DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 5, 2005

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] We plan to issue the fiscal year (FY) 2006[2] product and establishment invoices in August 2005,[3] and the fees will be due on October 1, 2005. To prepare for the FY 2006 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) a list of products and establishments subject to user fees (Attachment B). In addition, this year we are asking firms with biologic products to update Attachment B with the brand names[4] of your products so that the brand names may be included on future invoices. See section II.B below for instructions.

I. What Is Attached to This Letter?

Attachment A shows the contact information of the person designated by your company to receive correspondence, invoices, and inquiries concerning user fees. Attachment B is a list of the products and establishments for which you were assessed fees in FY 2005. This list contains all products and establishments that appeared on your FY 2005 invoice issued in August 2004.

II. What Information Does FDA Need to Ensure an Accurate Invoice for FY 2006?

To ensure that the FY 2006 product and establishment fees are accurately assessed 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 that we have on Attachment A and make any necessary additions or corrections. Then sign the attachment. Include your title and 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 letter dated June 12, 2002. If you wish to view that June 12, 2002, *Dear Colleague* letter, go to www.fda.gov/cder/pdufa/default.htm under letters.

[2] FY 2006 = October 1, 2005, to September 30, 2006.

[3] The invoices will be issued after a notice announcing the FY 2006 fees publishes in the *Federal Register*. We do not have an exact date for this publication.

[4] A brand name drug is a drug marketed under a proprietary, trademark-protected name.

B. Attachment B - Product List

Please review Attachment B and note the following items:

- Add any approved product not on the list that you believe should be assessed a fee (e.g., new approval) and include the reason why you believe it should be assessed a fee.
- Delete any product on the list for which you believe there is a valid reason it should not be assessed a fee (e.g., generic competition, no longer marketed) and include a brief explanation of why you believe it should not be assessed a fee.
- For all products that should be on the list, indicate the establishment or establishments where the final dosage forms of each product are produced.
- For ***biologic*** products: Next to the product name, print all brand names currently used by your firm. Do not list distributor brand names. If you have questions regarding this request, please contact CBER's Regulatory Information Management Staff at 301-827-3503 or e-mail CBERRIMS@cber.FDA.gov.

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 http://www.fda.gov/cder/ob/.[5] After making any necessary updates to the list of your products on 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, you have delisted it under section 510 of the Act (21 U.S.C. 360), and the product is on the Prescription Drug Products List, then you should alert the Orange Book Staff so the product can be moved to the Discontinued Drug Product List. Conversely, if you are marketing your drug product and it is on the Discontinued Drug Product List of the Orange Book, you should also notify the Orange Book Staff so the drug product can be moved to the Prescription Drug Product List of the Orange Book.

2. *Where can you find a current list of your company's billable, **licensed biologic 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 *biologic therapeutic products* where regulatory responsibility, review, and continuing oversight is held in CDER, a current list is available on the Internet at www.fda.gov/cder/biologics/pdufa/billable.pdf. For user fee eligible licensed *biologic products* where regulatory responsibility, review, and continuing oversight is held in CBER, 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 *biologic* products.

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[5] There are Orange Book data files at www.fda.gov/cder/orange/obreadme.htm that may assist you in viewing and identifying your firm's drug products.

C. Attachment B - Establishment List

If your FY 2006 invoice were issued today, we would assess establishment fees for the same establishments listed in your FY 2005 invoice. Please review the list and revise it as follows:

- Add to the list of establishments the name, site address, and central file number (CFN) (if known) of any additional approved manufacturing sites (not the corporate headquarters address) engaged in the manufacture of final dosage forms of any of your prescription drug products on Attachment B - Product List. Include establishments owned by contract manufacturers. Do not include establishments that function solely as packagers or those that do not make final dosage forms.

- Number all establishments that should be on the list. For example, if you have 10 establishments, number them 1 through 10. Then go back to Attachment B - Product List and write the corresponding establishment number next to each product produced in final dosage form at that establishment.

- Delete any establishments from the list that do not manufacture any prescription drug products in final dosage form. Please include a brief statement of the reason for deletion (e.g., state the operation performed at the establishment to be deleted). If an establishment owned by your firm is not associated with the production of any of *your* products, but contracts to make user fee products for another firm, please indicate (1) that the facility serves as a contract manufacturer only, (2) which products it manufactures, and (3) for which firms it manufactures the products.

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 as soon as possible, and no later than close of business Friday, **June 17, 2005**. If you have any questions, please call Michael Jones, Beverly Friedman, or Tawni Schwemer at 301-594-2041. Please return Attachments A and B by facsimile to Michael Jones, at 301-827-5562. If you wish to send a paper copy confirming the faxed information, you can mail it to:

Michael Jones
Special Assistant
Office of Regulatory Policy, HFD-5
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you wish to send it using an overnight courier service (e.g., FedEx, DHL), you can send it to:

Michael Jones
Special Assistant, Office of Regulatory Policy, HFD-5
Center for Drug Evaluation and Research
Food and Drug Administration
5515 Security Lane, Room 1118
Rockville, MD 20852

B. CBER's Regulatory Information Management Staff

CBER's Regulatory Information Management Staff works with the Center for Drug Evaluation and Research's (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 Regulatory Information Management Staff and User Fee 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 biological products, please call the Regulatory Information Management Staff at 301-827-3503.

C. Orange Book Staff

The Orange Book Staff requests that you return to them any changes to the current list of your company's products located on the Internet at http://www.fda.gov/cder/ob/. For the Orange Book Staff to receive your 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 **Thursday, June 30, 2005.** Please send your Orange Book changes by facsimile to 301-827-5911. If you wish to send a paper copy confirming the faxed information, you can mail it (by regular mail or by overnight 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 list, please call the Orange Book Staff at 301-827-5846 or send an e-mail to drugproducts@cder.fda.gov. To ensure changes made are reflected in your invoices, please send a courtesy copy of any information sent to the Orange Book Staff to the User Fee 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,

Helen S. Horn

Helen S. Horn, Director
Office of Financial Management

Attachments:
Attachment A - User Fee Contact Information
Attachment B – List of Products and Establishments Invoiced for FY 2005 (Sent in August 2004)