Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@eop.gov*.

Dated: July 27, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–6619 Filed 8–1–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0980–0270]

Submission for OMB Review; Comment Request; Developmental Disabilities Protection and Advocacy Statement of Goals and Priorities

Description: Federal statute and regulation require each State Protection and Advocacy (P&A) System to prepare and submit to public comment a Statement of Goals and Priorities (SGP) for the P&A for Developmental Disabilities (PADD) program for each coming fiscal year. While the P&A is mandated to protect and advocate under a range of different Federally authorized disabilities programs, only the PADD program requires an SGP. Following the required public input for the coming fiscal year, the P&As submit the final version of this SGP to the Administration on Developmental Disabilities (ADD). ADD will aggregate the information in the SGPs into a national profile of programmatic emphasis for P&A Systems in the coming year. This aggregation will provide ADD with a tool for monitoring of the public input requirement. Furthermore, it will provide an overview of program direction, and permit ADD to track accomplishments against goals/targets, permitting the formulation of technical assistance and compliance with the Government Performance and Results Act of 1993.

Respondents: State and Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP	57	1	44	2,508
Estimated Total Annual Burden Hours:				2,508

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection: E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: *Ketherine__T.__Astrich@omb.eop.gov.*

Dated: July 27, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–6620 Filed 8–1–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2007 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), authorizes FDA to collect user fees for certain animal drug applications, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2007.

For FY 2007, the animal drug user fee rates are: $168,600 for an animal drug application; $84,300 for a supplemental animal drug application for which safety or effectiveness data is required; $4,115 for an annual product fee; $51,350 for an annual establishment fee; and $44,850 for an annual sponsor fee. FDA will issue invoices for FY 2007 product, establishment, and sponsor fees by December 30, 2006, and these invoices will be due and payable by January 31, 2007.

The application fee rates are effective for applications submitted on or after October 1, 2006, and will remain in effect through September 30, 2007. Applications will not be accepted to review until FDA has received full payment of application fees and any other animal drug user fees owed.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/oc/adufa* or contact Robert Miller, Center for Veterinary Medicine (HFV–

10), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240–276–9707. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the act (21 U.S.C. 379j-12) establishes four different kinds of user fees: (1) Fees for certain types of animal drug applications and supplements, (2) annual fees for certain animal drug products, (3) annual fees for certain establishments where such products are made, and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j-12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j-12(d)).

For FY 2004 through FY 2008, the act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2004 are subject to adjustment for inflation and workload. Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for inflation and workload.

II. Revenue Amount for FY 2007 and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

ADUFA (Public Law 108–130) specifies that the aggregate revenue amount for FY 2007 for each of the four animal drug user fee categories is $2,500,000, before any adjustments for inflation or workload are made (see 21 U.S.C. 379j-12(b)(1)-(4)).

B. Inflation Adjustment to Fee Revenue Amount

ADUFA provides that fee revenue amounts for each FY after 2004 shall be adjusted for inflation (see 21 U.S.C. 379j-12(c)(1)). The adjustment must reflect the greater of: (1) The total percentage change that occurred in the Consumer Price Index (CPI) for all urban consumers (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 Washington, DC. ADUFA provides for this annual adjustment to be cumulative and compounded annually after FY 2004 (see 21 U.S.C. 379j-12(c)(1)).

The inflation adjustment for FY 2005 was 4.42 percent. This was the greater of the CPI increase during the 12-month period ending June 30, 2004, (3.27 percent) or the increase in pay for FY 2004 for Federal employees stationed in Washington, DC (4.42 percent).

The inflation adjustment for FY 2006 was 3.71 percent. This was the greater of the CPI increase during the 12-month period ending June 30, 2005, (2.53 percent) or the increase in pay for FY 2005 for Federal employees stationed in Washington, DC (3.71 percent).

The inflation adjustment for FY 2007 is 4.32 percent. This is the greater of the CPI increase for the 12-month period ending June 30, 2006, (4.32 percent) or the increase in pay for FY 2006 for Federal employees stationed in Washington, DC (3.44 percent).

