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.

For each FY beginning in FY 2004, PDUFA III provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect changes in workload for the process for the review of human drug applications (see 21 U.S.C. 379h(c)(2)). No workload adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

Since neither inflation nor workload adjustments apply to the revenue amounts established in PDUFA III for FY 2003, the levels specified in the statute are the amounts that fees set by FDA for FY 2003 should generate. Those statutory revenue amounts are $74,300,000 from application fees, $74,300,000 from establishment fees, and $74,300,000 from product fees.

III. Fee Calculations

PDUFA III provides that the fee rates for application, product, and establishment fees be established 60 days before the beginning of each FY (21 U.S.C. 379h(c)(4)). The fees are to be established so that they will generate the fee revenue amounts specified in the statute, as adjusted for inflation and workload.

A. Application Fee Revenues and Application Fees

Application fees are assessed at different rates for qualifying applications depending on whether the applications require clinical data for safety or effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A)). Applications that require clinical data are subject to the full application fee. Applications that do not require clinical data and supplements that require clinical data are assessed one-half the fee of applications that require clinical data. If FDA refuses to file an application or supplement, 75 percent of the application fee is refunded to the applicant (21 U.S.C. 379h(a)(1)(D)).

The application fee revenue amount that PDUFA III established for FY 2003 is $74,300,000 (21 U.S.C. 379h(b)). For FY 2003 no adjustment is to be made for either inflation or workload changes (21 U.S.C. 379h(c)). Application fees for FY 2003 will be set to generate $74,300,000.

B. Estimate of Numbers of Fee-Paying Applications and Establishment of Application Fees

For FY 2003 through FY 2007, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive each year by averaging the number of fee-paying FAEs received in each of the five most recent FYs. This use of the rolling average of the five most recent FYs is the same method that will also be applied in future years in making the workload adjustment.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2003, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FYs 1998 through 2001. For FY 2002, FDA is estimating the number of fee-paying FAEs for the full year based on the actual count for the first 9 months and estimating the number for the final 3 months.

Table 1, under column 2 of this document, shows the total number of each type of FAE received in the first 9 months of FY 2002, whether fees were paid or not. Column 3 shows the number of FAEs for which fees were waived or exempted during this period, and column 4 shows the number of fee-paying FAEs received through June 30, 2002. The last column estimates the 12-month total fee-paying FAEs for FY 2003 based on the applications received through June 30, 2002. All of the counts are in FAEs. A full application requiring clinical data counts as one FAE. An application not requiring clinical data counts one-half an FAE, as does a supplement requiring clinical data. An application that is withdrawn or refused for filing counts as one-fourth of an FAE if it initially paid a full application fee, or one-eighth of an FAE if it initially paid one-half of the full application fee amount.

TABLE 1.—FY 2002 FULL APPLICATION EQUIVALENTS (FAEs) RECEIVED THROUGH JUNE 30, 2002, AND PROJECTION

Application or Action	Total FAEs Received Through June 30, 2002	Fee Exempt or Waived FAEs Through June 30, 2002	Total Fee Paying FAEs Through June 30, 2002	12-Month Projection for Fee-Paying FAEs
Applications requiring clinical data	65.00	18.00	47.00	62.667
Applications not requiring clinical data	9.00	3.00	6.00	8.00
Supplements requiring clinical data	43.50	11.00	32.50	43.333
Withdrawn or refused to file	0.75	0.25	0.50	0.667
Total	118.25	32.25	86.00	114.67

In the first 9 months of FY 2002, FDA received 118.25 FAEs, of which 86 were fee-paying. Based on data from the last 5 FYs, on average, 25 percent of the applications submitted each year come in the final 3 months. Thus, dividing 86 by 3 and multiplying by 4 extrapolates the amount to the full 12 months of the FY and projects the number of fee-paying FAEs in FY 2002 at 114.7.

All pediatric supplements, which had been exempt from fees prior to January 4, 2002, were required to pay fees effective January 4, 2002. This is the result of section 5 of the Best Pharmaceuticals for Children Act that repealed the fee exemption for pediatric supplements effective January 4, 2002. Thus, in estimating FY 2003 fee-paying receipts we must assume all the pediatric supplements that were previously exempt from fees will be subject to fees in FY 2003. In FY 1998, 8 full fees were exempted for pediatric supplements; the exempted number of FAEs for pediatric supplements for FY 1999, FY 2000, FY 2001, and FY 2002, respectively, were 5.25, 12.5, 19, and 4.5. Since fees on these supplements will be paid for pediatric applications submitted in FY 2003, the number of pediatric supplement FAEs exempted from fees each year from FY 1998 through FY 2002 (the only years when fees were exempted) are added to the total of fee-paying FAEs received each year.

As table 2 of this document shows, the average number of fee-paying FAEs

received annually in the most recent 5-year period, assuming all pediatric supplements had paid fees, and including our estimate for FY 2002, is 139.3 FAEs. FDA will set fees for FY 2003 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 2.

