## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## Establishment of Prescription Drug User Fee Rates for Fiscal Year 1998

**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) 1998. 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 1998 were set by the FDAMA, subject to adjustment for inflation. Total application fee revenues fluctuate with FDA application review workload. Fees for establishments and products are based on 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 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)). Under the PDUFA, as amended, one-third of the total user fee revenue for each FY must come from each of the three types of fees.

For 1998 through 2002, under the amendments enacted in the FDAMA, the total fee revenues and fee rates for application fees are set in the statute, but are to be adjusted annually for cumulative inflation since 1997. In addition, total application fee revenues are structured to increase or decrease each year as the number of applications submitted to FDA increases or decreases.

For 1998 through 2002, FDA is authorized to set fee rates for establishment and for product categories each year, so that the 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 comes from each of the three types of fees.

This notice establishes fee rates for FY 1998 for application, establishment, and product fees. These fees are retroactive to October 1, 1997, and will remain in effect through September 30, 1998. Prior to the enactment of the FDAMA, only half of the application fee was due upon submission of the application, and the second half was due when FDA issued an action letter after review of the application. Beginning in FY 1998, the entire application fee is due upon submission of the application to FDA. For fees already paid on applications and supplements submitted on or after October 1, 1997, FDA will bill applicants for the difference between fees paid and fees due under the new fee schedules and under the new requirement that application fees be paid in full at the time an application is submitted. For applications and supplements submitted after December 31, 1997, the new fee schedule must be used. Invoices for establishment and product fees for FY 1998 will be issued in December 1997, 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 (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 FDAMA also structures the total application fee revenue to increase or decrease each year as the number of applications submitted to FDA increases or decreases. This provision allows revenues to rise or fall as FDA's workload rises or falls. To implement this provision each year, FDA will estimate the number of applications it anticipates receiving, based on its actual receipts the previous year, and making an allowance for waivers and refunds. FDA has made similar estimates each year since 1993 under the PDUFA fee setting process. The number of applications estimated by this process will then be multiplied by the inflation-adjusted statutory application fee. This calculation will produce the FDA's estimate of total application fee revenues to be received each year.

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 will be equal to the revenues FDA expects to collect from application fees that year. The PDUFA, as amended, provides that the new fee rates based on these calculations be published within 60 days after the end of each FY (21 U.S.C. 379h(c)(2)).

### III. Inflation and Workload Adjustment for Application Fees and Total Application Fee Revenue

The FDAMA provides that the application fee rates set out in the statute be adjusted each year for cumulative inflation. It also provides for total application fee revenues to increase or decrease, based on increases or decreases in FDA's application review workload.

#### *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 379(h)(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 1998 ($250,704 for applications requiring clinical data, and $125,352 for applications not requiring clinical data or supplements requiring clinical data) (21 U.S.C. 379h(b)(1)), but must be adjusted for inflation. For FY 1997, the total increase in the CPI was 2.15 percent, whereas the increase in applicable Federal salaries for FY 1998 is 2.45 percent. The higher of these, 2.45 percent, is to be used for computing the inflation adjustment for FY 1998. Since

1998 is the first year after 1997, the base year from which inflation accumulates and is compounded, there is no cumulative, compounded inflation from previous years to be added to this percentage for FY 1998. The adjusted application fee rates are computed by applying the inflation percentage for FY 1998 (102.45 percent) to the FY 1998 statutory application fee rates stated above. For FY 1998 the adjusted application fee rates are $256,846 for applications requiring clinical data, and $128,423 for applications not requiring clinical data or supplements requiring clinical data. These amounts must be submitted with all applications during FY 1998.

*B. Workload Adjustment and Total Application Fee Revenue*

Total application fee revenues for 1998 will be determined by the number of applications FDA receives from October 1, 1997, through September 30, 1998, 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 to equal total revenues FDA collects from application fees, FDA must estimate its total 1998 application fee revenues. To do this, FDA calculates the number of full application fees FDA received in 1997 and uses that figure as a basis for estimating 1998 application volume.

For FY 1997, FDA received, filed, and assessed fees for 118 applications that require clinical data, 19 applications that did not require clinical data, and 127 supplements that require clinical data. 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 subject to full application fees.

In addition, as of September 30, 1997, FDA assessed fees for one application 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 assessed fees in FY 1997 was 192, before any further decisions were made on requests for waivers or reductions. Under the FDAMA small businesses will receive a full waiver for their first application (rather than waiver of half the fee as was the case under the PDUFA). In addition, the FDAMA excludes from fees bulk biological products that are further manufactured, and provides new exceptions for certain orphan product applications and certain supplements for pediatric indications. Because of these changes, in FY 1998 FDA estimates that approximately 40 fewer equivalents of full applications will generate fees, or fees for them will be subject to waivers or reductions. This number is a substantial increase over the estimate that FDA would waive or reduce 16 equivalents of full fee applications made 1 year ago when fees for 1997 were established. Therefore, FDA estimates that approximately 152 equivalent applications that require clinical data will qualify for fees in FY 1998, after allowing for possible waivers or reductions.

