug Administration (FDA or the Agency) to assess and collect two types of user fees – human drug application fees and prescription drug program fees (program fees). Under PDUFA VII, a program fee is assessed annually for certain prescription drug products identified in a human drug application approved as of October 1 of such fiscal year (FY), with a maximum of five prescription drug program fees for a fiscal year for such prescription drug products identified in a single approved human drug application.[1,2]

This letter notifies you of certain changes in FDA's user fee policies relating to program fee assessment for prescription drug products under PDUFA VII. FDA will issue the FY 2024[3] program fee invoices for PDUFA fee-eligible products[4,5] in August 2023.[6] To ensure FDA has the most updated information available in preparation for the FY 2024 program fee invoices, FDA asks for your assistance in confirming or correcting your company's contact information and the program fee-eligible products according to the instructions below. Please submit your response to the information requested in Section II of this letter no later than **Thursday, June 1, 2023.**

I. Policy Changes Under PDUFA VII

PDUFA VII added or revised the following provisions under the FD&C Act, which will impact the annual program fee assessments: (1) the definition of "human drug application"[7] and "prescription drug product"[8] have been revised to exclude allergenic extract products licensed before October 1, 2022; therefore, allergenic extract product licensed on or after October 1, 2022, are now fee-eligible; (2) the term "skin-test diagnostic product" is now defined in the Act[9] and are exempt from fees[10]; (3) prescription drug products that are pharmaceutically equivalent are exempt from program

[1] Section 736(a)(2)(A) of the FD&C Act.
[2] Section 736(a)(2)(C) of the FD&C Act.
[3] FY 2024 = October 1, 2023, through September 30, 2024.
[4] Prescription drug products listed in the "Prescription Drug Product List" (the "active section") in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") and the Center for Drug Evaluation and Research (CDER)/Center for Biologics Evaluation and Research (CBER) Billable Biologic Lists as of October 1, 2023.
[5] FY 2024 clean-up invoices that are not issued during the annual invoice period in August 2023, will be issued in December 2024. In addition, FY 2023 PDUFA fee-eligible products that were not invoiced during the FY 2023 invoice period, in August 2022, will be issued in December 2023.
[6] The FY 2024 PDUFA fee rates will be published in a Federal Register notice in August 2023.
[7] Section 735(1) of the FD&C Act.
[8] Section 735(3) of the FD&C Act.
[9] Section 735(12) of the FD&C Act.
[10] Section 736(a)(2)(B)(iii) of the FD&C Act.

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fees; and (4) there is a special rule for previously discontinued drug products.[11] These changes are described in detail below.

1. Allergenic Extract Products Licensed on or After October 1, 2022

Section 735(3)(B) revised the definition of a "prescription drug product" and exclude allergenic extract products licensed before October 1, 2022. Therefore, allergenic extracts (including standardized allergenic extract products) that were approved prior to October 1, 2022, will not be assessed PDUFA user fees. However, allergenic extract products (including standardized allergenic extract products) licensed on or after October 1, 2022, will be subject to PDUFA user fees.[12]

2. "Skin-Test Diagnostic Product" Program Fee Exception

Section 736(a)(2)(B)(iii) of the FD&C Act, excepts skin-test diagnostic products from program fee assessment. The term "skin-test diagnostic product" means a product (including positive and negative controls required to interpret the result of such tests) meeting these criteria[13]:

- For prick, scratch, intradermal, or subcutaneous administration;
- Expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;
- Not intended to be preventive or therapeutic intervention; and
- Intended to detect an immediate or delayed-type skin hypersensitivity reaction to aid in the diagnosis of:
    - An allergy to an antimicrobial agent;
    - An allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or
    - Infection with fungal or mycobacterial pathogens.

3. "Pharmaceutically Equivalent Product" Program Fee Exception

In PDUFA VII, a prescription drug product that is "pharmaceutically equivalent," as defined in 21 CFR 314.3 (or a successor regulation), to another prescription drug product (approved under an application held by a different applicant) that is not on the "Discontinued Drug Product List" of the Orange Book, may qualify for an exception from a prescription drug program fee. Generally, FDA publishes its conclusions regarding pharmaceutical equivalence in the Orange Book as determined through the process for assigning therapeutic equivalence (TE) codes. However, some prescription drug products may not have conclusions regarding pharmaceutical equivalence published in the Orange Book (i.e., do not have a TE code in the Orange Book) but may be considered pharmaceutically equivalent.

Therefore, applicants who believe that their product qualifies for a fee exception based on

[11] Section 736(a)(2)(A)(ii) of the FD&C Act.
[12] Section 736(a)(2)(A) of the FD&C Act.
[13] Section 735(12)(A) of the FD&C Act.

pharmaceutical equivalence to another prescription drug product that is not in the Discontinued Drug Product List of the Orange Book may submit a written request to the Prescription Drug User Fee staff at CDERCollections@fda.hhs.gov. Such requests must be received no later than 180 calendar days after such fee is due in order to qualify.[14] For more information on how to submit a written waiver or refund request, please refer to the guidance for industry *Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products*.[15]

4. Provision for Previously Discontinued Drug Products

This provision states that if a drug product is approved in a human drug application as of October 1 of a fiscal year, but the drug product does not meet the definition of a "prescription drug product" as of October 1 of that fiscal year because the drug product is listed in the Discontinued Section of the Orange Book or the CBER/CDER Billable Biologic Lists, it will not receive an annual invoice. However, if on any subsequent day during the relevant fiscal year the drug product does meet the definition of a "prescription drug product" (i.e., the drug product is moved to the active section of the Orange Book or listed on the CBER/CDER Billable Biologic Lists), each person who is named as an applicant in a human drug application is subject to pay the annual prescription drug program fee for such prescription drug product.

For example, if a drug product is not considered a prescription drug product (i.e., was in the Discontinued Section of the Orange Book or the Discontinued Section of the CBER/CDER Billable Biologic Lists) as of October 1, 2023, it would not be issued an annual invoice for FY 2024. If the drug product then meets the definition of a prescription drug product (i.e., by moving to the Active Section of the Orange Book or CBER/CDER Billable Biologics Lists) on any day after October 1, 2023, and before September 30, 2024, then the applicant shall pay the annual prescription drug program fee established for FY 2024 for the prescription drug product.[16] In this example, such fee shall be invoiced with FY 2024 clean up invoices after the close of the fiscal year, issued in December 2024.

II. Review Your Company's Contact Information and Product List

Attachment A – Company Contact Information

Attachment A contains the contact information FDA has on file for the person designated by your company to receive correspondences, invoices, and inquiries concerning prescription drug user fees. Please review and make corrections on Attachment A or confirm that the information is correct as listed and return the signed form by email to the PDUFA User Fee staff at CDERCollections@fda.hhs.gov.

Attachment B – Product List

[14] Section 736(i) of the FD&C Act.
[15] See the guidance for industry *Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products* (October 2019) ("*Waivers Guidance*"), available at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[16] Section 736(a)(2) of the FD&C Act.

Attachment B contains a list of your products that FDA anticipates being eligible for the FY 2024 program fees. Please review your existing product list, cross out any products that you believe should not be assessed a program fee and include the reason why it should not be assessed a fee (e.g., transfer, revocation, or discontinuation of a product).

If any product is omitted that should be included on the existing product list, please add the relevant product information on the "Missing PDUFA Eligible Products List" page and include the reason why it should be assessed a fee. **Please make your changes directly on the list provided in Attachment B rather than creating a new list.** If there are no changes needed to the list, we still ask that you include Attachment B in your email to the PDUFA User Fee staff at CDERCollections@fda.hhs.gov.

III. Confirm Your NDA Prescription Drug Products in the Orange Book

A list of PDUFA fee-eligible prescription drug products for which CDER has regulatory responsibility can be found in the "Prescription Drug Product List" (the "active section") of the Orange Book, available at www.fda.gov/orangebook.

After making any necessary updates to the list of your products in Attachment B, we recommend reviewing your company's current list of drug products in the Orange Book and notifying the Agency of your product's marketing status (e.g., the product is being delayed from marketing after approval, the product is being discontinued, or the product is being withdrawn from sale).[17] To notify the Agency, applicants should submit a notification of changes to the products marketing status in a letter to the applicable new drug application (NDA) file through the Electronic Submissions Gateway (ESG).[18] The notification should prominently identify the submission as an "ADMINISTRATIVE CHANGE / NOT AVAILABLE FOR SALE."[19] Section 506I of the FD&C Act requires NDA holders notify FDA in writing 180 days prior to withdrawing an approved drug product for sale (or if that is not practicable, as soon as practicable but not later than the date of withdrawal).[20]

We note that if an application holder intends to market within 180 days of the date of approval of a drug, no notification under this section (i.e., the notification that a drug is not available for sale under section 506I(b) of the FD&C Act) to FDA is required. When you intend to commence commercial marketing of a drug for which you previously submitted a notification that the drug was not available for sale, FDA recommends that

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[17] The FDA Reauthorization Act of 2017 added section 506I to the Federal Food, Drug, and Cosmetic Act (FD&C Act) requiring application holders to notify the FDA of the marketing status of drug products approved under new drug applications and abbreviated new drug applications.

