DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project:

Title: Child Care and Development Fund Tribal Plan Preprint.

OMB No.: New.

Description: The Child Care and Development Fund Plan Preprint serves as the agreement between the grantee (Indian Tribe or tribal organization) and the Federal government as to how the Block Grant programs will be operated. The plans provide assurances that the CCDF funds will be administered in conformance with legislative requirements, Federal regulations at 45 CFR parts 98 and 99 and other applicable instructions or guidelines issued by the Administration for Children and Families (ACF). The Tribal Plan Preprint (ACF Form 118A) is currently approved through 5/31/00 under the Plan Preprint approval for both State and Indian Tribes (OMB Approval Number 0970–0114). Since the tribal plan preprint must be revised to reflect the CCDF amended regulations (published 7/24/98 at 63 FR 39936–39998), it is being disaggregated from the State plan preprint approval. Therefore, a new collection and OMB control number is requested.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Plan Preprint	253	.5	35	4,427
CCDF Plan Amendments	253	.5	3	380

Estimated Total Annual Burden Hours: 4,807.

In compliance with the requirements of Section 3506(c)(2)(A) the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 15, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–33792 Filed 12–21–98; 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 1999

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) 1999. 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 1999 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 (Pub. L. 102–571), as amended by the FDAMA (Pub. L. 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 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 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 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 (workload adjustment).

For 1998 through 2002, FDA is required to set fee rates for establishment and product categories each year, so that the total fee revenue from each of these two categories are projected to be equal to 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 fees--application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 1999 for application, establishment, and product fees. These fees are retroactive to October 1, 1998, and will remain in effect through September 30, 1999. For fees already paid on applications and supplements submitted on or after

October 1, 1998, 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, 1998, the new fee schedule must be used. Invoices for establishment and product fees for FY 1999 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), 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 on safety or effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A) and (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 previously are set out in the FDAMA for 1999 ($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 (all items; U.S. city average); 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) and the increase in applicable Federal salaries (2.45 percent).

The adjustment for FY 1999 is 3.68 percent. This is the greater of the CPI increase for FY 1998 (1.49 percent) and the increase in applicable Federal salaries (3.68 percent).

Compounding these amounts (1.0245 times 1.0368) yields a total compounded inflation of 6.22 percent for FY 1999. The adjusted application fee rates are computed by applying the inflation percentage for FY 1999 (106.22 percent) to the FY 1999 statutory application fee rates stated previously. For FY 1999 the adjusted application fee rates are $272,282 for applications requiring clinical data, and $136,141 for applications not requiring clinical data or supplements requiring clinical data. These amounts must be submitted with all applications during FY 1999.

B. Estimate of Total Application Fee Revenue

Total application fee revenues for 1999 will be determined by the number of fee-paying applications FDA receives in FY 1999 (from October 1, 1998, through September 30, 1999) multiplied 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 1999 application fee revenues. To do this FDA has traditionally calculated the number of full application fees FDA received in the preceding fiscal year, made an allowance for waivers and exemptions, and used that figure as a basis for estimating the next year's application volume.

For FY 1998, FDA received and filed 101 human drug applications that require clinical data for approval, 23 that did not require clinical data for approval, and 93 supplements to human drug applications that require 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 2. 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, 1998, FDA assessed fees for three applications that required clinical data, one application that did not require clinical data, and one supplement, all of which were refused filing or withdrawn before filing. After refunds, the full application paid one-fourth the full application fee and is counted as one-fourth of an application, and the application that did not require clinical data and the supplement each paid one-eighth of the full application fee and are each counted as one-eighth of an application.

Using this methodology, the approximate equivalent number of applications that required clinical data and were subject to fees in FY 1998 was 160, before any exemptions, waivers or reductions. Under the FDAMA, FDA may waive fees for certain small businesses submitting their first application and certain orphan products are exempted from application fees. In addition, the FDAMA excludes from fees bulk biological products that are further manufactured, and provides

exceptions for certain supplements for pediatric indications. In FY 1998 waivers or exemptions applied to 41.5 equivalents of full applications. Therefore, based solely on 1998 data, FDA estimates that approximately 118.5 (160 minus 41.5) equivalent applications that require clinical data will qualify for fees in FY 1999, after allowing for exemptions, waivers, or reductions.

This estimate based on the data from 1998 alone predicts a substantial drop in applications, and represents a substantial departure from FDA experience over the past 5 years. Over that period the estimated number of fee-paying applications increased fairly consistently at a rate of about 7 percent each year, as set out in Table 1 of this document.

TABLE 1.

