

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth and Families; 2005 Head Start Family Literacy Project; Notice of Correction for the FY 2005 Head Start Family Literacy Project Program Announcement, HHS-2005-ACF-ACYF-YL-0023, CFDA # 93.600

AGENCY: Head Start Bureau, Administration on Children, Youth and Families, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of correction.

SUMMARY: This notice is to inform interested parties of a correction made to the Head Start Family Literacy Project program announcement that was published on July 25, 2005. The following correction should be noted:

Under Section IV. Application and Submission Information, 1. Address to Request Application Package, please delete the following phone number for The Dixon Group: 1-800-351-2293.

Please replace the deleted phone number with the following: 1-866-796-1591.

All other information in this notice of correction is accurate and replaces information specified in the July 25 notice. Applications are still due by the deadline date that was published in the July 25 notice (due date for applications is September 8, 2005).

FOR FURTHER INFORMATION CONTACT: For further information please contact the Administration on Children, Youth and Families, Head Start Bureau, Willa Siegel at (202) 205-4011 or WSiegel@acf.hhs.gov.

Dated: July 26, 2005.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2006

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) 2006 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 2006.

For FY 2006, the animal drug user fee rates are: \$151,800 for an animal drug application; \$75,900 for a supplemental animal drug application for which safety or effectiveness data is required; \$3,905 for an annual product fee; \$49,200 for an annual establishment fee; and \$44,400 for an annual sponsor fee. FDA will issue invoices for FY 2006 product, establishment, and sponsor fees by December 30, 2005, and these invoices will be due and payable by January 31, 2006.

The application fee rates are effective for applications submitted on or after October 1, 2005, and will remain in effect through September 30, 2006. 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 Pl., 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 2006 and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

ADUFA (Public Law 108-130) specifies that the aggregate revenue amount for FY 2006 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 is 3.71 percent. This is 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).

Compounding these amounts (1.0442 times 1.0371) yields a total compounded inflation adjustment of 8.29 percent for FY 2006.

The inflation-adjusted revenue amount for each category of fees for FY 2006 is the statutory fee amount (\$2,500,000) increased by 8.29 percent, the inflation adjuster for FY 2006. The inflation-adjusted revenue amount is \$2,707,250 for each category of fee, for a total inflation-adjusted fee revenue amount of \$10,829,000 for all four categories of fees in FY 2006.