DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0422]

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Certifier R.LEDESMA

Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (#173) entitled "Guidance For Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)." This draft guidance describes how FDA intends to implement the Federal Food, Drug, and Cosmetic Act (the act) as it relates to animal drug sponsor fees.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 30 days after date of publication in the* **Federal Register**], to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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.

Submit written comments on the draft guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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

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http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

The Animal Drug User Fee Act of 2003 (ADUFA), enacted on November 18, 2003, amends the act by adding sections 739 and 740 (21 U.S.C. 379j-11 and 379j-12). Section 740 requires FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. This draft guidance represents FDA's current thinking on how it intends to implement the animal drug sponsor fee provision of ADUFA.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This draft guidance is being issued as a level 1 guidance consistent with our good guidance practices regulation (21 CFR 10.115). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of the applicable statutes and regulations.

III. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [2004D–0422] "Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act" and follow the directions. Copies of this guidance may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: 9/21/04
September 21, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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