Year	Estimated Number of Fee-Paying Full Application Equivalents
1993	116
1994	124
1995	131
1996	141
1997	169
1998	118.5

Since the volume of fee-paying applications FDA received in 1998 represents such a substantial departure from the trend experienced over the previous 5 years, and since sharp changes produce disruptive volatility in both fees and revenues, FDA reexamined the process to be used in estimating the next year's application volume. FDA considered several different approaches (continuation of current method, using a 2- or 3-year rolling average, and linear regression) and chose the linear regression projection method as the best alternative for this estimate.

Linear regression is well suited to situations like this where there are several years of historical data, the potential exists for shifts from year-to-year, and there is no obvious causative rationale to reasonably predict the year-to-year fluctuations. It also provides a damping effect on year-to-year fee and revenue fluctuations and allows for more stability in both fee levels paid by industry and in agency resource planning. Under this approach, the analysis takes into account the number of fee-paying PDUFA submissions each year since PDUFA began in 1993, adjusts those numbers conservatively to reflect additional exemptions/waivers that would have been granted between 1993 and 1997 if the current law governing exemptions and waivers had been in effect then, and fits the best line to those data points. The extension of that line to the next year estimates the number of submissions for that year. Beginning now for FY 1999, FDA will make this annual estimate based on a linear regression analysis of data on all fee-paying full application equivalent submissions from 1993 through the latest year (1998 in this case).

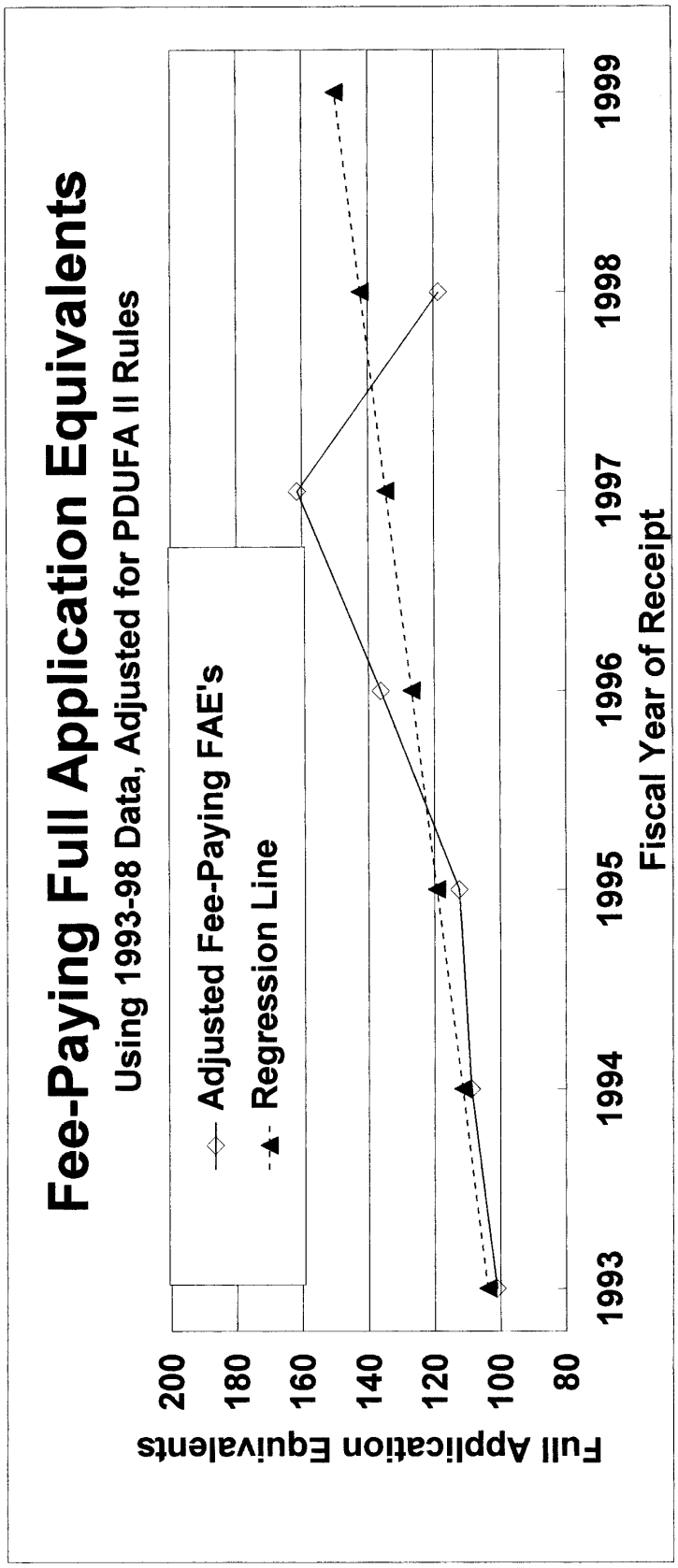
This will mean that our estimated number of applications will be higher in 1998 than it would have been under our previous estimating method. It will also mean that in future years, if there is a sudden rise in application volume, the regression analysis process will dampen the effect of such year-to-year increases as well. We believe that this is a fair and reasonable approach, and that it will insulate fees and revenues from significant fluctuations that may occur in any single year.

