ESTIMATES OF ANNUALIZED BURDEN HOURS—Continued

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Physicians/certification	300	1	10/60	50
Miners	5000	1	20/60	1,666
Mine operators	200	1	30/60	100
X-ray facilities	25	1	30/60	13
Total				2,329

Dated: July 27, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2008

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) 2008 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 2008.

For FY 2008, the animal drug user fee rates are: $172,500 for an animal drug application; $86,250 for a supplemental animal drug application for which safety or effectiveness data is required; $4,125 for an annual product fee; $52,700 for an annual establishment fee; and $43,900 for an annual sponsor fee. FDA will issue invoices for FY 2008 product, establishment and sponsor fees by December 30, 2007, and these invoices will be due and payable by January 31, 2008.

The application fee rates are effective for applications submitted on or after October 1, 2007, and will remain in effect through September 30, 2008. 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 Roxanne Schweitzer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9705. 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 2008 and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

ADUFA (Public Law 108–130) specifies that the aggregate revenue amount for FY 2008 for each of the four animal drug user fee categories is $2,500,000, before any adjustments for inflation or workload are made (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 the following: (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 (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 was 4.32 percent. This was 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).

The inflation adjustment for FY 2008 is 2.69 percent. This is the greater of the CPI increase for the 12-month period ending June 30, 2007, (2.69 percent) or the increase in pay for FY 2007 for Federal employees stationed in Washington, DC (2.64 percent).

Compounding these amounts (1.0442 times 1.0371 times 1.0432 times 1.0269) yields a total compounded inflation adjustment of 16.01 percent for FY 2008.

The inflation-adjusted revenue amount for each category of fees for FY 2008 is the statutory fee amount ($2,500,000) increased by 16.01 percent, the inflation adjuster for FY 2008. The inflation-adjusted revenue amount is $2,900,000 for each category of fee, rounded to the nearest thousand dollars, for a total inflation-adjusted fee revenue amount of $11,600,000 for all four categories of fees in FY 2008.

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, 2007.

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 the table the sum of the values in column 5 is added, reflecting a total change in workload of negative 16.7 percent for FY 2008. This is the workload adjuster for FY 2008.

TABLE 1.—WORKLOAD ADJUSTER CALCULATION (NUMBERS MAY NOT ADD DUE TO ROUNDING)

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 Percent Change
New Animal Drug Applications (NADAs)	22	13	-39%	4%	-1.5%
Supplemental NADA's with Safety or Efficacy Data	31	12	-62%	2%	-1.4%
Manufacturing Supplements	368	409	+11%	16%	+1.8%
Investigational Study Submissions	272	217	-20%	60%	-12.1%
Investigational Protocol Submissions	283	229	-19%	18%	-3.4%
FY 2008 Workload Adjuster					-16.7%

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 2008, and the inflation-adjusted revenue amount for each category of fees for FY 2008 ($2,900,000) becomes the revenue target for fees in FY 2008, for a total inflation-adjusted fee revenue target in FY 2008 of $11,600,000 for fees from all four categories.

III. Adjustment for Excess Collections in Previous Years

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 its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379j–12(g)(4)).

In FY 2004, Congress appropriated a total of $5,000,000 to FDA in ADUFA fee revenue. As of July 1, 2007, collections for FY 2004 totaled $5,154,700—or $154,700 in excess of the appropriation limit. Also, in FY 2005 Congress appropriated a total of $8,354,000 to FDA in ADUFA fee revenue, and FDA collected a total of $8,519,101 as of July 1, 2007. This is $165,101 in excess of appropriations. The total in excess collections for the 2 years is $319,801. These are the only fiscal years since ADUFA began in which FDA has collected more in ADUFA fees than Congress appropriated.

The total of $319,801 will be offset against FY 2008 revenue collections, lowering the net amount that would otherwise be collected. One-fourth of this amount, or $80,000, rounded to the nearest thousand dollars, will be subtracted from the FY 2008 adjusted revenue amount for each fee category in the previous section. Thus, after adjustment for prior-year excess collections, the adjusted FY 2008 revenue target for each fee category is:

- Application Fee Revenue Amount: $2,820,000 ($2,900,000 minus $80,000)
- Establishment Fee Revenue Amount: $2,820,000 ($2,900,000 minus $80,000)
- Product Fee Revenue Amount: $2,820,000 ($2,900,000 minus $80,000)
- Sponsor Fee Revenue Amount: $2,820,000 ($2,900,000 minus $80,000)

Thus the adjusted revenue amount from all 4 categories after this adjustment totals $11,280,000.

