



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAY 5 2004

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.<sup>1</sup> We plan to issue the fiscal year (FY) 2005<sup>2</sup> product and establishment invoices in August 2004,<sup>3</sup> and the fees will be due on October 1, 2004. To prepare for the FY 2005 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).

**I. What Is Attached to This Letter?**

Attachment A shows the name, address, telephone number, and facsimile number of the person designated by your company to receive all 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 2004. This list contains all products and establishments that appeared on your FY 2004 invoice issued in August 2003.

**II. What Information Does FDA Need to Ensure an Accurate Invoice for FY 2005?**

To ensure that the FY 2005 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, add an e-mail address, and make any necessary corrections. Then sign the attachment. Include your title and date.

<sup>1</sup> 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](http://www.fda.gov/cder/pdufa/default.htm) under letters.

<sup>2</sup> October 1, 2004, to September 30, 2005.

<sup>3</sup> The invoices will be issued after a notice announcing the FY 2005 fees publishes in the *Federal Register*. We do not have an exact date for this publication.

## **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 form of the product is produced.

### *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/>.<sup>4</sup> 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 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 *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.htm](http://www.fda.gov/cder/biologics/pdufa/billable.htm). 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](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 *biologic products*.

During the past year, CBER performed a review of all biologic products approved under section 351 of the Public Health Service Act, comparing the package insert and information from other

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<sup>4</sup> There are Orange Book data files at [www.fda.gov/cder/orange/obreadme.htm](http://www.fda.gov/cder/orange/obreadme.htm) that may assist you in viewing and identifying your firm's drug products.

sources with the data listed in its database to ensure that the potency and proprietary name information is up-to-date. Some discrepancies were discovered for products that are prepared as powders for reconstitution. The FDA considers the amount of powder in the vial before reconstitution to be the finished dosage form, which is user fee liable.<sup>5</sup> Therefore, each vial that has a different amount of powder is assessed a separate product fee.

CBER has corrected its records with regard to user fee billing information for these products, and the changes will be reflected in this year's invoices.<sup>6</sup> CBER will contact the affected firms to inform them of the discrepancies and address any questions prior to the August invoice. Questions regarding this issue should be directed to Carla Vincent, Regulatory Information Management Staff, Center for Biologics Evaluation and Research (CBER) at 301-827-3503.

### **C. Attachment B - Establishment List**

If your FY 2005 invoice were issued today, we would assess establishment fees for the same establishments listed in your FY 2004 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 that the facility serves as a contract manufacturer only and for which firms it manufactures.

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<sup>5</sup> According to the user fee provisions of the Act, the term *prescription drug product* means a specific strength or potency of a drug in final dosage form for which a human drug application has been approved and which may be dispensed only under prescription under section 503(b) of the Act (21 U.S.C. 353(b)). 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. Products manufactured in vials containing different amounts of powder are assessed separate fees. No further manufacturing is required to commercially distribute these products for administration to patients. It is the powder in a vial for reconstitution that is approved by FDA. Reconstitution of a vial before administering the product to a patient is not further manufacturing, but rather an act performed according to directions in the manufacturer's approved labeling. Therefore, each vial is assessed a separate product fee.

<sup>6</sup> Please note, this is not a change in the procedure that FDA uses to determine how powders for reconstitution are billed. We are merely correcting discrepancies that have been discovered.

### **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 18, 2004**. 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 to 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

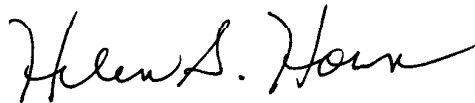
information you provide and factor it into the billing, the Orange Book Staff requests that you send your changes to them as soon as possible but no later than **Wednesday, June 30, 2004**. Please send your Orange Book changes by facsimile to 301-827-5911. If you wish to send a paper copy confirming 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](mailto: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, Director  
Office of Financial Management

Attachments:

Attachment A - User Fee Contact Information

Attachment B – List of Products and Establishments Invoiced for FY 2004 (Sent in August 2003)