Department of Health and Human Services **Public Health Service**
Food and Drug Administration
Silver Spring, MD 20993

May 5, 2016

Dear Colleague:

The Prescription Drug User Fee Amendments of 2012 (PDUFA V) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize the Food and Drug Administration (FDA) to assess and collect three types of user fees — application, product, and establishment fees — from applicants who submit certain new drug and biological product applications and supplements.[1]

FDA will issue the fiscal year (FY) 2017[2] product and establishment invoices in August 2016.[3] To prepare the FY 2017 invoices, we ask for your assistance in updating our records. Please provide the following information: (1) company contact information (Attachment A), and (2) lists of products and establishments subject to user fees (Attachment B). **Submit your response by Friday, June 10, 2016.**

I. Attachment A – Company Contact Information

Attachment A shows the contact information FDA has on file for the person designated by your company to receive correspondence, invoices, and inquiries concerning prescription drug user fees. Please review the contact information on Attachment A, make any necessary corrections on the PDF form, and return the signed form by email to the Dear Colleague Letter Coordinator (CDERCollections@fda.hhs.gov).

II. Attachment B – Product List

Attachment B contains a list of the products and establishments that appeared on your FY 2016 invoice, issued on August 15, 2015. Please update the Product List according to the following instructions:

- Add any approved product that you believe should be assessed a fee (e.g., new strength approved) to the list and include the reason why you believe it should be assessed a fee. **Please make your changes directly on the product and establishment list provided rather than recreating the list.**
- Delete from the list any product that you have reason to believe should not be assessed a fee (e.g., generic competition for new drug application (NDA) products, revocation or discontinuation of a biological product) and include the reason why you believe it should not be assessed a fee.
- For all products on your updated list, provide the establishment or establishments where the final dosage forms of each product are manufactured (see instructions below in section III).

[1] Sections 735 and 736 of the FD&C Act (21 U.S.C. §§ 379g and 379h) as amended by PDUFA V.
[2] FY 2017 = October 1, 2016, through September 30, 2017.
[3] The FY 2017 fees will be published in a *Federal Register* notice anticipated in August 2016.

A. Instruction for NDA Prescription Drug Products

A current 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 *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) on the Orange Book website.[4]

After making any necessary updates to the list of your products in Attachment B, please review your company's current list of drug products in the Orange Book.

To avoid assessment of FY 2017 product fees for drug products that are no longer marketed, notify the Orange Book staff in writing of changes to the Prescription Drug Product List no later than **June 30, 2016**. If you notify the Orange Book staff of the drug product marketing status after June 30, 2016, the product may be included on the FY 2017 invoice.

Failure to move a product to the discontinued section of the Orange Book could result in the assessment of fees, even if the product is not marketed. However, you may be eligible for a refund of the assessed FY 2017 product and establishment fees provided the Orange Book staff receives the notification to move a product from the Prescription Drug Product List to the Discontinued Product List no later than **September 30, 2016**.

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.[5] If you plan to resume marketing of your drug product and it is on the Discontinued Drug Product List, you should notify the Orange Book staff so the drug product can be moved to the Prescription Drug Product List.

The Orange Book staff requests that you notify them of any changes to the current list of your company's products (please refer to the Orange Book website for the current list). For the Orange Book staff to receive changes in a consistent format, please print your company's list of products from the FDA website and note any changes directly on the printed list. Email your changes to the Orange Book staff at OrangeBook@fda.hhs.gov no later than **June 30, 2016**. To ensure that all changes are reflected in your invoice, please send the User Fee staff (CDERCollections@fda.hhs.gov) a courtesy copy of any information sent to the Orange Book staff.

[4] *See* The Orange Book website, *available at*: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.
[5] Section 736(i) of the FD&C Act (21 U.S.C. § 379h (i)).

B. Instruction for Biological Products

For a current list of user fee-eligible licensed *therapeutic biological products* for which **CDER** has regulatory responsibility, please click here.[6]

For a current list of user fee-eligible licensed *biological products* for which the Center for Biologic Evaluation and Research (**CBER**) has regulatory responsibility, please click here.[7]

You will need to review both websites to obtain a complete list of your user fee-eligible 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 either of the billable biologics lists, you should alert the User Fee staff and request in writing that FDA move it to the Discontinued Products List.

