Department of Health and Human Services Public Health Service
Food and Drug Administration
Rockville, MD 20857

May 5, 2014

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) 2015[2] product and establishment invoices in August 2014.[3] To prepare the FY 2015 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 11, 2014.**

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 2014 invoice issued on August 15, 2013.

II. What Information Does FDA Need for FY 2015?

To prepare for FY 2015 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h) as amended by PDUFA V.
[2] FY 2015 = October 1, 2014, through September 30, 2015.
[3] The FY 2015 fees will be published in a *Federal Register* notice. The exact date is not known, but we anticipate the notice will publish in August 2014.

B. Attachment B – Product List

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

- Add to the list any approved product that you believe should be assessed a fee (e.g., new strength approved) and include the reason why you believe it should be assessed a fee.[4]

- 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 your company's prescription drug 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.[5] 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.[6] *Note: 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] FDA prefers that you make changes directly on the product and establishment lists provided rather than recreating the list.

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

[6] To avoid assessment of FY 2015 product fees with the FY 2015 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, 2014. If you notify the Orange Book Staff of the drug product marketing status after June 30, 2014, the product may be included on the FY 2015 invoice. However, you may still be eligible for a refund of the assessed FY 2015 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, 2014. *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 on the Internet 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 on the Internet at http://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.[7] 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. *Note: 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.[8] Examples of this include sites that manufacture lyophilized products before reconstitution, capsules, tablets, or perform the filtration and/or sterilization of the product, even if the product is finished in bulk and filled or packaged elsewhere. Note: 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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[7] To avoid assessment of FY 2015 product fees with the FY 2015 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, 2014. If you notify FDA of the discontinued biologic notice after June 30, 2014, the product may be included on the FY 2015 invoice. However, you may still be eligible for a refund of the assessed FY 2015 product and establishment fees provided FDA receives the discontinued product notice no later than September 30, 2014. *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).

[8] 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 name(s) and include the operation(s) 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 11, 2014.** If you have any questions, please call Katie Stronati or Beverly Friedman at 301-796-7900. Please return Attachments A and B by email to Ashley Jones at CDERCollections@fda.hhs.gov. If you wish to send a paper copy confirming the emailed information, you can forward it (by regular mail or by courier service) to:

Ashley Jones
PDUFA User Fee Staff
Office of Management
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 6257
Silver Spring, MD 20993-0002

Please note: Only FedEx and UPS deliver directly to the 6th floor.

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 email Carla Vincent at 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 **Monday, June 30, 2014.** Please send your Orange Book changes and any questions about your company's current product list to the Orange Book Staff to drugproducts@fda.hhs.gov.[9]

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.[10]

Your assistance **and your response to the User Fee Staff by June 11, 2014**, is greatly appreciated. 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 2014 (Invoices were mailed August 15, 2013)

[9] The Office of Generic Drugs is in the process of moving and as a result will be changing their phone number and address. As soon as we are informed of the updated contact information, it will be posted on the PDUFA website at www.fda.gov/PDUFA.
[10] See above on how to contact the User Fee Staff.