Using this approach, a linear regression line based on the adjusted number of fee-paying full application equivalent submissions since 1993 projects the receipt of 150 fee-paying full application equivalent submissions in 1999, as reflected in Table 2 and the graphic of this document.

TABLE 2.

Year	1993	1994	1995	1996	1997	1998	1999
Adjusted Fee-Paying Full Application Equivalents	101.0	108.9	112.5	136.3	161.5	118.5	
Regression Line	103.9	111.6	119.3	127.0	134.6	142.3	150.0

BILLING CODE 4160–01–F



BILLING CODE 4160–01–C

The total FY 1999 application fee revenue is estimated by multiplying the adjusted application fee rate ($272,282) by the equivalent number of applications projected to qualify for fees in FY 1999 (150), for a total estimated application fee revenue in 1999 of $40,842,300. 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 1998 the establishment fee was based on an estimate of 275 establishments subject to fees. By the end of FY 1998, 343 establishments qualified for and were billed for establishment fees, before all decisions on requests for waivers or reductions were made. We estimate that a total of 25 establishment fee waivers will be granted in 1998, for a net of 318 fee-paying establishments. In FY 1999 fees will be based on an estimate of 318 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 ($40,842,300), by the estimated 318 establishments, for an establishment fee rate for FY 1999 of $128,435 (rounded to the nearest dollar).

B. Product Fees

At the beginning of FY 1998 the product fee was based on an estimate that 2,100 products would be subject to product fees. By the end of FY 1998, 2,279 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 2,224 products will qualify for product fees in FY 1999, after allowing for waivers and exemptions. Accordingly, the FY 1999 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($40,842,300) by the estimated 2,224 products for a product fee rate of $18,364 (rounded to the nearest dollar).

V. Adjusted Fee Schedules for FY 1999

The fee rates for FY 1999 are set out in Table 3 of this document.

TABLE 3.

Fee Category	Fee Rates For FY 1999
Applications	
Requiring clinical data	$272,282
Not requiring clinical data	$136,141
Supplements requiring clinical data	$136,141
Establishments	$128,435
Products	$18,364

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, 1998, must be accompanied by the appropriate application fee established in the new fee schedule. Payment must be made in United States 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, they can be sent 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 (P.O. Box 360909) is on the enclosed check.

FDA will bill applicants who submitted application fees between October 1, 1998, and December 31, 1998, based on the adjusted rate schedule.

B. Establishment and Product Fees

By December 31, 1998, FDA will issue invoices for establishments and product fees for FY 1999 under the new fee schedules. Payment will be due by January 31, 1999. FDA will issue invoices in October 1999 for any products and establishments subject to fees for FY 1999 that qualify for fees after the December 1998 billing.

Dated: December 15, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–33831 Filed 12–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

List of Recipients of Indian Health Scholarship Under the Indian Health Scholarship Program

The regulations governing Indian Health Care Improvement Act Programs (Pub. L. 94–437) provide a 42 CFR 36.334 that the Indian Health Service shall publish annually in the **Federal Register** a list of recipients of Indian Health Scholarships, including the name of each recipient, school and tribal affiliation, if applicable. These scholarships were awarded under the authority of Section 103 and 104 of the Indian Health Care Improvement Act, 25 U.S.C. 1613–1613a, as amended by the Indian Health Care Amendments of 1988, Pub. L. 100–713.

The following is a list of Indian Health Professions Scholarship Recipients for Fiscal Year 1998:

Ables, Millicent Elaine, University of Kansas, Choctaw Nation of Oklahoma
Abold-Arellano, Carol Ann, University of South Dakota, Oglala Sioux of the Pine Ridge Reservation
Adair, Roger Willard, Arizona State University, Cherokee Nation of Oklahoma
Adams, Hayley M., University of Alaska/Anchorage, Nenana Native Association, AK
Aguilar, Dolores E., Presentation College, Cheyenne River Sioux Tribe
Akers, Margaret Ann, University of Tulsa, Muskogee (Creek) Nation, Oklahoma
Albert, Corrina D., University of New Mexico, Pueblo of Laguna
Alexander, Andrea Lynn, Oklahoma State University, Seminole Nation of Oklahoma
Alexander, Lisa Kalliah, University of Washington School of Med., Confederated Tribes of the Grand Ronde
Allery, Crystal Vernelle, Minot State University, Turtle Mountain Band Chippewa
Allick, Albert P., University of Minnesota Duluth Med School, Turtle Mountain Band of Chippewa
Allison, Rochelle Jade, University of New Mexico, Navajo Tribe of AZ, NM, & UT