May 6, 2019

Dear Colleague:

The Prescription Drug User Fee Amendments of 2017 (PDUFA VI) 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 VI, a program fee is assessed annually for each prescription drug product identified in an approved human drug application, with a maximum of five program fees assessed for a single approved application.[1, 2]

FDA will issue the fiscal year (FY) 2020[3] program fee invoices in August 2019.[4] To prepare the FY 2020 invoices, we ask for your assistance in confirming or correcting your company's contact information and the PDUFA program fee-eligible products according to the instructions below. Please submit your response by **Monday, June 3, 2019**.

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 2020 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., products with therapeutic equivalence identified in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) by an "A" therapeutic code,[5] revocation or discontinuation of a product).

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[1] Section 736(a)(2)(A) of the FD&C Act.
[2] Section 736(a)(2)(C) of the FD&C Act.
[3] FY 2020 = October 1, 2019, through September 30, 2020.
[4] The FY 2020 fees will be published in a *Federal Register* notice in August 2019.
[5] For additional information, please refer to the guidance for Industry *Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017* (PDUFA VI guidance). The PDUFA VI guidance is available on the Internet at www.fda.gov/Drugs under Guidance (Drugs).

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 lists provided in Attachment B rather than creating a separate list.**

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

A list of user 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" 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 if your product is being discontinued or withdrawn from sale. FDA regulations require new drug application (NDA) holders to notify the Agency of the marketing status of approved drug products.[6] The applicant should submit a notification of withdrawal from sale in a letter to the applicable NDA file through the electronic submissions gateway.[7] The notification should prominently identify the submission as an "ADMINISTRATIVE CHANGE / NOT AVAILABLE FOR SALE."[8] NDA holders are required to provide a written notification to FDA 180 days prior to withdrawing an approved drug product for sale.[9, 10] For FY 2020 invoices, such submission should be made **no later than June 30, 2019**, and a courtesy email notification should be sent to the Orange Book staff (OrangeBook@fda.hhs.gov).

If you submit a drug product's marketing status change after June 30, 2019, the product may be included on your FY 2020 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, 2019**. To be eligible for a refund, you

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[6] 21 CFR 314.81(b)(2)(ii)(a) and 314.81(b)(3)(iv).
[7] 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) Team at esub@fda.hhs.gov.
[8] See draft guidance for industry *Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format* available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM630099.pdf.
[9] 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; and (5) last distribution date of the drug product.
[10] We note that there may be user fee implications associated with moves to and from the discontinued section. 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.

must submit a refund request in writing to the User Fee Staff at CDERCollections@fda.hhs.gov no later than 180 days after the fee is due.[11]

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. If you plan to resume marketing your drug product and the product is on the Discontinued Drug Product List, you should notify FDA of marketing commencement in a letter[12] to the applicable NDA file and send a courtesy email notification to the Orange Book staff (OrangeBook@fda.hhs.gov).

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

For a current list of user fee-eligible licensed therapeutic biological products for which **CDER** has regulatory responsibility, please see the *CDER Billable Biologic List* at https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm164641.pdf

For a current list of user fee-eligible licensed biological products for which the Center for Biologics Evaluation and Research (**CBER**) has regulatory responsibility, please see CBER's list of *User Fee Billable Biologic Products and Potencies Approved Under Section 351 of the PHS Act* (CBER Billable Biologic List) athttps://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/UCM606472.pdf.

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 do the following:

- For CDER regulated products, contact the CDER User Fee Staff and request in writing that FDA move the product to the *CDER Discontinued Product List*.

- For CBER regulated 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.

Please notify FDA by **June 30, 2019**, if changes need to be made:

- For CDER biological products, email the CDER User Fee Staff at CDERCollections@fda.hhs.gov.

[11] Section 736(i) of the FD&C Act (21 U.S.C. § 379h(i)).
[12] The application holder should determine whether the submission of a supplement is required prior to the reintroduction of the drug product(s) into the market.

- For CBER biological products, email the CBER User Fee Staff at CBERPDUFAstaff@fda.hhs.gov. Please include CDERCollections@fda.hhs.gov on correspondence sent to the CBER User Fee Staff.

If you notify the User Fee Staff about the discontinuation of a biological product after June 30, 2019, the product may be included on the invoice issued in August. However, you may be eligible for a refund of the program fee(s) provided the User Fee Staff receives notification to move the product to the Discontinued Product List no later than **September 30, 2019**. Please note: to be eligible for a refund, you must submit the refund request in writing to the User Fee Staff no later than 180 days after the fee is due.[13]

Failure to move a product to the Discontinued Product 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 on the Discontinued Product List, you should notify the User Fee Staff so the product can be moved to the appropriate CDER or CBER Billable Biologic Product List.

IV. How to Provide the Requested Information

Please return Attachments A and B (including the updated product list) **no later than June 3, 2019**, 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 -S5

Digitally signed by Jeen S. Min -S5
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Jeen S. Min -S5, 0.9.2342.19200300.100.1.1=1300149120
Date: 2019.04.22 08:45:35 -04'00'

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

Attachments:
Attachment A – Company Contact Information
Attachment B – Lists of Products subject to user fees

[13] Section 736(i) of the FD&C Act (21 U.S.C. § 379h(i)).