Type of FAE	1998	1999	2000	2001	2002	5-year Average
Fee-paying FAEs	118.7	153.0	153.4	107.6	114.7	129.5
Exempt pediatric supplement FAEs	8.0	5.3	12.5	19.0	4.5	9.9
Total	126.7	158.3	165.9	126.6	119.2	139.3

The FY 2003 application fee is estimated by dividing the estimated number of full applications that will pay fees, 139.3, into the statutorily set amount to be derived from application fees in FY 2003, $74,300,000. The result, rounded to the nearest one hundred dollars, is a fee of $533,400 per full application requiring clinical data, and $266,700 per application not requiring clinical data or per supplement requiring clinical data.

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of PDUFA, as amended, if the agency collects more fees than were provided for in appropriations in any year after 1997, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379h(g)(4)).

In FY 1998, Congress appropriated a total of $117,122,000 to FDA in PDUFA fee revenue. To date, collections for FY 1998 total $117,737,470—a total of $615,470 in excess of the appropriation limit. This is the only FY since 1997 in which FDA has collected more in PDUFA fees than Congress appropriated.

FDA also has requests for waivers or reductions of FY 1998 fees that have been decided but that are pending appeals. For this reason, FDA is not reducing its FY 2003 fees to offset excess collections at this time. An offset will be considered in a future year, if FDA still has collections in excess of appropriations for FY 1998 after the pending appeals for FY 1998 waivers and reductions have been resolved.

V. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2002, the establishment fee was based on an estimate that 354 establishments would be subject to and would pay fees. By the end of FY 2002, FDA estimates that 379 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA again estimates that a total of 25 establishment fee waivers or reductions will be made for FY 2002, for a net of 354 fee-paying establishments. FDA will use this number, 354, for its FY 2003 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($74,300,000), by the estimated 354 establishments, for an establishment fee rate for FY 2003 of $209,900 (rounded to the nearest one hundred dollars).

B. Product Fees

At the beginning of FY 2002, the product fee was based on an estimate that 2,293 products would be subject to and pay product fees. By the end of FY 2002, FDA estimates that 2,348 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. Assuming that there will be about 55 waivers and reductions made, FDA estimates that 2,293 products will qualify for product fees in FY 2002, after allowing for waivers and reductions, and will use this number for its FY 2003 estimate. Accordingly, the FY 2003 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($74,300,000) by the estimated 2,293 products for a product fee rate of $32,400 (rounded to the nearest ten dollars).

VI. Fee Schedule for FY 2003

The fee rates for FY 2003 are set out in table 3 of this document:

TABLE 3.

Fee Category	Fee rates for FY 2003
Applications	
Requiring clinical data	$533,400
Not requiring clinical data	$266,700
Supplements requiring clinical data	$266,700
Establishments	$209,900
Products	$32,400

VII. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under PDUFA that is submitted after September 30, 2002, must be accompanied by the appropriate application fee established in the new fee schedule. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the U.S. Food and Drug Administration. Please include the user fee ID number on your check. Your check can be mailed to: U.S. Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251–6909.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Food and Drug Administration (360909), Mellon Client Service Center, rm. 670, 500 Ross St., Pittsburgh, PA 15262–0001. (Note: This Mellon Bank address is for courier delivery only.)

Please make sure that the FDA P.O. Box number (P.O. Box 360909) is on the enclosed check. The tax identification number of the U.S. Food and Drug Administration is 530 19 6965.

B. Establishment and Product Fees

By August 31, 2002, FDA will issue invoices for establishment and product fees for FY 2003 under the new fee schedule. Payment will be due on October 1, 2002. FDA will issue invoices in October 2003 for any products and establishments subject to fees for FY 2003 that qualify for fees after the August 2002 billing.

Dated: July 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19594 Filed 7–31–02; 9:59 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms—(OMB No.0915–0044)—Revision

The HPSL Program provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, and an associate degree, a baccalaureate degree, or a graduate degree in nursing. Participating HPSL and NSL schools are responsible for determining eligibility of applicants, making loan, and collecting monies owed by borrowers on their outstanding loans. The deferment form (HRSA form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR–HRSA form 501) provides the Federal Government with information from participating and non-participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The estimates of burden for the forms are as follows:

Form and number	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Defer-HRSA–519	6,000	1	6,000	10 min	1,000
AOR–HRSA–501	1,048	1	1,048	4 hrs.	4,192
Total Burden	7,048	.....	7,048		5,192

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11A–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 25, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–19496 Filed 8–1–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The National Health Service Corps (NHSC) Professional Training and Information Questionnaire (PTIQ) (OMB No. 0915–0208)—Revision

The NHSC of the HRSA's Bureau of Health Professions (BHPr), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The NHSC (authorized by the Public Health Service Act, section 331) collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

The PTIQ is used to collect data related to professional practice from NHSC Scholarship Program recipients including physicians, dentists, physician assistants (PAs), nurse practioners (Nps), and certified nurse midwives (CNMs), in the current year's placement cycle. This data is used to match an individual health care professional with an appropriate clinical practice setting.

The PTIQ will be mailed twelve months in advance of the intended service availability date.

Estimates of annualized reporting burden are as follows: