visiting the NCVHS website (http://ncvhs.hhs.gov)) where an agenda for the meeting will be posted when available.

Additional information may be obtained by calling Carolyn Rimes, Lead Staff Person for the NCVHS Subcommittee on Populations, Office of Research and Demonstrations, Health Care Financing Administration, MS–C–13–01, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850, telephone (410) 786–6620; or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245.

Note: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, individuals without a government identification card may need to have the guard call for an escort to the meeting room.

Dated: December 21, 1999.

James Scanlon,

Director, Division of Data Policy.

[FR Doc. 99–33621 Filed 12–27–99; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Advisory Committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and date: 8:30 a.m.–4 p.m., January 20, 2000.

Place: The Wyndham Garden Hotel, 125 10th Street, Atlanta, Georgia 30309.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 25 people.

Purpose: The committee will anticipate, identify, and propose solutions to strategic and broad issues facing CDC.

Matters to be Discussed: Agenda items will include updates from Dr. Jeffrey P. Koplan, M.D., M.P.H., Director, CDC, regarding the Top 10 Public Health Challenges for the Next Century.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Kathy Cahill, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–24, Atlanta, Georgia 30333. Telephone 404/639–7060.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 17, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. 99–33560 Filed 12–27–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to States for Social Services Expenditures, Pursuant to Title XX, Block Grants to States for Social Services; *Revised* Promulgation for Fiscal Year 2000.

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notification of allocation of title XX—social services block grant allotments for Fiscal Year 2000.

SUMMARY: The initial **Federal Register** notice was published on November 10, 1998 based on the authorization level of $2.380 billion. The grant awards for Fiscal Year 2000 will be issued based upon the appropriation amount of $1.775 billion. Of this amount, $425,000,000 shall not be available for obligation until September 29, 2000. These figures are available on the ACF homepage on the internet: http://www.acf.dhhs.gov/programs/ocs/ssbg.

Further notification of revised allotments for SSBG will no longer be published in the **Federal Register,** but will be available on the internet address given above.

FOR FURTHER INFORMATION CONTACT: Margaret Washnitzer, (202) 401–2333.

EFFECTIVE DATE: The allotments are effective October 1, 1999.

Dated: December 20, 1999.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 99–33533 Filed 12–27–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2000

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2000. The Prescription Drug User Fee Act of 1992 (the PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (the FDAMA), 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. Fees for applications for FY 2000 were set by the FDAMA, subject to adjustment for inflation. Total application fee revenues fluctuate with the number of fee-paying applications FDA receives. Fees for establishments and products are calculated so that total revenues from each category will approximate FDA's estimate of the revenues to be derived from applications.

FOR FURTHER INFORMATION CONTACT: Michael E. Roosevelt, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5088.

SUPPLEMENTARY INFORMATION:

I. Background

The PDUFA (Public Law 102–571), as amended by the FDAMA (Public Law 105–115), establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biologic 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 1998 through 2002, under the amendments enacted in the FDAMA, the application fee rates are set in the statute, but are to be adjusted annually for cumulative inflation since FY 1997. Total application fee revenues are structured to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases.

Each year from FY 1998 through 2002, FDA is required to set establishment fees and product fees so that the estimated total fee revenue from each of these two categories will equal the total revenue FDA expects to collect from application fees that year. This procedure continues the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fee: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2000 for application, establishment, and

product fees. These fees are retroactive to October 1, 1999, and will remain in effect through September 30, 2000. For fees already paid on applications and supplements submitted on or after October 1, 1999, FDA will bill applicants for the difference between fees paid and fees due under the new fee schedule. For applications and supplements submitted after December 31, 1999, the new fee schedule must be used. Invoices for establishment and product fees for FY 2000 will be issued in December 1999, using the new fee schedules.

II. Inflation and Workload Adjustment Process

The PDUFA, as amended by the FDAMA, provides that fee rates for each FY shall be adjusted by notice in the **Federal Register**. The adjustment must reflect the greater of: (1) The total percentage change that occurred during the preceding FY in the Consumer Price Index (CPI) (all items; U.S. city average), or (2) the total percentage pay change for that FY for Federal employees stationed in the Washington, DC metropolitan area. The FDAMA provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)(1)).