The following calculations summarize the determination of FY 1998 application estimates, based on 1997 data:

- 118 applications that require clinical data, + (19÷2) applications that do not require clinical data, + (127÷2) supplements that require clinical data, + (1÷4) applications that require clinical data and which FDA refuses to file or the sponsor withdraws before filing + (2÷8) supplements which FDA refuses to file or the sponsor withdraws before filing minus 40 waivers, reductions or exceptions = 152 (the estimated number of ''full fee'' applications for FY 1998 based on FY 1997 experience, and rounded up).

The total FY 1998 application fee revenue is estimated by multiplying the adjusted application fee rate ($256,846) by the equivalent number of applications projected to qualify for fees in FY 1998 (152), for a total estimated application fee revenue in 1998 of $39,040,592. This is the amount of revenue that FDA is also expected to derive from establishment fees and from product fees.

## IV. Fee Calculations for Establishment, and Product Fees

*A. Establishment Fees*

The FY 1997 establishment fee was based on an estimate of 250 establishments subject to fees. In FY 1997, 263 establishments qualified for fees before any decisions on requests for waivers or reductions were made. Under the FDAMA, the basis for assessment of establishment fees is amended. The responsibility for the fee is placed on the applicant whose product is manufactured at the facility, and not on the owner of the facility. Contract manufacturing establishments will now be subject to fees, to be paid by the applicant whose product is manufactured at that establishment. FDA believes this will subject additional establishments to fees, and estimates that approximately 275 establishments will qualify for fees in FY 1998 after allowing for possible waivers or reductions. Thus, the number 275 is used in setting the new establishment fee rate. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($39,040,592), by the estimated 275 establishments, for an establishment fee rate for FY 1998 of $141,966 (rounded to the nearest dollar).

*B. Product Fees*

The FY 1997 product fee was based on an estimate that 2,200 products would be subject to product fees in FY 1997. For FY 1997, 2,267 products qualified for fees before any decisions on requests for waivers or reductions were made. FDA estimates that only 2,100 products will qualify for product fees in FY 1998, after allowing for the fact that about 140 antibiotic products and 11 products manufactured by state governments that paid fees in 1997 will no longer be subject to fees in 1998 under the FDAMA, and for the fact that an additional 17 large volume parenteral products that were subject to fees in 1997 are now regulated as generic drugs and will not be subject to fees in 1998. Accordingly, the FY 1998 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($39,040,592) by the estimated 2,100 products for a product fee rate of $18,591 (rounded to the nearest dollar).

## V. Adjusted Fee Schedules for FY 1998

The fee rates for FY 1998 are set out in the following table:

| Fee category | Fee rates for FY 1997 |
|---|---|
| Applications | |
| Requiring clinical data | $256,846 |
| Not requiring clinical data | $128,423 |

| Fee category | Fee rates for FY 1997 |
|---|---|
| Supplements requiring clinical data .... | $128,423 |
| Establishments ..... | $141,966 |
| Products ..... | $18,591 |

### 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, 1997, must be accompanied by the appropriate application fee established in the new fee schedule. FDA will bill applicants who submitted application fees between October 1, 1997, and December 31, 1997, based on the adjusted rate schedule.

*B. Establishment and Product Fees*

By December 31, 1997, FDA will issue invoices for establishments and product fees for FY 1998 under the new fee schedules. Payment will be due by January 31, 1998. FDA will issue invoices in October 1998 for any products and establishments subject to fees for FY 1998 that qualify for fees after the December 1997 billing.

Dated: December 3, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0151]**

### Agency Information Collection Activities; Announcement of OMB Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Applications for Exemption from Preemptions of Medical Device Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 16, 1997 (62 FR 27059), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0129. The approval expires on July 31, 2000.

Dated: December 2, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–32166 Filed 12–8–97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0266]**

### Agency Information Collection Activities; Announcement of OMB Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Administrative Detention and Banned Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 16, 1997 (62 FR 38095), the agency announced that the proposed information 3collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0114. The approval expires on September 30, 2000.

Dated: November 30, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–484]**

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection without change; *Title of Information Collection:* Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations 42 CFR 410.38 and 42 CFR 424.5; *Form Number:* HCFA–484 (OMB approval #0938–0534); *Use:* To determine oxygen is reasonable and necessary pursuant to Medicare Statute, Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information including estimate length of need (# of months), diagnosis codes (ICD–9) and:

1. Results and date of the most recent arterial blood gas $PO_2$ and/or oxygen saturation tests.

2. The most recent arterial blood gas $PO_2$ and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR