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Guidance for Industry

Animal Drug Sponsor Fees under the Animal Drug User Fee Act (ADUFA)

Draft Guidance

This draft guidance is being distributed for comment purposes only.

This draft guidance discusses how the Food and Drug Administration intends to implement the animal drug sponsor fee provision of ADUFA.

Comments and suggestions regarding this document should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket No. 2004D-0422. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

For questions regarding this document, contact: David Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6967, e-mail: dnewkirk@cvm.fda.gov.

Additional copies of this draft guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855 and may be viewed on the Internet at http://www.fda.gov/cvm.

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. This draft guidance contains no new collections of information.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
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Guidance for Industry
Animal Drug Sponsor Fees under the Animal Drug User Fee Act (ADUFA)[1]

This draft guidance, when finalized, will represent the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the contact number listed on the title page of this guidance.

I. INTRODUCTION

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

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. DETERMINING WHETHER YOU ARE SUBJECT TO THE ANIMAL DRUG SPONSOR FEE

Section 740 of the act, as amended by ADUFA, requires FDA to assess and collect animal drug sponsor fees. You are subject to sponsor fees if you: (1) meet the definition of an

[1] This guidance has been prepared by the Office of New Animal Drug Evaluation in the Center for Veterinary Medicine, FDA.

animal drug sponsor within a fiscal year; and (2) after September 1, 2003, had pending before FDA an animal drug application, a supplemental animal drug application, or an investigational animal drug submission. (Section 740(a)(4) of the act) (21 U.S.C. 379j-12(a)(4)). This two-part test is discussed in more detail below.

1. Determining whether you are an animal drug sponsor.

You are an "animal drug sponsor" if you are either:

- ?? An applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the act; or
- ?? A person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by FDA.

(Section 739(6) of the act) (21 U.S.C. 379j-11(6)).

An "animal drug application" is an application for approval of any new animal drug submitted under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)), and is commonly referred to as a new animal drug application (NADA). It does not include a new animal drug application submitted under 512(b)(2) of the act (21 U.S.C. 360b(b)(2)), commonly referred to as an abbreviated new animal drug application (ANADA), or a supplemental animal drug application. Thus, you are an animal drug sponsor if you are named as an applicant in any NADA.[2]

An "investigational animal drug submission" is either:

- ?? The filing of a claim for an investigational exemption under 512(j) of the act for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, which means the submission of a "Notice of Claimed Investigational Exemption for a New Animal Drug" in accordance with 21 CFR 511.1(b)(4); or
- ?? The submission of information for the purpose of enabling FDA to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

Section 739(5) of the act (21 U.S.C. 379j-11(5)).

FDA will establish an INAD file no later than at the time a sponsor begins clinical studies and is required by 21 CFR 511.1(b)(4) to submit a Notice of Claimed Investigational Exemption. But, as an administrative matter, FDA intends to establish an INAD file prior to the shipment of new animal drug for clinical tests if a sponsor submits any information

[2] FDA believes that this includes products approved prior to 1962 and then found effective under the Drug Efficacy Study Implementation (DESI) review process.

that enables FDA to evaluate the safety or effectiveness of a new animal drug. Thus, the existence of an INAD will enable FDA to identify those persons who meet the definition of an animal drug sponsor. The existence of the INAD file will also help to make clear that the submitted information is subject to the confidentiality provisions of 21 CFR 514.12.

Not all submissions concerning an investigational product will meet the definition of an "investigational animal drug submission." In general, submissions requesting only administrative actions are not investigational animal drug submissions. For example, submissions asking whether a product under development is a new animal drug subject to FDA regulation and submissions asking about FDA's administrative process for submitting a "Notice of Claimed Investigational Exemption for a New Animal Drug", investigational information, or an NADA, by themselves, are not investigational animal drug submissions. However, if you wish to discuss investigational or submission requirements and provide advance materials for FDA to review, FDA would likely establish an INAD file for these materials and you would be considered an animal drug sponsor.

You will no longer be an animal drug sponsor if:

- ?? You withdraw all of your NADAs, which includes removing all subject products from listing under section 510 of the act (21 U.S.C. 360); and
- ?? All of your INAD files are either terminated, pursuant to 21 CFR 511.1(d), or are rendered inactive.