[18] The Electronic Submissions Gateway is available at https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/. Questions related to electronic submissions should be emailed to the CDER Electronic Submission (ESUB) Support Team at esub@fda.hhs.gov.

[19] For more instructions or information, see the guidance for industry *Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act* (August 2020) available at https://www.fda.gov/media/120095/download.

[20] Section 506I(a) of the FD&C Act.

you notify FDA 30 to 60 days before the anticipated launch date in a letter to the application through the ESG. The notification should prominently identify the submission as an "ADMINISTRATIVE CHANGE/NOTIFICATION OF COMMERCIAL MARKETING."[21]

In addition, applicants that have decided to delay marketing of a newly approved product for an extended period of time should request to have the product moved to the discontinued section as soon as possible to give FDA sufficient time to process the request before fees are assessed. However, please note that if the product is marketed at any time during the same fiscal year, the product may be assessed program fee. For FY 2024 invoices, such submission should be submitted through the ESG gateway **no later than June 30, 2023**.[22] In addition, a courtesy email notification regarding your product marketing status change should be sent to CDERCollections@fda.hhs.gov.

If you submit a drug product's marketing status change after June 30, 2023, or if the drug product's marketing status is not reflected in the Orange Book June Cumulative Supplement update and remains in the "active section" of the Orange Book, the product may be included on your FY 2024 invoice. You may be eligible for a refund of the assessed program fee provided you submit the drug product's marketing status change to the applicable NDA no later than September 30, 2023. To qualify for a refund, you must submit a refund request in writing to the User Fee staff at CDERCollections@fda.hhs.gov **no later than 180 calendar days** after the fee is due.[23]

IV. Confirm Your Biological Products on the CDER and CBER Lists

For a current list of PDUFA fee-eligible licensed therapeutic biological products for which CDER has regulatory responsibility, please see the "CDER Therapeutic Biologic Product" list (CDER Billable Biologics List) at https://www.fda.gov/media/76650/download.

For a current list of PDUFA fee-eligible licensed biological products for which CBER has regulatory responsibility, please see CBER's "User Fee Billable Biologic Products and Potencies Approved Under Section 351 of the PHS Act" list (CBER Billable Biologics List) at https://www.fda.gov/media/113210/download.

We recommend reviewing the information on both websites to obtain a complete list of your biological products. If you are no longer marketing a biological product and have delisted it under section 510 of the FD&C Act (21 U.S.C. 360), but the product is on the CDER or CBER Billable Biologics List, please notify FDA no later than **June 30, 2023,** to ensure you are not invoiced for it:

1. For CDER-regulated biological products, submit a Product Correspondence to

[21] See footnote 19.
[22] Section 506I of the FD&C Act requires NDA holders to provide written notification to FDA 180 days prior to withdrawing an approved product from sale, or as soon as practicable, but no later than the date of withdrawal.
[23] See footnote 14.

the Review Office requesting a change to the product's marketing status and contact the CDER User Fee staff at CDERCollections@fda.hhs.gov requesting in writing that FDA move the product to the CDER Discontinued Biologic Product List.

2. For CBER-regulated biological products, submit a Product Correspondence to the Product Review Office requesting a change to the product's marketing status and contact the CBER and CDER User Fee staff at CBERUserFeeStaff@fda.hhs.gov and CDERCollections@fda.hhs.gov requesting that the product be moved to the CBER Discontinued Products List.

If you notify the User Fee staff about the discontinuation of a biological product after June 30, 2023, the product may be included on the invoice issued in August. However, you may be eligible for a refund of the program fee provided the User Fee staff receives notification[24] to move the product to the discontinued section of the CDER or CBER Billable Biologics List no later than **September 30, 2023**. To qualify for a refund, you must submit a refund request in writing to the User Fee staff **no later than 180 calendar days** after the fee is due.[25]

If you plan to resume marketing your biological product and it is in the discontinued section of the CDER or CBER Billable Biologics List, you should notify the User Fee staff so the product can be moved to the appropriate CDER or CBER Billable Biologics List.

V. How to Provide the Requested Information

Please return Attachments A and B (including the updated product list) **no later than June 1, 2023**, by email to the Prescription Drug User Fee staff at CDERCollections@fda.hhs.gov.

If you have any questions, please contact us by email at CDERCollections@fda.hhs.gov.

Sincerely,

Jeen S. Min -S Digitally signed by Jeen S. Min -S
Date: 2023.04.26 07:05:07 -04'00'

Jeen Min, R.Ph., RAC
CDR, United States Public Health Service
Branch Chief, Division of User Fee Management
Office of Management
Center for Drug Evaluation and Research

[24] See footnote 17.
[25] See footnote 14.

Attachments:
Attachment A – Company Contact Information
Attachment B – Lists of Products Subject to User Fees