

Per Capita Income Levels Matched to FY 2012 Federal Medical Assistance Percentage		
To determine an Indian tribe's Federal Medical Assistance Percentage (FMAP) for Fiscal Year 2012, find the Indian tribe's per capita income, using American Community Survey 5-year estimates for the American Indian/Alaska Native "alone" population for 2005-2009, in the list of FMAPs below.		
<b>U.S. Per Capita Income (2005-2009)</b>	\$27,401	
FMAP Formula: $1 - 0.45 \times (\text{Indian Tribe Per Capita Income}^2 / \text{U.S. Per Capita Income}^2)$		
Tribal Per Capita Income Range from American Community Survey Estimates for FY 2005-2009		Resulting FMAP
Income Greater Than or Equal to	Income Less Than or Equal to	
\$0	\$17,329	83%
\$17,330	\$17,804	82%
\$17,805	\$18,267	81%
\$18,268	\$18,718	80%
\$18,719	\$19,159	79%
\$19,160	\$19,589	78%
\$19,590	\$20,010	77%
\$20,011	\$20,423	76%
\$20,424	\$20,828	75%
\$20,829	\$21,224	74%
\$21,225	\$21,614	73%
\$21,615	\$21,996	72%
\$21,997	\$22,372	71%
\$22,373	\$22,742	70%
\$22,743	\$23,106	69%
\$23,107	\$23,464	68%
\$23,465	\$23,817	67%
\$23,818	\$24,165	66%
\$24,166	\$24,508	65%
\$24,509	\$24,846	64%
\$24,847	\$25,179	63%
\$25,180	\$25,509	62%
\$25,510	\$25,834	61%
\$25,835	\$26,155	60%
\$26,156	\$26,472	59%
\$26,473	\$26,785	58%
\$26,786	\$27,095	57%
\$27,096	\$27,401	56%
\$27,402	\$27,703	55%
\$27,704	\$28,003	54%
\$28,004	\$28,299	53%
\$28,300	\$28,593	52%
\$28,594	\$28,883	51%
\$28,884		50%

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Committee on Vital and Health Statistics: Meeting**

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date: August 26, 2011: 3 p.m.-5 p.m., E.D.T.

Place: Teleconference. Dial-In Number: 1-877-939-9305, participant code is 4431134.

Status: Open.

Purpose: This teleconference is being held to discuss a letter to the HHS Secretary regarding the President's Council of Advisors on Science and Technology (PCAST) Report on

Health Information Technology and to approve the final draft.

**FOR FURTHER INFORMATION CONTACT:**

Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web

site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: July 25, 2011.

**James Scanlon,**

*Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0548]

#### Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2012

**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) 2012 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA) and the Animal Drug User Fee Amendments of 2008 (ADUFA II), authorizes FDA to collect user fees for certain animal drug applications and supplements, 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 2012.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm> or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240-276-9718. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: [cvmadufa@fda.hhs.gov](mailto:cvmadufa@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 740 of the FD&C 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 2009 through FY 2013, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2009 are subject to adjustment for 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 workload.

For FY 2012, the animal drug user fee rates are: \$372,100 for an animal drug application; \$186,050 for a supplemental animal drug application for which safety or effectiveness data is required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); \$7,935 for an annual product fee; \$93,050 for an annual establishment fee; and \$67,200 for an annual sponsor fee. FDA will issue invoices for FY 2012 product, establishment, and sponsor fees by December 31, 2011, and these invoices will be due and payable within 30 days of issuance of the invoice. The application fee rates are effective for applications submitted on or after October 1, 2011, and will remain in effect through September 30, 2012. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed.

##### II. Revenue Amount for FY 2012

###### A. Statutory Fee Revenue Amounts

ADUFA II (Pub. L. 110-316 signed by the President on August 14, 2008) specifies that the aggregate revenue

amount for FY 2012 for each of the four animal drug user fee categories is \$5,442,000 before any adjustment for workload is made. (See 21 U.S.C. 379j-12(b)(1) through (b)(4).)

###### B. Inflation Adjustment to Fee Revenue Amount

The amounts established in ADUFA II for each year for FY 2009 through FY 2013 include an inflation adjustment; so, no further inflation adjustment is required.

###### C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2010, ADUFA provides that fee revenue amounts shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j-12(c)(1)).

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 5-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 5-year period that ended on June 30, 2011.

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 5-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 5 years. Column 5 of table 1 of this document 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 31 percent for FY 2012. This is the workload adjuster for FY 2012.