IV. Final Year Adjustment

Under the provisions of ADUFA, the Secretary of Health and Human Services may, in addition to the inflation and workload adjustments, further increase the fees and fee revenues if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of FY

2009. The rational for the amount of this increase shall be contained in the annual notice establishing fee revenues and fees for FY 2008 (21 U.S.C. 379j–12(c)(3)).

As of June 30, 2007, FDA has unallocated cash carryover balances of $4,453,000. In addition, the agency is estimating that application fees over the final 3 months of FY 2007 will add another $675,000 to this balance, for an estimated cash carryover of $5,128,000 on September 30, 2007.

In FY 2008, FDA expects to collect a total of $11,280,000 after adjustments, as noted at the end of section III of this document. To sustain current operations in FY 2008, FDA expects to obligate a total of $13,084,000 (compared with anticipated obligations in FY 2007 of about $12,355,000). The anticipated obligations of $13,084,000 will be about $1,768,000 more than anticipated collections. This will reduce the estimated carryover balance over the course of FY 2008 from $5,128,000 to an estimated $3,360,000 ($5,128,000 minus $1,768,000).

To sustain operations supported from user fees for the first 3 months of FY 2009, FDA estimates that it will need one-fourth of the $13,084,000 it expects to spend in FY 2008, or $3,271,000 (rounded to the nearest thousand). However this amount will need to be increased for inflation by an estimated 5.9 percent (the average amount by which FDA's costs per full-time employee have increased over the past 5 years). The amount needed to sustain operations for the first 3 months of FY 2009 is thus estimated at $3,464,000 (rounded to the nearest thousand), while the estimated carryover balance at the beginning of FY 2009 is estimated at only $3,360,000. Thus FDA will need an additional $104,000 as the final year adjustment to assure sufficient operating reserves for the first 3 months of FY 2009. One-fourth of this amount or $26,000 will be added to the FY 2008 adjusted revenue amount for each of the four fee categories in the previous section. Thus, after the final-year adjustment, the adjusted FY 2008 revenue target for each fee category is:

- Application Fee Revenue Amount: $2,846,000 ($2,820,000 plus $26,000)
- Establishment Fee Revenue Amount: $2,846,000 ($2,820,000 plus $26,000)
- Product Fee Revenue Amount: $2,846,000 ($2,820,000 plus $26,000)
- Sponsor Fee Revenue Amount: $2,846,000 ($2,820,000 plus $26,000)

Thus, after the final year adjustment, the adjusted FY 2008 revenue target from all fee types combined totals $11,384,000.

V. Application Fee Calculations for FY 2008

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 $2,846,000 in fee revenue for FY 2008. 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, for excess collections in previous years as set out in section III of this document, and for the final year adjustment as set out in section IV 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 (21 U.S.C. 379j–12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $2,846,000, FDA must first make some assumptions about the number of fee-paying applications and supplements it will receive in FY 2008.

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 2008, FDA is assuming that the number of applications that will pay fees in FY 2008 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 4 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 15. Over this same period, the average number of supplemental applications that would have been subject to half of the full fee was 12.5, including the number for the most recent year, estimated at 13.

Thus, for FY 2008, FDA estimates receipt of 10.25 fee paying original applications and 12.5 fee-paying supplemental animal drug applications.

B. Fee Rates for FY 2008

FDA must set the fee rates for FY 2008 so that the estimated 10.25 applications that pay the full fee and the estimated 12.5 supplements that pay half of the full fee will generate a total of $2,846,000. To generate this amount, the fee for an animal drug application, rounded to the nearest hundred dollars, will have to be $172,500, and the fee for a supplemental animal drug application for which safety or effectiveness data are required will have to be $86,250.

VI. Product Fee Calculations for FY 2008

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 (21 U.S.C. 360), and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003, (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 $2,846,000 in fee revenue for FY 2008. 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, for excess collections in previous years as set out in section III of this document, and for the final year adjustment as set out in section IV of this document.

To set animal drug product fees to realize $2,846,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2008. 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 767 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 767 products will be subject to this fee in FY 2008.

In estimating the fee revenue to be generated by animal drug product fees in FY 2008, FDA is assuming that 10 percent of the products invoiced, or 77, will not pay fees in FY 2008 due to fee waivers and reductions. Based on experience with other user fee programs

and the first 4 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2008.

