

TABLE 2.—FY 2008 FEE RATES—Continued

Animal Drug User Fee Category	Fee Rate for FY 2008
Animal Drug Establishment Fee <sup>1</sup>	\$52,700
Animal Drug Sponsor Fee <sup>2</sup>	\$43,900

<sup>1</sup>An animal drug establishment is subject to only one such fee each FY.

<sup>2</sup>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.*

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## 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

their behalf as their representatives, must file a Request Form and the documentation required under SEPPA and its implementing regulations (42 CFR Part 102) to show that they are eligible.

Requesters must submit appropriate documentation to allow the Secretary to

determine if the requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is filing as a smallpox vaccine recipient, a vaccinia contact, a survivor, or a representative of an estate.

All requesters must submit medical records sufficient to demonstrate that a covered injury was sustained by a smallpox vaccine recipient or a vaccinia contact.

The Estimated Annual Burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Request Form .....	25	1	25	5	125
Certification .....	25	1	25	1	25
<b>Total .....</b>	<b>25</b>	<b>.....</b>	<b>25</b>	<b>.....</b>	<b>150</b>

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: July 25, 2007.

**Alexandra Huttinger,**  
Acting Director, Division of Policy Review and Coordination.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**National Advisory Committee on Rural Health and Human Services; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the following committee will convene its fifty-seventh meeting.

*Name:* National Advisory Committee on Rural Health and Human Services.

*Dates and Times:* September 12, 2007, 8 a.m.-5:30 p.m.; September 13, 2007, 8 a.m.-5 p.m.; September 14, 2007, 8 a.m.-11 a.m.

*Place:* Best Western Inn on the Park, 22 South Carroll Street, Madison, WI 53703, Phone: 608-257-8811.

*Status:* The meeting will be open to the public.

*Purpose:* The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of

health and human services in rural areas.

*Agenda:* Wednesday morning, at 8 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley. The first session will be a snapshot of Wisconsin, focusing on the challenges related to jobs, income, and educational level and a look at health and human services assets and liabilities. The next presentation will examine collaborative approaches to increase the supply of physicians for rural Wisconsin.

Following this presentation will be discussions on State Medicaid waivers to improve access to healthcare and welfare reform. The next presentation will be a panel discussion by Toyota on health and human services integration in Tupelo, Mississippi, and the implications on the community of the new Toyota factory. The Committee will break into Subcommittee format for the remainder of the day's meeting. The Wednesday meeting will close at 5:30 p.m.

Thursday morning, September 13, at 8 a.m., the Committee will meet briefly to discuss the site visit. At 8:30 a.m., the Committee will depart for Sauk City, Wisconsin. The Committee will hear presentations on health and human services issues facing the community. Transportation to the site visit will not be provided. The Committee will return to the Best Western Inn on the Park to resume the meeting in Subcommittee format at 2 p.m. The Thursday meeting will close at 5 p.m.

The final session will be convened Friday morning, September 14, at 8 a.m. The Committee will have a discussion on the site visit. Following this discussion will be a report by the Subcommittees on the progress with the report chapters; discussion on the letter to the Secretary; and discussion on the

upcoming February meeting. The meeting will be adjourned at 11 a.m.

**FOR FURTHER INFORMATION CONTACT:** Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), telephone (301) 443-0835. The Committee meeting agenda will be posted on ORHP's Web site <http://www.ruralhealth.hrsa.gov>.

Dated: July 24, 2007.

**Alexandra Huttinger,**  
Acting Director, Division of Policy Review and Coordination.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.