

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Animal Drug User Fee Act of 2003; Interim Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing interim procedures relating to the Animal Drug User Fee Act (ADUFA) of 2003, which was signed by the President on November 18, 2003. This act amends the Federal Food, Drug, and Cosmetic Act, and authorizes FDA to collect four types of user fees: Application fees, establishment fees, product fees, and sponsor fees. Before FDA can begin collecting these fees, enabling appropriations must be enacted. Until further notice, such fees should not be submitted to FDA. However, sponsors should continue to submit new animal drug applications as in the past until additional direction is provided. Certain types of applications submitted on or after September 1, 2003, will be subject to fees, but an invoice for those fees will not be issued until after enabling appropriations are enacted. FDA will publish another **Federal Register** notice specifying fee amounts and procedures for submitting payments.

ADDRESSES: Visit the FDA Web site that provides further information on ADUFA at: <http://www.fda.gov/oc/adufa>.

FOR FURTHER INFORMATION CONTACT: Robert Miller, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-5436; e-mail: rmiller2@cvm.fda.gov. For general cv03137

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questions, you may also contact the Center for Veterinary Medicine at:
mailto:cvmadufa@fda.gov.

SUPPLEMENTARY INFORMATION: ADUFA authorizes FDA to collect fees for: (1) Certain types of animal drug applications and supplemental animal drug applications submitted on or after September 1, 2003, (2) certain animal drug products, (3) certain establishments where such products are manufactured in final dosage form, and (4) certain sponsors of animal drug applications or investigational animal drug submissions. However, FDA may not begin to collect these fees until enabling appropriations are enacted. After the enactment of enabling appropriations, FDA will publish a **Federal Register** notice with detailed payment procedures.

For FY 2004 through FY 2008, ADUFA establishes overall fee revenue amounts for application fees, establishment fees, product fees, and sponsor fees. Revenue amounts established for years after FY 2004 are subject to annual adjustments for inflation and workload. Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that revenues will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. FDA will publish a **Federal Register** notice with the FY 2004 fee rates and detailed payment instructions.

In an effort to better ensure broad awareness of interim procedures relating to ADUFA, FDA has established a Web site that provides further information at *http://www.fda.gov/oc/adufa*.

Dated: 1/7/04
January 7, 2004.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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