To avoid assessment of FY 2017 product fees for biological products that are no longer marketed, notify the FDA in writing of your request to discontinue the product no later than **June 30, 2016**. If you notify FDA of the discontinued biologic after June 30, 2016, the product may be included on the FY 2017 invoice.

Failure to move a product to the Discontinued Product List may result in the assessment of fees, even if the product is not marketed. However, you may still be eligible for a refund of the assessed FY 2017 product and establishment fees provided FDA receives the discontinued product notice no later than **September 30, 2016**.

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.[8] If you plan to resume marketing your drug product and it is on the Discontinued Product List, you should notify the User Fee staff so the drug product may be moved to the appropriate billable biologics list.

The Office of Biotechnology Products (OBP) requests that you notify them of any changes to the current list of your company's products for which CDER has regulatory responsibility. Please send changes regarding your CDER biological products to CDR Kimberly Rains, OBP, at Kimberly.Rains@fda.hhs.gov. Please include CDERCollections@fda.hhs.gov on any correspondence sent to OBP.

CBER's User Fee staff requests that you notify them of any changes to the current list of your company's products for which CBER has regulatory responsibility. Please send changes regarding your CBER biological products to Carla Vincent, CBER User Fee staff, at Carla.Vincent@fda.hhs.gov. Please include CDERCollections@fda.hhs.gov on any correspondence sent to the CBER User Fee staff.

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[6] *See* CDER Billable Biologic Product List, *available at* http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM164641.pdf.
[7] *See* CBER Billable Biologic Product List, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122936.htm.
[8] Section 736(i) of the FD&C Act (21 U.S.C. § 379h(i)).

III. Attachment B – Establishment List

Each establishment that manufactures the product in *final dosage form* is assessed an establishment fee. For user fee billing purposes, the final dosage form means a finished dosage form which is approved for administration to a patient without substantial further manufacturing.[9] Examples of this include sites that manufacture capsules, tablets, lyophilized products before reconstitution, or perform the filtration and/or sterilization of the product, even if the product is finished in bulk and filled or packaged elsewhere. Sites where only labeling and packaging occur are not considered final dosage form manufacturing sites.

Please review the Establishment List and update it as follows:

- Add the name and site address (not the corporate headquarters address) of any additional approved manufacturing sites engaged in the manufacture of final dosage forms of any of the drug and biologic products on your updated product list. Include establishments owned by contract manufacturers.

- Delete any establishments that do not manufacture in final dosage form any of the drug and biologic products on your updated product list. Include a brief statement of the reason for deletion (e.g., no longer manufacturing product), provide product names, and include the operations formerly performed at the establishment.

- Number the establishments on your updated establishment list. For example, if you have 10 establishments listed, number them 1 through 10. Then go back to your updated product list and write the corresponding establishment number where the product is manufactured in final dosage form next to each product. If a product is manufactured in final dosage form at more than one site, please note next to the product the numbers of all establishments that manufacture that product.

If your firm owns an establishment that is not associated with the production of any of *your* products but contracts to make products for another firm, please include the name and site address of the establishment on a separate page. Indicate that the facility serves as a contract manufacturer only and list (1) the products manufactured and (2) the firms for which the products are manufactured.

[9] Section 735(4) of the FD&C Act (21 U.S.C. § 379g(4)).

IV. How to Provide the Requested Information

Please return Attachments A and B (including the updated product and establishment lists) **no later than June 10, 2016**, by email to the Prescription Drug User Fee staff at CDERCollections@fda.hhs.gov.

If you have any questions, please call 301-796-7900 and ask to speak to the Dear Colleague Letter Coordinator. If you have any questions regarding your CBER biological products, please contact Carla Vincent, CBER User Fee staff, at 240-402-8177 or email Carla.Vincent@fda.hhs.gov. Please include CDERCollections@fda.hhs.gov on any correspondence sent to the CBER User Fee staff.

We look forward to receiving your responses by **June 10, 2016.**

Sincerely yours,

Donal Parks, Director
Division of User Fee Management & Budget Formulation
Office of Management
Center for Drug Evaluation and Research
US Food and Drug Administration

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