TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form FDA 2830	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total						1,753

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 26, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19493 Filed 8–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members of Public Advisory Committee; Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Food Advisory Committee (the Committee) in FDA's Center for Food Safety and Applied Nutrition (CFSAN) and six subcommittees. Nominations will be accepted for current vacancies and vacancies that will or may occur on the Committee during the next 12 months.

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations from these groups. Final selection from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: September 3, 2002.

ADDRESSES: All nominations for membership should be sent to Catherine M. DeRoever (*see* **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: *Regarding all nominations for membership*: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–6), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397, FAX 301–436–2633, e-mail: *Catherine.DeRoever@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for members to serve on the advisory committees listed below. Individuals should have expertise in the activity of the Committee. Vacancies will begin June 30, 2002.

Food Advisory Committee

The Committee provides advice primarily to the Director, Center for Food Safety and Applied Nutrition (CFSAN), and as needed, to the Commissioner of Food and Drugs (the Commissioner), and other appropriate officials, on emerging food safety, food science, nutrition, and other food-related issues that FDA considers of primary importance for its food and cosmetics program. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food or cosmetic related issues, (2) the safety of new foods and food ingredients, (3) labeling of foods and cosmetics, (4) nutrient needs and nutritional adequacy, and (5) safe exposure limits for food contaminants. The Committee also may be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

The Committee was restructured on July 28, 2000, to consist of a ''parent'' Committee and four standing Subcommittees. The Subcommittees are as follows: (1) Additives and Ingredients, (2) Contaminants and Natural Toxicants, (3) Dietary Supplements, and (4) Food Biotechnology. Two additional Subcommittees are being added to the ''parent'' Committee: (1) Infant Formula, and (2) Nutrition.

The purpose of the new Subcommittees is to provide highly specialized expertise in the review and analysis of assigned topics. Meetings of the subcommittees will be open to the public except as otherwise determined by the Commissioner or designee. The Subcommittee's findings, conclusions, and recommendations will be reported to the ''parent'' Committee. As a general matter, included in this report will be a recommendation(s) from the Subcommittee on the final disposition of an assigned topic. Generally, matters that cross-cut agency program areas will fall under the purview of the ''parent'' Committee. Issues relating to the microbiological safety of food will be addressed by the National Advisory Committee on Microbiological Criteria for Foods.

Criteria for Members

Persons nominated for membership on the Committee shall be knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment and other relevant scientific and technical disciplines. The agency particularly is interested in considering candidates with a comprehensive background in food technology, molecular biology, genetics, biotechnology, and a variety of medical specialties, as many issues brought before the Committee involve medical or epidemiological impact on nutrients, additives, contaminants, or other constituents of the diet, such as dietary supplements. The term of office is up to 4 years.

The Committee includes technically qualified members who are identified with consumer interests and representatives of industry interests.

Nomination Procedures

Interested persons may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude Committee membership. Additionally, the nominee's mailing address, telephone number, and curriculum vitae must accompany the nomination. The agency cannot guarantee further consideration of nominations that do not include this requested information. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, employment, consultancies, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or

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]

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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.