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

May 4, 2007

Dear Colleague:

The Federal Food, Drug, and Cosmetic Act (the Act) authorizes the Food and Drug Administration (FDA) to collect annual user fees for certain products and establishments.[1] Reauthorization of the prescription drug user fee program is under consideration by Congress. If legislation is passed that allows FDA to collect fees under a new prescription drug user fee program, invoices will be issued for any fees authorized under the new legislation. We will also notify you of any further changes in the program including any changes in the performance goals. To prepare for the FY 2008[2] invoices,[3] assuming reauthorization, 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).

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 2007 invoice issued in August 2006.

II. What Information Does FDA Need for FY 2008?

To prepare for FY 2008 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.

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[1] See sections 735 and 736 of the Act (21 U.S.C. 379g and 379h). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 amended the Act and authorized FDA to collect fees through September 30, 2007. We described the technical amendments to the Act in a *Dear Colleague* letter dated June 12, 2002, available on the Internet at www.fda.gov/cder/pdufa/default.htm under letters.

[2] FY 2008 = October 1, 2007, through September 30, 2008.

[3] Please note that FY 2007 invoices were issued August 15, 2006, and payment was due October 1, 2006. FDA anticipates that if the statute is reauthorized, payment for the FY 2008 invoices would be due October 1, 2007. FY 2008 invoices would be sent as far in advance of the October 1, 2007, payment due date as practical, depending on the date of enactment of the reauthorization.

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 to the list approval) 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 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.[5] Conversely, if you are 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]

*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 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

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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] Please note, the criteria for product fee assessment is based, in part, on whether the product is listed in the Prescription Drug Product List of the Orange Book, not on whether a product is marketed.

[6] To avoid assessment of FY 2008 product fees with the FY 2008 invoices for drug products that are no longer marketed, notify the Orange Book Staff of changes to the Prescription Drug Product List no later than June 29, 2007. If you notify the Orange Book Staff of the drug product marketing status after June 2007, the product may be included on the FY 2008 invoice. However, you may be eligible for a refund of the assessed FY 2008 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, 2006. *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).

the Internet at http://www.fda.gov/cder/biologics/pdufa/billable.pdf. For user fee eligible licensed *biological products* for which CBER has regulatory responsibility, including review and continuing oversight, a current list is available on the Internet at 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.[7]

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 prescription drug products on your updated product list.[8] 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 prescription drug products on your updated product list. Please include a brief statement of the reason for deletion (e.g., state the operation that was performed at the establishment to be deleted).

- Number all 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 next to each product produced in final dosage form at that establishment. If a product is manufactured in final dosage form at more than one site, please note the multiple establishment numbers next to 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.

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[7] To avoid assessment of FY 2008 product fees with the FY 2008 invoices for biological products that are no longer marketed, notify the FDA of your voluntary revocation request of the biologic product in writing no later than June 29, 2007. Please submit your voluntary revocation request to the office/division responsible for regulatory oversight of your product and provide a copy of the revocation request to the User Fee Staff. If you notify FDA of the voluntary revocation request after June 2007, the product may be included on the FY 2008 invoice. However, you may be eligible for a refund of the assessed FY 2008 product and establishment fees provided FDA receives the revocation request no later than September 30, 2007. *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] 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).

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 Friday, **June 15, 2007**. If you have any questions, please call Michael Jones or Beverly Friedman at 301-594-2041. Please return Attachments A and B by facsimile to Michael Jones, at 301-827-1226. If you wish to send a paper copy confirming the faxed information, you can forward it to one of the following addresses:

If sent by U.S. Postal Service	If sent by courier service
Michael Jones Special Assistant Office of Regulatory Policy, HFD-5 Center for Drug Evaluation and Research Food and Drug Administration 5600 Fishers Lane (Rockwall II, Rm. 1101) Rockville, MD 20857	Michael Jones Special Assistant Office of Regulatory Policy, HFD-5 Center for Drug Evaluation and Research Food and Drug Administration 5515 Security Lane, Rm. 1101 Rockville, MD 20852

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 staffs 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 biological products that are overseen by CBER, please call Carla Vincent of the Regulatory Information Management Staff 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 changes to them as soon as possible, but no later than **Friday, June 29, 2007.** 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 301-827-5846 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 is greatly appreciated. FDA is committed to continue working jointly with industry to ensure the continued success of this program.

Sincerely yours,

Glenda Conroy, Acting
John P. Gentile, Director
Office of Financial Management

Attachments:
Attachment A - User Fee Contact Information
Attachment B – Lists of Products and Establishments Invoiced for FY 2007 (Sent in August 2006)