FDA will consider an INAD file as being rendered inactive if it receives a request from the animal drug sponsor to close the INAD file and the request states that the sponsor has ceased all investigations and recalled or destroyed all unused supplies of the new animal drug. FDA considers an INAD file that is rendered inactive to have the same status as an INAD file that has been terminated. Therefore, FDA asks that your request to close an INAD file include a waiver to a right to a hearing regarding termination.

Veterinary Master Files (VMFs) and Public Master Files (PMFs) are not considered animal drug applications or investigational animal drug submissions. Creation of, and submissions to, VMFs or PMFs do not, by themselves, make a person an animal drug sponsor.

2. Determining whether you have an animal drug application, a supplemental animal drug application, or an investigational animal drug submission pending before FDA after September 1, 2003.

The terms "animal drug application" and "investigational animal drug submission" are explained above. A "supplemental animal drug application" is:

- ?? A supplement, manufacturing or non-manufacturing, to an application approved under section 512(c)(1) of the act (21 U.S.C. 360b(c)(1)) (i.e., a supplement to an NADA), regardless of whether data with respect to safety or effectiveness are required for approval; or
- ?? A supplement, manufacturing or non-manufacturing, to an application approved under section 512(c)(2) of the act (21 U.S.C. 360b(c)(2)) (i.e., a supplement to an ANADA), provided that data with respect to safety or effectiveness are required for the supplement to be approved.

An application was "pending after September 1, 2003," if:

- ?? It was accepted for filing after September 1, 2003; or
- ?? It was accepted for filing before September 1, 2003, and it had not been completely processed[3] by that date.

Likewise, an investigational animal drug submission was "pending after September 1, 2003," if:

- ?? FDA established an INAD file for the animal drug sponsor after September 1, 2003;
- ?? The animal drug sponsor filed, after September 1, 2003, information for the purpose of enabling FDA to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing; or
- ?? The animal drug sponsor submitted, before September 1, 2003, information for the purpose of enabling FDA to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing and the submission had not been completely processed[4] prior to September 1, 2003.

Thus, FDA will not consider an INAD file to be pending after September 1, 2003, if the sponsor did not have any data or information pending as of that date and has not submitted any data or information to the file since that date. As discussed above, FDA does not intend to consider submissions that are unrelated to safety or effectiveness, such as a request to terminate the INAD file, to be investigational animal drug submissions.

[3]FDA considers an application or submission to be "completely processed" when FDA has completed its review, identified in its tracking system that the review is complete, mailed any related letters, and put the submission and related documentation in the administrative file.

[4] See footnote 3.

3. Animal Drug Sponsor Fee Implementation.

Appendix 1 provides some illustrations of how FDA intends to implement the animal drug sponsor fee. The examples in the appendix are not all inclusive. The answers in a row are specific to the facts in that row and assume there is no other information relevant to the "person making the submission" or "the submission."

III. PAYMENT INFORMATION FOR THOSE SUBJECT TO THE ANIMAL DRUG SPONSOR FEE

The animal drug sponsor fee is assessed annually and must be paid on or before January 31 of each year. (Section 740(a)(4) of the act) (21 U.S.C. 379j-12(a)(4)). If you become subject to the animal drug sponsor fee for the first time after the invoices issue for the January 31st payment, you will be assessed the animal drug sponsor fee for that fiscal year the following October and thereafter be billed annually with payment due by January 31. Each animal drug sponsor is responsible for paying only one sponsor fee each fiscal year whether a sponsor has one INAD file or NADA or has multiple INAD files or NADAs. (Section 740(a)(4) of the act) (21 U.S.C. 379j-12(a)(4)). FDA's invoices for sponsor fees will include complete payment instructions. The invoices are based on fee rates established each year and the fee rates will be announced in the Federal Register. (Section 740(c)(5) of the act) (21 U.S.C. 379j-12(c)(5)).

A sponsor may submit a written request for a waiver or reduction of a sponsor or other user fee. To qualify for consideration of a waiver or reduction, a person must submit the written request no later than 180 days after the fee is due. (Section 740(i)) of the act) (21 U.S.C. 379j-12(i)). The conditions under which FDA must grant such a waiver or reduction are defined in section 740(d) of the act (21 U.S.C. 379j-12(d)). Further guidance regarding fee waivers and reductions is provided in Guidance # 170: "Animal Drug User Fees and Fee Waivers and Reductions."