Compounding these amounts (1.0442 times 1.0371 times 1.0432) yields a total compounded inflation adjustment of 12.97 percent for FY 2007.

The inflation-adjusted revenue amount for each category of fees for FY 2007 is the statutory fee amount ($2,500,000) increased by 12.97 percent, the inflation adjuster for FY 2007. The inflation-adjusted revenue amount is $2,824,250 for each category of fee, for a total inflation-adjusted fee revenue amount of $11,297,000 for all four categories of fees in FY 2007.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2005, ADUFA provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j-12(c)(2)).

FDA calculated the average number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 3-year period that ended on September 30, 2002 (the base years), and the average number of each of these types of applications and submissions over the most recent 3-year period that ended May 31, 2006.

The results of these calculations are presented in the first two columns of table 1 of this document. Column 3 reflects the percent change in workload over the two 3-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA animal drug review workload was accounted for by each type of application or submission in the table during the most recent 3 years. Column 5 of table 1 is the weighted percent change in each category of workload, and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of table 1 the sum of the values in column 5 is added, reflecting a total change in workload of negative 10.5 percent for FY 2007. This is the workload adjuster for FY 2007.

TABLE 1.—WORKLOAD ADJUSTER CALCULATION

Application Type	Column 1 3–Year Avg. (Base Years)	Column 2 Latest 3–Year Avg.	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted % Change
New Animal Drug Applications (NADAs)	22	13	-41%	3%	-1.2%
Supplemental NADAs with Safety or Efficacy Data	31	13	-58%	12%	-7.0%
Manufacturing Supplements	368	424	+15%	25%	+3.8%
Investigational Study Submissions	272	259	-5%	46%	-2.3%
Investigational Protocol Submissions	283	208	-27%	14%	-3.8%

TABLE 1.—WORKLOAD ADJUSTER CALCULATION—Continued

Application Type	Column 1 3–Year Avg. (Base Years)	Column 2 Latest 3–Year Avg.	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted % Change
FY 2007 Workload Adjuster					-10.5%

ADUFA specifies that the workload adjuster may not result in fees that are less than the inflation-adjusted revenue amount (21 U.S.C. 379j-12(c)(2)(B)). For this reason, the workload adjustment will not be applied in FY 2007, and the inflation-adjusted revenue amount for each category of fees for FY 2007 ($2,824,250) becomes the revenue target for fees in FY 2007, for a total inflation-adjusted fee revenue target in FY 2007 of $11,297,000 for fees from all four categories.

III. Application Fee Calculations for FY 2007

The terms ''animal drug applications'' and ''supplemental animal drug applications'' are defined in 21 U.S.C. 379j–11(1).

A. Application Fee Revenues and Numbers of Fee-Paying Applications

The application fee must be paid for any animal drug application or supplemental animal drug application that is subject to fees under ADUFA and that is submitted on or after September 1, 2003. The application fees are to be set so that they will generate $2,824,250 in fee revenue for FY 2007. This is the amount set out in the statute after it has been adjusted for inflation and workload, as set out in section II of this document. The fee for a supplemental animal drug application for which safety or effectiveness data are required is to be set at 50 percent of the animal drug application fee (see 21 U.S.C. 379j-12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $2,824,250, FDA must first make some assumptions about the number of fee-paying applications and supplements it will receive in FY 2007.

The agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2007, FDA is assuming that the number of applications that will pay fees in FY 2007 will equal the average number of submissions over the 4 most recent years (including an estimate for the current year). This may not fully account for possible year to year fluctuations in numbers of fee-paying applications, but FDA believes that this is a reasonable approach after nearly 3 years of experience with this program.

Over the past 4 years, the average number of animal drug applications that would have been subject to the full fee was 10.25, including the number for the most recent year, estimated at 6. Over this same period, the average number of supplemental applications that would have been subject to half of the full fee was 13, including the number for the most recent year, estimated at 16.

Thus, for FY 2007, FDA estimates receipt of 10.25 fee paying original applications and 13 fee-paying supplemental animal drug applications.

B. Fee Rates for FY 2007

FDA must set the fee rates for FY 2007 so that the estimated 10.3 applications that pay the full fee and the estimated 13 supplements that pay half of the full fee will generate a total of $2,824,250. To generate this amount, the fee for an animal drug application, rounded to the nearest hundred dollars, will have to be $168,600, and the fee for a supplemental animal drug application for which safety or effectiveness data are required will have to be $84,300.

IV. Product Fee Calculations for FY 2007

A. Product Fee Revenues and Numbers of Fee-Paying Products

The animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the act, and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003 (see 21 U.S.C. 379j-12(a)(2)). The term ''animal drug product'' is defined in 21 U.S.C. 379j-11(3). The product fees are to be set so that they will generate $2,824,250 in fee revenue for FY 2007. This is the amount set out in the statute after it has been adjusted for inflation and workload, as set out in section II of this document.

To set animal drug product fees to realize $2,824,250, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2007. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the act, and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of July 1, 2007, FDA found a total of 762 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that a total of 762 products will be subject to this fee in FY 2007.

In estimating the fee revenue to be generated by animal drug product fees in FY 2007, FDA is assuming that 10 percent of the products invoiced, or 76, will not pay fees in FY 2007 due to fee waivers and reductions. Based on experience with other user fee programs and the first 3 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2007.

Accordingly, the agency estimates that a total of 686 (762 minus 76) products will be subject to product fees in FY 2007.

B. Product Fee Rates for FY 2007

FDA must set the fee rates for FY 2007 so that the estimated 686 products that pay fees will generate a total of $2,824,250. To generate this amount will require the fee for an animal drug product, rounded to the nearest 5 dollars, to be $4,115.

V. Establishment Fee Calculations for FY 2007

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

The animal drug establishment fee (also referred to as the establishment fee) must be paid annually by the person who: (1) Owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year (see 21 U.S.C.

379j-12(a)(3)). An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year (see 21 U.S.C. 379j-12(a)(3)). The term ''animal drug establishment'' is defined in 21 U.S.C. 379j-11(4). The establishment fees are to be set so that they will generate $2,824,250 in fee revenue for FY 2007. This is the amount set out in the statute after it has been adjusted for inflation and workload, as set out in section II of this document.

To set animal drug establishment fees to realize $2,824,250, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2007. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of July 1, 2007, FDA found a total of 61 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 61 establishments will be subject to this fee in FY 2007.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2007, FDA is assuming that 10 percent of the establishments invoiced, or six, will not pay fees in FY 2007 due to fee waivers and reductions. Based on experience with the first 3 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2007.

Accordingly, the agency estimates that a total of 55 establishments (61 minus 6) will be subject to establishment fees in FY 2007.

B. Establishment Fee Rates for FY 2007

FDA must set the fee rates for FY 2007 so that the estimated 55 establishments that pay fees will generate a total of $2,824,250. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest 50 dollars, to be $51,350.

VI. Sponsor Fee Calculations for FY 2007

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who: (1) Is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the act or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive; and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see 21 U.S.C. 379j-11(6) and 379j-12(a)(4)). An animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j-12(a)(4)). The sponsor fees are to be set so that they will generate $2,824,250 in fee revenue for FY 2007. This is the amount set out in the statute after it has been adjusted for inflation and workload, as set out in section II of this document.

To set animal drug sponsor fees to realize $2,824,250, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2007. Based on the number of firms that would have met this definition in each of the past 3 years, FDA estimates that a total of 133 sponsors will meet this definition in FY 2007.

Careful review indicates that about one third or 33 percent of all of these sponsors will qualify for minor use/minor species exemption. Based on the agency's experience with sponsor fees in FY 2004, FY 2005 and FY 2006, FDA's current best estimate is that an additional 20 percent will qualify for other waivers or reductions, for a total of 53 percent of the sponsors invoiced, or 70, who will not pay fees in FY 2007 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2007.

Accordingly, the agency estimates that a total of 63 sponsors (133 minus 70) will be subject to sponsor fees in FY 2007.

B. Sponsor Fee Rates for FY 2007

FDA must set the fee rates for FY 2007 so that the estimated 63 sponsors that pay fees will generate a total of $2,824,250. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest 50 dollars, to be $44,850.