The FDAMA also structures the total application fee revenue to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases. This provision allows revenues to rise or fall as this portion of FDA's workload rises or falls. To implement this provision, each year FDA will estimate the number of fee-paying applications it anticipates receiving. The number of applications estimated will then be multiplied by the inflation-adjusted statutory application fee. This calculation will produce the FDA estimate of total application fee revenues to be received.

The PDUFA also provides that FDA shall adjust the rates for establishment and product fees so that the total revenues from each of these categories is projected to equal the revenues FDA expects to collect from application fees that year. The FDAMA provides that the new fee rates based on these calculations be adjusted within 60 days after the end of each FY (21 U.S.C. 379h(c)(2)).

III. Inflation Adjustment and Estimate of Total Application Fee Revenue

The FDAMA provides that the application fee rates set out in the statute be adjusted each year for cumulative inflation since 1997. It also provides for total application fee revenues to increase or decrease based on increases or decreases in the number of fee-paying applications submitted.

A. Inflation Adjustment to 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) and 379h(b)). 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 fees described above are set out in the FDAMA for FY 2000 ($256,338 for applications requiring clinical data, and $128,169 for applications not requiring clinical data or supplements requiring clinical data) (21 U.S.C. 379h(b)(1)), but must be adjusted for cumulative inflation since 1997. That adjustment each year is to be the greater of: (1) The total percentage change that occurred during the preceding FY in the CPI, or (2) the total percentage pay change for that FY for Federal employees, as adjusted for any locality-based payment applicable to employees stationed in the District of Columbia. The FDAMA provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)).

The adjustment for FY 1998 was 2.45 percent (62 FR 64849, December 9, 1997). This was the greater of the CPI increase for FY 1997 (2.15 percent) or the increase in applicable Federal salaries (2.45 percent).

The adjustment for FY 1999 was 3.68 percent (63 FR 70777 at 70778, December 22, 1998). This was the greater of the CPI increase for FY 1998 (1.49 percent) or the increase in applicable Federal salaries (3.68 percent).

The adjustment for FY 2000 is 4.94 percent. This is the greater of the CPI increase for FY 1999 (2.62 percent) or the increase in applicable Federal salaries (4.94 percent).

Compounding these amounts (1.0245 times 1.0368 times 1.0494) yields a total compounded inflation increase of 11.47 percent for FY 2000. The adjusted application fee rates are computed by adding one to the decimal equivalent of this percent (0.1147) and multiplying this amount (1.1147) by the FY 2000 statutory application fee rates stated above ($256,338 for applications requiring clinical data, and $128,169 for applications not requiring clinical data or supplements requiring clinical data). For FY 2000 the adjusted application fee rates are $285,740 for applications requiring clinical data, and $142,870 for applications not requiring clinical data or supplements requiring clinical data. These amounts must be submitted with all applications during FY 2000.

B. Estimate of Total Application Fee Revenue

Total application fee revenues for FY 2000 will be estimated by multiplying the number of fee-paying applications FDA receives in FY 2000 (from October 1, 1999, through September 30, 2000) by the fee rates calculated in the preceding paragraph. Before fees can be set for establishment and product fee categories, each of which are projected to be equal to total revenues FDA collects from application fees, FDA must first estimate its total FY 2000 application fee revenues. To do this FDA first determines its FY 1999 fee-paying full application equivalents, and uses that number in a linear regression analysis to predict the number of fee-paying full application equivalents expected in FY 2000. This is the same technique applied last year.

In FY 1999, FDA received and filed 119 human drug applications that required clinical data for approval, 17 that did not require clinical data for approval, and 112 supplements to human drug applications that required clinical data for approval. Because applications that do not require clinical data and supplements that require clinical data are assessed only one-half the full fee, the equivalent number of these applications subject to the full fee is determined by summing these categories and dividing by two. This amount is then added to the number of applications that require clinical data to arrive at the equivalent number of applications that may be subject to full application fees.

In addition, as of September 30, 1999, FDA refused to file, or firms withdrew before filing, six applications that required clinical data, three applications that did not require clinical data, and four supplements requiring clinical data. The full applications refused for filing or withdrawn before filing pay one-fourth the full application fee and are counted as one-fourth of an application; the applications that do not require clinical data and the supplements refused for filing or withdrawn before filing pay one-eighth

of the full application fee and are each counted as one-eighth of an application.

