

May 3, 2021

Dear Colleague:

The Prescription Drug User Fee Amendments of 2017 (PDUFA VI) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizing the Food and Drug Administration (FDA or Agency) to assess and collect two types of user fees – human drug application fees and prescription drug program fees (program fees). Under PDUFA VI, a program fee is assessed annually for each prescription drug product identified in a human drug application approved as of October 1 of the fiscal year (FY), with a maximum of five program fees assessed for a single approved application.^{1, 2}

FDA will issue the FY 2022³ program fee invoices for PDUFA fee-eligible products^{4, 5} in August 2021.⁶ To prepare the FY 2022 invoices, we ask for your assistance in confirming or correcting your company's contact information and the PDUFA fee-eligible products according to the instructions below. Please submit your response by **Tuesday, June 1, 2021**.

I. Review Your Company's Contact Information and Products 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

Attachment B contains a list of the products that are currently liable for the FY 2022 program fees. Please review your existing product list, cross out any products that you

¹ Section 736(a)(2)(A) of the FD&C Act.

² Section 736(a)(2)(C) of the FD&C Act.

³ FY 2022 = October 1, 2021, through September 30, 2022.

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, 2021.

⁵ FY 2022 clean-up invoices (for PDUFA fee-eligible products not invoiced during annual invoices in August 2021) will be sent in December 2021.

⁶ The FY 2022 fees will be published in a *Federal Register* notice in August 2021.

believe should not be assessed a program fee and include the reason why it should not be assessed a fee (e.g., generic competition, 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 separate list.**

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

A list of PDUFA fee-eligible prescription drug products for which the Center for Drug Evaluation and Research (CDER) has regulatory responsibility can be found in the “Prescription Drug Product List” (the “active section”) of the Orange Book, available at <https://www.accessdata.fda.gov/scripts/cder/ob/>.

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).⁷ You should submit a notification of changes to your product marketing status in a letter to the applicable new drug application (NDA) file through the Electronic Submissions Gateway.⁸ The notification should prominently identify the submission as an “ADMINISTRATIVE CHANGE / NOT AVAILABLE FOR SALE.”⁹ NDA holders are required to provide a written notification to FDA 180 days prior (or as practicable) to withdrawing an approved drug product for sale.^{10, 11} For FY 2022 invoices, such submission should be submitted **no later than June 30, 2021**.¹² A courtesy email notification regarding your product marketing status change should be sent to CDERCollections@fda.hhs.gov.

⁷ The FDA Reauthorization Act of 2017 added section 506I to the 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.

⁸ 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.

⁹ 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>.

¹⁰ The Agency may verify marketing status by requesting information from the applicant including: (1) the date on which the drug is expected to no longer be available for sale; (2) the last date of distribution of the drug product; (3) the last manufacturing date of the final dosage form of the drug product with lot numbers; (4) expiration dates.

¹¹ We note that there may be user fee implications associated with moves to and from the “Discontinued Drug Product List” (the “discontinued section”) of the Orange Book. We also note that a routine, temporary interruption in the manufacturing, supplying, and distribution of a product or a request that may be made to circumvent the annual invoicing process is generally not considered a withdrawal from sale.

¹² 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.

If you submit a drug product's marketing status change after June 30, 2021, 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 2022 invoice. You may be eligible for a refund of the assessed program fee provided you submit¹³ the drug product's marketing status change to the applicable NDA no later than **September 30, 2021**. 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.¹⁴

Failure to move a product to the "Discontinued Drug Product List" of the Orange Book could result in the assessment of fees, even if the product is not marketed.

III. 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 Billable Biologic List" at <https://www.fda.gov/media/76650/download>.

For a current list of PDUFA fee-eligible licensed biological products for which the Center for Biologics Evaluation and Research (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 Biologic 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 Biologic List, please notify FDA by **June 30, 2021**:

- For CDER-regulated biological products, contact the CDER User Fee staff at CDERCollections@fda.hhs.gov and request in writing that FDA move the product to the CDER Discontinued Biologic Product List.
- For CBER-regulated biological products, submit a Product Correspondence to the Product Review Office requesting that the product be moved to the CBER Discontinued Products List and copy the CBER User Fee staff at CBERPDUFAstaff@fda.hhs.gov. Please include CDERCollections@fda.hhs.gov on correspondences sent to the CBER User Fee staff.

¹³ FDA intends to consider the product to have been moved to the "discontinued section" of the Orange Book on the date the request is received or on the date the product is no longer marketed, whichever is later. See the guidance for industry *Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017* (November 2020) available at <https://www.fda.gov/media/108233/download>.

¹⁴ Section 736(i) of the FD&C Act (21 U.S.C. 379h(i)).

If you notify the User Fee staff about the discontinuation of a biological product after June 30, 2021, 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 notification¹⁵ to move the product to the discontinued section of the CDER or CBER Billable Biologics List no later than **September 30, 2021**. 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.¹⁶

Failure to move a product to the discontinued section of the CDER or CBER Billable Biologics List could result in the assessment of a program fee, even if the product is not marketed. 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 Biologic List.

IV. How to Provide the Requested Information

Please return Attachments A and B (including the updated product list) **no later than June 1, 2021**, 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 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

Attachments:

Attachment A – Company Contact Information

Attachment B – Lists of Products Subject to User Fees

¹⁵ See footnote 13.

¹⁶ Section 736(i) of the FD&C Act (21 U.S.C. 379h(i)).