VII. Adjustment for Excess Collections

Under the provisions of ADUFA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce the adjusted aggregate revenue amount in a subsequent year by that excess amount (21 U.S.C. 379j-12(g)(4)). In FY 2004 FDA collected $170,150 more than was provided for in appropriations, and in FY 2005 at the end of the year the amount collected was less than provided in appropriations. No adjustment under this provision is being made for fees assessed in FY 2007, however, because a number of waiver requests for fees submitted in FY 2004 are still under consideration. Only after those waiver requests have been evaluated will FDA be able to determine if collections in FY 2004, net of waivers granted, still exceeded the appropriation.

VIII. Fee Schedule for FY 2007

The fee rates for FY 2007 are summarized in table 2.

TABLE 2.—FY 2007 FEE RATES

Animal Drug User Fee Category	Fee Rate for FY 2007
Animal Drug Application Fee	
Animal Drug Application	$168,600
Supplemental Animal Drug Application for which Safety or Effectiveness Data are Required	$84,300
Animal Drug Product Fee	$4,115
Animal Drug Establishment Fee[1]	$51,350
Animal Drug Sponsor Fee[2]	$44,850

[1]An animal drug establishment is subject to only one such fee each fiscal year.

[2]An animal drug sponsor is subject to only one such fee each fiscal year.

IX. Procedures for Paying the FY 2007 Fees

A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA that is submitted after September 30, 2006. Payment must be made in U. S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. On your check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number, beginning with the letters AD, from the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 953877, St. Louis, MO, 63195–3877.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the check and printed copy of the cover sheet to: US Bank, Attn: Government Lockbox

953877, 1005 Convention Plaza, St. Louis, Missouri 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the US Bank at 314–418–4821. This phone number is only for questions about courier delivery.)

The tax identification number of the Food and Drug Administration is 530 19 6965. (Note: In no case should the check for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the application arrives at FDA's Center for Veterinary Medicine. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's Center for Veterinary Medicine, or the date US Bank notifies FDA that your check in the full amount of the payment due has been received. US Bank is required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the ADUFA website at *http://www.fda.gov/oc/adufa* and, under the ''Forms'' heading, click on the link ''User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process. It may take a day or two to get the organization number and have the user account and password established.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the Cover Sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the Payment for your application as described in section IX.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Place, Rockville, Maryland 20855.

C. Product, Establishment and Sponsor Fees

By December 30, 2006, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2007 using this Fee Schedule. Payment will be due and payable by January 31, 2007. FDA will issue invoices in October 2007 for any products, establishments, and sponsors subject to fees for FY 2007 that qualify for fees after the December 2006 billing.

Dated: July 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12396 Filed 8–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Prescription Drug User Fee Rates for Fiscal Year 2007

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) 2007. The Federal Food, Drug, and Cosmetic Act, as amended by the Prescription Drug User Fee Amendments of 2002 (Title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (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. Base revenue amounts for application fees, establishment fees, and product fees for FY 2007 were established by PDUFA III. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the revenue levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2007 for application fees for an application requiring clinical data ($896,200), for an application not requiring clinical data or a supplement requiring clinical data ($448,100), for establishment fees ($313,100), and for product fees ($49,750). These fees are effective on October 1, 2006, and will remain in effect through September 30, 2007. For applications and supplements that are submitted on or after October 1, 2006, the new fee schedule must be used. Invoices for establishment and product fees for FY 2007 will be issued in August 2006, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

The FFDCA, sections 735 and 736 (21 U.S.C. 379g and h), establishes three different kinds of user fees. Fees are assessed on the following: (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, base revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III. Base 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 revenue 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 2007 for application, establishment, and product fees. These fees are effective on October 1, 2006, and will remain in effect through September 30, 2007.

II. Revenue Amounts for FY 2007, and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

PDUFA III specifies that the fee revenue amount for FY 2007 for application fees is $86,434,000 and for both product and establishment fees is $86,433,000, for a total of $259,300,000 from all three categories of fees (21 U.S.C. 379h(b), before any adjustments are made.