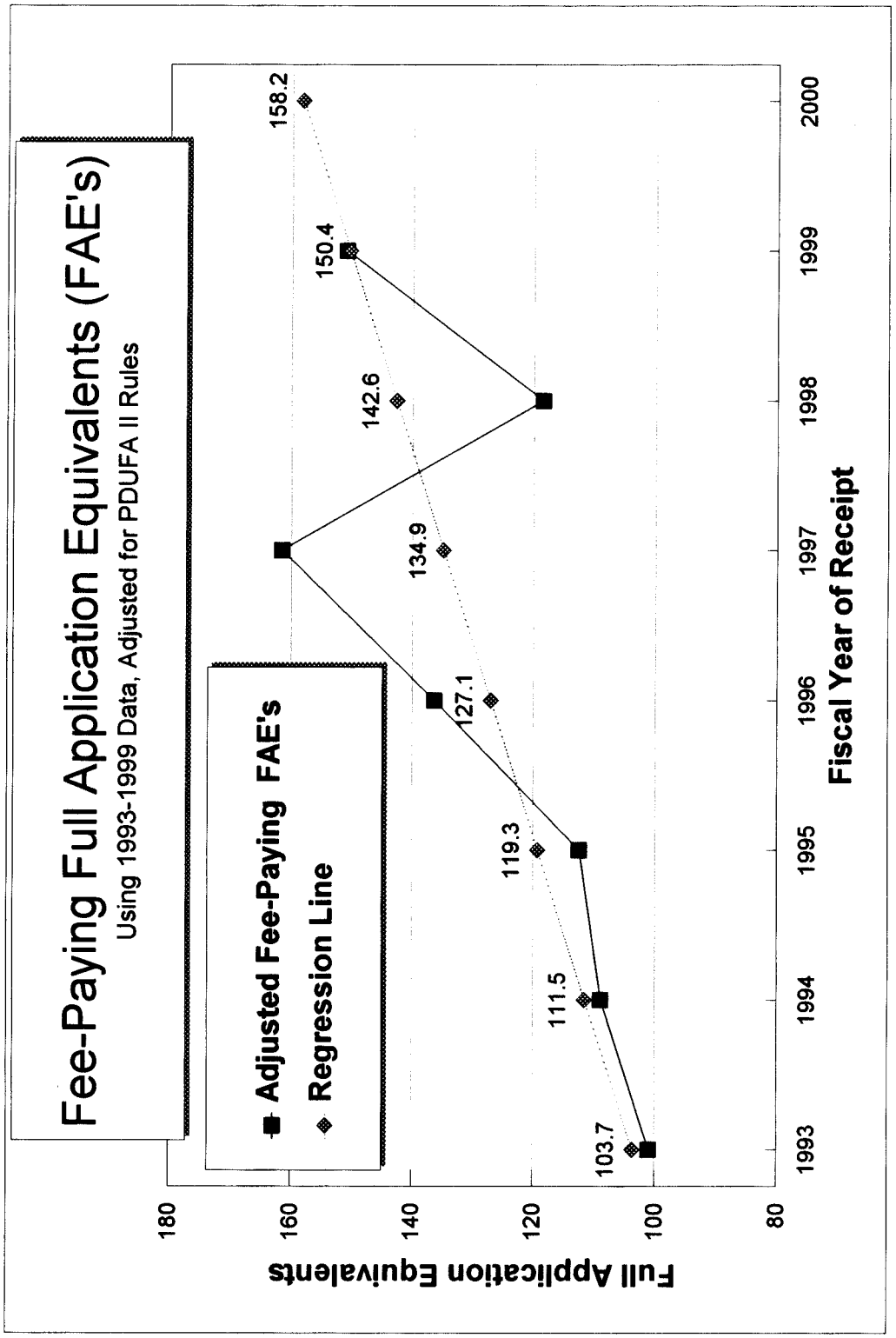
Using this methodology, the number of full application equivalents that were submitted for review in FY 1999 was 186, before any exemptions, waivers or reductions. Under the FDAMA, FDA waives fees for certain small businesses submitting their first application and certain orphan products, and certain supplements for pediatric indications are exempted from application fees. In addition, the FDAMA provides a number of other grounds for waivers (public health necessity, preventing significant barriers to innovation, and fees exceed the cost). In FY 1999, waivers or exemptions were applied to 35 full application equivalents (thirteen for orphan products, seven for small businesses, five for pediatric supplements, and ten miscellaneous exemptions/waivers). Therefore, for FY 1999, FDA estimates that it received the equivalent of 151 (186 minus 35) full application equivalents that will pay fees, after allowing for exemptions, waivers and reductions.

A linear regression line based on the adjusted number of fee-paying full application equivalent submissions since 1993, and including our FY 1999 total of 151 fee-paying full application equivalents, projects the receipt of 158 fee-paying full application equivalent submissions in FY 2000, as reflected in Table 1 of this document and the graph below.

Table 1.

Fiscal Year	1993	1994	1995	1996	1997	1998	1999	2000
Adjusted fee-paying FAE's	101.0	108.9	112.5	136.3	161.5	118.5	150.9	
Regression line	103.7	111.5	119.3	127.1	134.9	142.6	150.4	158.2

BILLING CODE 4160–01–F


Fee-Paying Full Application Equivalents (FAE's)
Using 1993-1999 Data, Adjusted for PDUFA II Rules
Adjusted Fee-Paying FAE's
Regression Line
158.2
150.4
142.6
134.9
127.1
119.3
111.5
103.7
180
160
140
120
100
80
1993
1994
1995
1996
1997
1998
1999
2000
Fiscal Year of Receipt
Full Application Equivalents

The total FY 2000 application fee revenue is estimated by multiplying the adjusted application fee rate ($285,740) by the equivalent number of applications projected to qualify for fees in FY 2000 (158), for a total estimated application fee revenue in FY 2000 of $45,146,920. This is the amount of revenue that FDA is also expected to derive both from establishment fees and from product fees.

IV. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 1999, the establishment fee was based on an estimate of 318 establishments subject to fees. For FY 1999, 343 establishments qualified for and were billed for establishment fees, before all decisions on requests for waivers or reductions were made. FDA estimates that a total of 25 establishment fee waivers will be granted in FY1999, for a net of 318 fee-paying establishments, and will use this number again for its FY 2000 estimate of establishments paying fees, after taking waivers into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($45,146,920), by the estimated 318 establishments, for an establishment fee rate for FY 2000 of $141,971 (rounded to the nearest dollar).

B. Product Fees

At the beginning of FY 1999, the product fee was based on an estimate that 2,224 products would be subject to product fees. By the end of FY 1999, 2,317 products qualified and were billed for product fees before all decisions on requests for waivers or reductions were made. Assuming that there will be about 55 waivers granted, FDA estimates that 2,262 products will qualify for product fees in FY 1999, after allowing for waivers and exemptions, and will use this number for its FY 2000 estimate. Accordingly, the FY 2000 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($45,146,920) by the estimated 2,262 products for a product fee rate of $19,959 (rounded to the nearest dollar).

V. Adjusted Fee Schedules for FY 2000

The fee rates for FY 2000 are set out in Table 2 of this document:

Table 2.

Fee Category	Fee Rates for FY 2000
Applications:	
Requiring clinical data	$285,740
Not requiring clinical data	$142,870
Supplements requiring clinical data	$142,870
Establishments	$141,971
Products	$19,959

VI. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under the PDUFA that is submitted after December 31, 1999, 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: 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: Mellon Bank, Three Mellon Bank Center, 27th Floor (FDA 360909), Pittsburgh, PA 15259–0001. (Note: This Mellon Bank Address is for courier delivery only.) Please make sure that the FDA P.O. Box number (PO Box 360909) is on the enclosed check.

FDA will bill applicants who submitted application fees from October 1 to December 31, 1999, for the difference between the amount they submitted and the amount specified in the Adjusted Fee Schedule for FY 2000.

B. Establishment and Product Fees

By December 31, 1999, FDA will issue invoices for establishment and product fees for FY 2000 under the new Adjusted Fee Schedule. Payment will be due by January 31, 2000. FDA will issue invoices in October 2000 for any products and establishments subject to fees for FY 2000 that qualify for fees after the December 1999 billing.

Dated: December 21, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–33685 Filed 12–22–99; 5:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are 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: National Registry of Effective Prevention Programs

New—Section 515(d) of the Public Health Service Act (42 USC 290bb–21) requires that the Director of SAMHSA's Center for Substance Abuse Prevention (CSAP)establish a national data base providing information on programs for the prevention of substance abuse and specifies that the data base shall contain information appropriate for use by public entities and information