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

May 5, 2015

Dear Colleague:

The Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), which was signed into law on July 9, 2012, amended the Federal Food, Drug, and Cosmetic Act (the Act). FDASIA includes the Prescription Drug User Fee Amendments of 2012 (PDUFA V) which authorizes the Food and Drug Administration (FDA) to continue to 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] The Act continues to provide increased resources for FDA to implement improvements in the drug and biological product review processes and conduct risk management activities for these products. The resources supported by user fees help FDA significantly expedite the drug review process.

We plan to issue the fiscal year (FY) 2016[2] product and establishment invoices in August 2015.[3] To prepare the FY 2016 invoices, we are asking for your assistance in updating our records. Please provide the following information for your company: (1) contact for user fee invoices (Attachment A), and (2) lists of products and establishments subject to user fees (Attachment B). **Your response is requested by Wednesday, June 10, 2015.**

I. What Is Attached to This Letter?

Attachment A shows the contact information we have on file for the person designated by your company to receive correspondence, invoices, and inquiries concerning prescription drug user fees. Attachment B contains lists of the products and establishments that appeared on your FY 2015 invoice issued on August 15, 2014.

II. What Information Does FDA Need for FY 2016?

To prepare for FY 2016 product and establishment fee assessments under the Act, we ask that you provide the information described in the following subsections.

A. Attachment A – User Fee Contact Information

Review the contact information on Attachment A and make any necessary additions or corrections. Then sign the attachment. Please include your title and the date.

[1] Sections 735 and 736 of the Act (21 U.S.C. 379g and 379h) as amended by PDUFA V.
[2] FY 2016 = October 1, 2015, through September 30, 2016.
[3] The FY 2016 fees will be published in a *Federal Register* notice. The exact date is not known, but we anticipate the notice will publish in August 2015.

B. Attachment B – Product List

Please review the Attachment B Product List and update it as follows:

- 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. FDA prefers that you make changes directly on the product and establishment lists 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., due to generic competition for new drug application (NDA) products, or revocation of a biological product license) and include a brief explanation of why you believe it should not be assessed a fee.

- For all products on your updated list, indicate the establishment or establishments where the final dosage forms of each product are manufactured (see instructions in section II.C).

1. Where can you find a current list of your company's *prescription drug products*?

For user fee-eligible *prescription drug products* for which the Center for Drug Evaluation and Research (CDER) has regulatory responsibility, a current list of products is included in the Prescription Drug Product List of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). The Orange Book can be viewed on the Internet at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.[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. If you find that the Orange Book is not up to date, please contact the Orange Book staff with any corrections. For example, if you are no longer marketing a drug product, and have delisted it under section 510 of the Act (21 U.S.C. 360), but the product is on the Prescription Drug Product List of the Orange Book, then you should alert the Orange Book staff so the product can be moved to the Discontinued Drug Product List. Conversely, if you plan to resume marketing your drug product and it is on the Discontinued Drug Product List, you should also notify the Orange Book staff so the drug product can be moved to the Prescription Drug Product List.[5] Failure to move a product to the discontinued section can result in the assessment of fees, even if the product is not marketed, so please make sure your list is correct.

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[4] Orange Book data files are available on the Internet and may assist you in viewing and identifying your firm's drug products.

[5] To avoid assessment of FY 2016 product fees with the FY 2016 invoices 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, 2015. If you notify the Orange Book staff of the drug product marketing status after June 30, 2015, the product may be included on the FY 2016 invoice. However, you may still be eligible for a refund of the assessed FY 2016 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, 2015. **In addition, requests for a refund of user fees must be submitted in writing to the User Fee staff no later than 180 days after the fee is due** (see section 736(i) of the Act).

2. Where can you find a current list of your company's billable, licensed *biological products*?

For user fee-eligible licensed *therapeutic biological products* for which CDER has regulatory responsibility, a current list is available at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM164641.pdf. For user fee-billable licensed *biological products* for which the Center for Biologic Evaluation and Research (CBER) has regulatory responsibility, a current list is available at http://www.fda.gov/aboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122936.htmhttp://www.fda.gov/aboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122936.htm.

