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

May 5, 2009

Dear Colleague:

On September 27, 2007, the President signed the Food and Drug Administration Amendments Act of 2007, which includes the Prescription Drug User Fee Amendments of 2007 (PDUFA IV). PDUFA IV 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] These amendments to the Federal Food, Drug, and Cosmetic Act (the Act) provide increased resources for FDA to implement more 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 development process and the review of human drug applications.

We plan to issue the fiscal year (FY) 2010[2] product and establishment invoices in August 2009.[3] To prepare the FY 2010 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 Tuesday, June 16, 2009.**

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 user fees. Attachment B contains lists of the products and establishments that appeared on your FY 2009 invoice issued in August 2008.

II. What Information Does FDA Need for FY 2010?

To prepare for FY 2010 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.

B. Attachment B – Product List

[1] Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h) as amended by PDUFA IV.
[2] FY 2010 = October 1, 2009, through September 30, 2010.
[3] The FY 2010 fees will be published in a *Federal Register* notice. We do not have an exact date, but we anticipate the notice will publish in August 2009.

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.

- Delete from the list any product that you have reason to believe should not be assessed a fee (e.g., generic competition for NDA products, biological product license revoked) 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 produced (see instructions in section II.C).

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

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 www.fda.gov/cder/ob/.[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] *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.*

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

On October 1, 2003, FDA transferred certain product oversight responsibilities from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation

[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 2010 product fees with the FY 2010 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, 2009. If you notify the Orange Book Staff of the drug product marketing status after June 2009, the product may be included on the FY 2010 invoice. However, you may still be eligible for a refund of the assessed FY 2010 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, 2009. *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).

and Research (CDER). For user fee eligible licensed *therapeutic biological products* for which CDER has regulatory responsibility, including review and continuing oversight, a current list is available on the Internet at http://www.fda.gov/cder/biologics/pdufa/billable.pdf. For user fee billable licensed *biological products* for which CBER has regulatory responsibility, including review and continuing oversight, a current list is available on the Internet at http://www.fda.gov/cber/pdufa/billable.htm. You may need to view both Web sites 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 office or division responsible for the regulatory oversight of your product and request in writing that the User Fee Staff 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 office or division responsible for the regulatory oversight of your product as well as the User Fee Staff so the drug product can be moved to the appropriate billable biologics list. *Note: Failure to move a product to the Discontinued Product List can 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:

- 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.[7] Include establishments owned by contract manufacturers.

- Do not include establishments that function solely as packagers or those that do not make final dosage forms.

- 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 of deletion (e.g., state the operation that was performed at the establishment to be deleted).

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[6] To avoid assessment of FY 2010 product fees with the FY 2010 invoices for biological products that are no longer marketed, notify the FDA in writing of your request for the voluntary revocation of the license for your biologic product or its discontinued status no later than June 30, 2009. Please submit your voluntary revocation request or notice of a discontinued biologic to the office/division responsible for regulatory oversight of your product and provide a copy of the voluntary revocation request or discontinued biologic notice to the User Fee Staff. If you notify FDA of the voluntary revocation request or discontinued biologic notice after June 2009, the product may be included on the FY 2010 invoice. However, you may still be eligible for a refund of the assessed FY 2010 product and establishment fees provided FDA receives the voluntary revocation request or discontinued product notice no later than September 30, 2009. *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] The term "final dosage form" means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (section 735(4) of the Act).

- 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 Tuesday, June 16, 2009.** If you have any questions, please call Michael Jones or Beverly Friedman at 301-796-3602. Please return Attachments A and B by facsimile to Michael Jones, at 301-847-8711. If you wish to send a paper copy confirming the faxed information, you can forward it (by regular mail or by courier service) to:

Michael Jones
Special Assistant
Office of Regulatory Policy
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 6216
Silver Spring, MD 20993-0002

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

B. CBER's Regulatory Information Management Staff

CBER's Regulatory Information Management Staff works with CDER's User Fee Staff in processing the information that you provide to the User Fee Staff (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 the Regulatory Information Management Staff. However, if you have any questions regarding your CBER biological products, please call Carla Vincent at 301-827-3503.

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 www.fda.gov/cder/ob/. 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, 2009.** Please send your Orange Book changes by facsimile to 240-276-8974. If you wish to send a paper copy confirming the faxed information, you can forward it (by regular mail or by courier service) to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7500 Standish Place
Rockville, MD 20855-2773

If you have any questions about your company's current product list, please call the Orange Book Staff at 240-276-8400 or send an e-mail to drugproducts@cder.fda.gov. 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.

Your assistance **and your response to the User Fee Staff by June 16, 2009**, is greatly appreciated. FDA is committed to continue working jointly with industry to ensure the continued success of this program.

Sincerely yours,

John P. Gentile
Associate Commissioner for Operations

Attachments:
Attachment A – User Fee Contact Information
Attachment B – Lists of Products and Establishments Invoiced for FY 2009 (Invoices were mailed, August 15, 2008)