Accordingly, the agency estimates that a total of 690 (767 minus 77) products will be subject to product fees in FY 2008.

B. Product Fee Rates for FY 2008

FDA must set the fee rates for FY 2008 so that the estimated 690 products that pay fees will generate a total of $2,846,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest five dollars, to be $4,125.

VII. Establishment Fee Calculations for FY 2008

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 FY (21 U.S.C. 379j–12(a)(3)). An establishment subject to animal drug establishment fees is assessed only one such fee per FY (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 $2,846,000 in fee revenue for FY 2008. 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, for excess collections in previous years as set out in section III of this document, and for the final year adjustment as set out in section IV of this document.

To set animal drug establishment fees to realize $2,846,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2008. 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 60 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 60 establishments will be subject to this fee in FY 2008.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2008, FDA is assuming that 10 percent of the establishments invoiced, or six, will not pay fees in FY 2008 due to fee waivers and reductions. Based on experience with the first 4 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2008.

Accordingly, the agency estimates that a total of 54 establishments (60 minus 6) will be subject to establishment fees in FY 2008.

B. Establishment Fee Rates for FY 2008

FDA must set the fee rates for FY 2008 so that the estimated 54 establishments that pay fees will generate a total of $2,846,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest 50 dollars, to be $52,700.

VIII. Sponsor Fee Calculations for FY 2008

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, (21 U.S.C. 379j–11(6) and 379j–12(a)(4)). An animal drug sponsor is subject to only one such fee each FY (21 U.S.C. 379j–12(a)(4)). The sponsor fees are to be set so that they will generate $2,846,000 in fee revenue for FY 2008. 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, for excess collections in previous years as set out in section III of this document, and for the final year adjustment as set out in section IV of this document.

To set animal drug sponsor fees to realize $2,846,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2008. Based on the number of firms that would have met this definition in each of the past 4 years, FDA estimates that a total of 138 sponsors will meet this definition in FY 2008.

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 to date with sponsor fees, 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 73, who will not pay fees in FY 2008 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2008.

Accordingly, the agency estimates that a total of 65 sponsors (138 minus 73) will be subject to sponsor fees in FY 2008.

B. Sponsor Fee Rates for FY 2008

FDA must set the fee rates for FY 2008 so that the estimated 65 sponsors that pay fees will generate a total of $$2,846,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest 50 dollars, to be $43,900.

IX. Fee Schedule for FY 2008

The fee rates for FY 2008 are summarized in table 2 of this document.

TABLE 2.—FY 2008 FEE RATES

Animal Drug User Fee Category	Fee Rate for FY 2008
Animal Drug Application Fee	
Animal Drug Application	$172,500
Supplemental Animal Drug Application for which Safety or Effectiveness Data are Required	$86,250
Animal Drug Product Fee	$4,125

TABLE 2.—FY 2008 FEE RATES—Continued

Animal Drug User Fee Category	Fee Rate for FY 2008
Animal Drug Establishment Fee[1]	$52,700
Animal Drug Sponsor Fee[2]	$43,900

[1]An animal drug establishment is subject to only one such fee each FY.
[2]An animal drug sponsor is subject to only one such fee each FY.

X. Procedures for Paying the FY 2008 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, 2007. 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 (PO 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, MO 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 530196965. (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 Web site 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.

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 X.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 Pl., Rockville, MD 20855.

C. Product, Establishment and Sponsor Fees

By December 30, 2007, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2008 using this Fee Schedule. Payment will be due and payable by January 31, 2008. FDA will issue invoices in October 2008 for any products, establishments, and sponsors subject to fees for FY 2008 that qualify for fees after the December 2007 billing.

Dated: July 27, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. 07–3782 Filed 7–30–07; 4:29 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

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

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

Proposed Project: The Smallpox Vaccine Injury Compensation Program (OMB No. 0915–0282)—Extension

The Smallpox Emergency Personnel Protection Act (SEPPA) authorized the Secretary of Health and Human Services to establish The Smallpox Vaccine Injury Compensation Program, which provides benefits and/or compensation to certain persons harmed as a direct result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a direct result of contracting vaccinia through certain accidental exposures.

The benefits available under the Program include compensation for unreimbursed medical care expenses, lost employment income, and survivor death benefits. To be considered for Program benefits, requesters (i.e., smallpox vaccine recipients, vaccinia contacts, survivors, or the representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), or persons filing on