You will need to view both websites to obtain a complete list of your user fee-eligible biological products.[6] If you are no longer marketing a biological product and have delisted it under section 510 of the 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 the FDA move it to the *Discontinued Products List.* Conversely, 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. Failure to move a product to the Discontinued Product List may result in the assessment of fees, even if the product is not marketed, so please make sure your list is correct.

C. Attachment B – Establishment List

Please review the Attachment B Establishment List and update it as follows:

- 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.[7] 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.

- Add to the list 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.

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[6] To avoid assessment of FY 2016 product fees with the FY 2016 invoices 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, 2015. If you notify FDA of the discontinued biologic notice after June 30, 2015, the product may be included on the FY 2016 invoice. However, you may still be eligible for a refund of the assessed FY 2016 product and establishment fees provided FDA receives the discontinued product notice no later than September 30, 2015. **In addition, requests for a refund of user fees must be submitted in writing to the User Fee staff no later than 180 days after the fee is due** (see section 736(i) of the Act).

[7] Section 735(4) of the Act.

- Delete from the list any establishments that do not manufacture in final dosage form any of the drug and biologic products on your updated product list. Please 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 all 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 user fee 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.

III. How and When Does FDA Want the Requested Information?

A. User Fee Staff

To allow time for us to process the information you provide, the User Fee staff requests you return Attachments A and B (including the updated product and establishment lists) **as soon as possible, and no later than close of business Wednesday, June 10, 2015.** If you have any questions, please call Tearra Brown or Beverly Friedman at 301-796-7900. Please return Attachments A and B by email to the Prescription Drug User Fee staff at CDERCollections@fda.hhs.gov or via facsimile to 301-431-6324. If you wish to send a paper copy confirming the emailed information, you can forward it (by regular mail or by courier service) to:

PDUFA User Fee Staff
Office of Management
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Avenue
Hillandale Building, Room 3179
Silver Spring, MD 20993-0002

B. CBER's User Fee Staff

CBER's User Fee staff works with CDER's User Fee staff in processing the information that you provide (i.e., Attachments A and B). Because the CBER and CDER staff work together to accurately assess user fees for your licensed biological products, you do not need to send any separate updates to CBER. However, if you have any questions

regarding your CBER biological products, please contact Carla Vincent at 240-402-8177 or email Carla.Vincent@fda.hhs.gov.

C. Orange Book Staff

The Orange Book staff requests that you notify them of any changes to the current list of your company's products located on the Internet at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. For the Orange Book staff to receive changes in a consistent format please print your company's list of products from the Internet and note any changes directly on the printed list. To allow time to process the information you provide and factor it into the billing, the Orange Book staff requests that you send your Orange Book changes to them as soon as possible, but no later than **Tuesday, June 30, 2015**. Please send your Orange Book changes and any questions about your company's current product list to the Orange Book Staff at drugproducts@cder.fda.gov or via facsimile to 301-595-1446.

To ensure that changes made are reflected in your invoices, please send the User Fee staff a courtesy copy of any information sent to the Orange Book staff.[8]

Your assistance **and your response to the User Fee staff by June 10, 2015**, is greatly appreciated. Please note that the User Fee staff is moving towards electronic communications and will discontinue sending out correspondences via mail or courier delivery services in the near future. Any questions or concerns can be directed to CDERCollections@fda.hhs.gov.

FDA is committed to continue working jointly with industry to ensure the continued success of this program.

Sincerely yours,

William Collinson
Director, FDA Office of Financial Management

Attachments:
Attachment A – User Fee Contact Information
Attachment B – Lists of Products and Establishments Invoiced for FY 2015 (Invoices were mailed August 15, 2014)

[8] See above on how to contact the User Fee staff.