

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 2004D-0124]

### **Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#170) entitled “Animal Drug User Fees and Fee Waivers and Reductions.” The purpose of this document is to provide guidance to industry on the fee waiver provisions of the Animal Drug User Fee Act of 2003 (ADUFA). The guidance document is immediately in effect, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written comments on the guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of the guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

**FOR FURTHER INFORMATION CONTACT:** David Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: *dnewkirk@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On November 18, 2003, ADUFA (Public Law 108-130) was enacted. ADUFA amends the Federal Food, Drug, and Cosmetic Act and requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the agency to grant a waiver from or a reduction of fees in certain circumstances.

The purpose of the guidance document is to provide guidance on the types of fees FDA is authorized to collect and how to request waivers and reductions from FDA's animal drug user fees. It describes the types of fees and fee waivers and reductions, what information FDA recommends you submit in support of a request for a fee waiver or reduction, how to submit such a request, and FDA's process for reviewing requests.

FDA is making this guidance document immediately available because prior public participation was not feasible or appropriate. ADUFA's user fee provisions are already in effect, and it is essential for the agency to provide guidance on how to request fee waivers and reductions as quickly as possible. Although it was not feasible or appropriate to obtain comments before issuing

the guidance, in accordance with this agency's procedures, FDA will accept comments on the guidance at any time.

## **II. Paperwork Reduction Act of 1995**

FDA is announcing that a collection of information entitled "Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions" has been approved by the Office of Management and Budget (OMB) under the emergency processing provisions of the Paperwork Reduction Act of 1995 (the PRA). According to the PRA, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910-0540. It expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

## **III. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the fee waiver provisions of ADUFA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## **IV. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments may be seen

in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Persons with access to the Internet may obtain this guidance from the CVM home page at <http://www.fda.gov/cvm>.

Dated: March 15, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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