

compliance, other than under section 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement may depend on the facts of a particular situation. FDA intends to issue guidance to provide additional information about the circumstances under which FDA would consider non-compliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from “the responsible party for each domestic facility (as defined in section 415(b) (21 U.S.C. 350d) and the United States agent for each foreign facility subject to a reinspection” to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term “reinspection” with respect to domestic facilities as “1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of th[e] Act, specifically to determine whether compliance has been achieved to the Secretary’s satisfaction.”

The FD&C Act does not contain a definition of “reinspection” specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the United States agent of a foreign facility subject to a reinspection, the Agency is using the following definition of “reinspection” for purposes of assessing and collecting fees under section 743(a)(1)(A), with respect to a foreign facility: “1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified non-compliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary’s (and, by delegation, FDA’s) satisfaction.”

This definition allows FDA to fulfill the mandate to assess and collect fees from the United States agent of a foreign facility in the event that an inspection reveals non-compliance materially related to a food safety requirement causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary’s (and, by delegation, FDA’s) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made

the requisite identification at an initial inspection of non-compliance materially related to a food safety requirement of the FD&C Act. The definition of “reinspection-related costs” in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A).

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the United States agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) or 412(f) of the FD&C Act to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does

not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm’s failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

V. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 20, 2012, from 8 a.m. to 5 p.m. and September 21, 2012, from 8 a.m. to 4 p.m.

Location: 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following links: On September 20, 2012, Blood Products Advisory Committee Day 1, <http://fda.yorkcast.com/webcast/Viewer/?peid=27146555dd9347f09571f29589297e0c1d> and on September 21, 2012, Blood Products Advisory Committee Day 2, <http://fda.yorkcast.com/webcast/Viewer/?peid=8effe88a1e834779b4932f882b67e3391d>.

Contact Person: Bryan Emery or Pearlina Muckelvine, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1281, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 20, 2012, the committee will discuss hepatitis E virus and blood transfusion safety. In the afternoon, the committee will discuss Octapharma's biologics license application for Pooled Plasma (Human, Solvent/Detergent Treated). On September 21, 2012, the committee will discuss considerations for strategies to further reduce the risk of bacterial contamination in Platelets. In the late afternoon the committee will hear the following update: Summary of September 6-7, 2012, public workshop on the risks and benefits of hydroxyethyl starch solutions.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 13, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:15 a.m. and 3:30 p.m. to 4 p.m. on September 20, 2012, and also between approximately 1 p.m. and 2 p.m. on September 21, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 5, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 6, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. The public is encouraged to watch the free Web cast if you are unable to attend this meeting. The link for the Web cast will be available at 8 a.m. each day September 20-21, 2012, located under the *Location* section of this notice.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery, 301-827-1277, or Pearlina Muckelvine, 301-827-1281, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/Advisory>

Committees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 26, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2013

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (Title 1 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, which was signed by the President on July 9, 2012) (PDUFA V)), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Base revenue amounts to be generated from PDUFA fees were established by PDUFA V, with provisions for certain adjustments. Fee revenue amounts for applications, establishments, and products are to be established each year by FDA so that one-third of the PDUFA fee revenues FDA collects each year will be generated from each of these categories. This document establishes fee rates for FY 2013 for application fees for an application requiring clinical data (\$1,958,800), for an application not requiring clinical data or a supplement requiring clinical data (\$979,400), for establishment fees (\$526,500), and for product fees (\$98,380). These fees are effective on October 1, 2012, and will remain in effect through September 30, 2013. For applications and supplements that are submitted on or after October 1, 2012, the new fee schedule must be used. Invoices for establishment and product fees for FY 2013 will be issued