

organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with their peers to provide their selections representing industry interests within 60 days. In the event that selections have not been provided to FDA within 60 days, the Commissioner may select an industry representative for each such vacancy from the list of industry nominees. The agency is interested in nominees that possess the scientific credentials needed to participate fully and knowledgeably in the Committee's deliberations and had special insight into, and direct experience in, specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 23, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02-19494 Filed 8-1-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA Food Labeling and Allergen Declaration; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Friday, March 29, 2002 (67 FR 15211). The document announced a public workshop entitled "FDA Food Labeling and Allergen Declaration" that intends to provide information about FDA food labeling regulations, allergen declaration, and other related matters to the regulated industry, particularly small business and startups. The document was published with some inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT:

David Arvelo, Food and Drug Administration, 4040 North Central Expwy., suite 900, Dallas, TX 75204, 214-253-4952, FAX 214-253-4970.

SUPPLEMENTARY INFORMATION: In FR Doc. 02-7583, appearing on page 15211 in the **Federal Register** of Friday, March 29, 2002, the following correction is made:

1. On page 15211, in the third column, under "Contact", beginning in the fourth line, "7920 Elmbrook Dr., suite 102, Dallas, TX 75247, 214-655-8100, ext. 130 or 128, FAX 214-655-8114," is corrected to read "4040 North Central Expwy., suite 900, Dallas, TX 75204, 214-253-4952, FAX 214-253-4970."

Dated: July 26, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-19495 Filed 8-1-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2003

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) 2003. The Federal Food, Drug, and Cosmetic Act (the act), as amended most recently by the Prescription Drug User Fee Amendments of 2002 (Title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PHSBPRA or PDUFA III)), 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. This notice establishes fee rates by PDUFA for FY 2003 for application fees (\$533,400 for an application requiring clinical data, and \$266,700 for an application not requiring clinical data or a supplement requiring clinical data), establishment fees (\$209,900), and product fees (\$32,400). These fees are effective on October 1, 2002, and will remain in effect through September 30, 2003. For applications and supplements that are submitted on or after October 1, 2002, the new fee schedule must be used. Invoices for establishment and product fees for FY 2003 will be issued in

August 2002 using the new fee schedule.

FOR FURTHER INFORMATION CONTACT:

Frank Claunts, Office of Management and Systems (HFA-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the act (21 U.S.C. 379g and 379h), establish three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)). For FY 2003 through FY 2007 revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III. Revenue amounts established for years after FY 2003 are subject to adjustment for inflation and workload. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. The revenue levels established by PDUFA III continue the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2003 for application, establishment, and product fees. These fees are effective on October 1, 2002, and will remain in effect through September 30, 2003.

II. Inflation and Workload Adjustment Process

PDUFA III provides that fee revenue amounts for each FY after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of: (1) The total percentage change that occurred in the Consumer Price Index (CPI) (all items; U.S. city average) during the 12-month period ending June 30 preceding the FY for which fees are being set, or (2) the total percentage pay change for the previous FY for Federal employees stationed in the Washington, DC metropolitan area. PDUFA III provides for this annual adjustment to be cumulative and compounded annually after 2003 (see 21 U.S.C. 379h(c)(1)). No inflation adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.