

Guidance for Industry Animal Drug User Fees and Fee Waivers and Reductions

FINAL GUIDANCE

This version of the guidance replaces that which was made available on March 14, 2004, and September 4, 2008. This guidance document has been revised in response to the Animal Drug User Fees Amendments of 2008 to reflect that now animal drug applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will only pay a supplemental animal drug application fee rate (50% of the full application fee rate) instead of a full application fee. This final guidance also corrects the contact information in regard to this document. This second revision of the guidance clarifies that the definitions of “minor use” and “minor species” were defined in 21 CFR 516.3(b).

Comments and suggestions regarding this guidance 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-0124. Comments may also be submitted electronically via the Internet at <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

For questions regarding this document, contact Diane L. Heinz, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240-276-8234, e-mail: diane.heinz@fda.hhs.gov.

Additional copies of this final guidance 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>.

Paperwork Reduction Act Public Burden Statement

According to the Paperwork Reduction Act of 1995, 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 February 28, 2011. The time required to complete this information collection is estimated to average 2 hours per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection.

**U.S. Department of Health and Human Services
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GUIDANCE FOR INDUSTRY

Animal Drug User Fees and Fee Waivers and Reductions

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this 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 appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The purpose of this document is to provide guidance on the types of fees the Food and Drug Administration (FDA or the Agency) is authorized to collect under the Animal Drug User Fee Act of 2003 (ADUFA) and how to request waivers and reductions from these fees. This guidance 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.

Enacted on November 18, 2003, ADUFA (Public Law 108-130) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and requires the 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 those fees in certain circumstances.

The Animal Drug User Fee Amendments of 2008 further amended the FD&C Act to revise and reauthorize the ADUFA program for fiscal years 2009 through 2013. Revisions to the ADUFA provisions include refinements to the ADUFA fee structure.

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. Payment of Fees Pending a Decision on a Waiver/Reduction Request

An animal drug application or supplemental animal drug application submitted by a person subject to application fees is considered incomplete and will not be accepted for filing by FDA until all fees owed by such person have been paid. Section 740(e) of the FD&C Act. FDA considers fees to be due even if the person has a request for a fee waiver or reduction pending, meaning that either FDA has not yet granted or denied the request or the requestor has asked for agency reconsideration or review of a denial. If FDA grants a waiver or reduction of a fee that has been paid, it will issue a refund as anticipated by section 740(i) of the FD&C Act.

III. Types of Fees

A. Animal Drug Application and Supplement Fee

ADUFA requires FDA to collect fees from each person who submits certain animal drug applications or supplements on or after September 1, 2003. Section 740(a)(1)(A) of the FD&C Act.

All animal drug applications submitted under section 512(b)(1) of the FD&C Act are subject to fees. Section 740(a)(1)(A)(i) of the FD&C Act. Animal drug applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act, and supplemental animal drug applications that request a change for which safety or effectiveness data are required (whether the change is to an application that had been approved under section 512(c)(1) or 512(c)(2) of the FD&C Act), are subject to fees. Sections 739(2) and 740(a)(1)(A)(ii) of the FD&C Act. Supplemental animal drug applications for which safety and effectiveness data are not required and abbreviated new animal drug applications, which are submitted under section 512(b)(2) of the FD&C Act, are not subject to application fees, under ADUFA.

If you have paid the fee for an application or supplement which was accepted for filing, but was either not approved or was withdrawn without a waiver or refund, then if you or your licensee, assignee, or successor submit an application or supplement for the same product (i.e., a reactivation), it will not be subject to an application fee. Section 740(a)(1)(C) of the FD&C Act.

An applicant may submit an amendment to an application or supplement. If you amend a pending application or supplement, the unamended application may be considered as withdrawn and the amended application considered resubmitted. 21 CFR 514.6. FDA intends to accept minor changes without considering the amended application as resubmitted.

B. Animal Drug Product Fee

Under specified circumstances, ADUFA requires FDA to collect an annual product fee for each drug product which has been submitted for listing under section 510 of the FD&C Act. Section 740(a)(2) of the FD&C Act. FDA believes that this requirement applies to approved animal drug products that have been listed or submitted for listing. ADUFA defines the term “animal drug product” to mean “each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been

approved.” Section 739(3) of the FD&C Act. The product fee is assessed to the person named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product that has been submitted for listing and who, after September 1, 2003, had pending with FDA an animal drug application or supplemental animal drug application. Section 740(a)(2) of the FD&C Act.

C. Animal Drug Establishment Fee

ADUFA requires FDA to collect an annual establishment fee from each person who 1) owns or operates, directly or through an affiliate, an animal drug establishment; 2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510 of the FD&C Act; and 3) after September 1, 2003, had pending with FDA an animal drug application or supplemental animal drug application. Section 740(a)(3) of the FD&C Act. The person is assessed an establishment fee for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures that animal drug product. Section 740(a)(3) of the FD&C Act. If an animal drug establishment listed in an application does not engage in the manufacture of the animal drug product during a particular fiscal year, an annual establishment fee will not be assessed for that fiscal year on the basis of that product. Section 740(a)(3) of the FD&C Act.

If a single establishment manufactures both animal drug products and human prescription drug products as defined in section 735(3) of the FD&C Act, such establishment shall be assessed both the animal drug establishment fee (under ADUFA) and the prescription drug establishment fee (under PDUFA). Section 740(a)(3) of the FD&C Act.

D. Animal Drug Sponsor Fee

ADUFA requires FDA to collect animal drug sponsor fees. An animal drug sponsor is defined in section 739(6) of the FD&C Act as 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 FD&C Act, or *a person who has submitted an investigational animal drug submission* that has not been terminated or otherwise rendered inactive by the Agency. A person who meets this definition within a fiscal year is assessed a fee in that fiscal year if, after September 1, 2003, the person had pending with FDA an animal drug application, a supplemental animal drug application, or an investigational animal drug submission. Section 740(a)(4) of the FD&C Act. Each sponsor will pay only one such fee each fiscal year. Section 740(a)(4) of the FD&C Act.

IV. Types of Fee Waivers and Reductions

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This section contains a summary of each of the specific provisions under which a waiver or reduction may be requested.

A. Significant Barrier to Innovation

Section 740(d)(1)(A) of the FD&C Act provides that FDA shall grant a waiver from or a reduction of one or more of the fees where FDA finds that:

the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances.

FDA interprets this provision to mean that a waiver or reduction is appropriate when: (1) the product for which the waiver is being requested is innovative, or the requestor is otherwise pursuing innovative animal drug products or technology; and (2) the fee would be a significant barrier to the requestor's ability to develop, manufacture, or market the innovative product or technology. If the request is based on limited resources, FDA believes that the most important considerations are likely to be the total ADUFA fees that the requestor would be required to pay in the fiscal year, the requestor's annual gross revenue, and all other resources available to the requestor. FDA interprets "person" in this provision to include the requestor's affiliates, as that term is defined in section 735(9) of the FD&C Act.

B. Fees Exceed Costs

Section 740(d)(1)(B) of the FD&C Act provides that FDA shall grant a waiver from or a reduction of one or more of the fees where FDA finds that:

the fees to be paid by such person will exceed the anticipated present and future costs incurred by [FDA] in conducting the process for the review of animal drug applications for such person.

In making this finding, FDA may use standard costs. Section 740(d)(2) of the FD&C Act.

FDA interprets "person" in this provision to include the requestor's affiliates, as that term is defined in section 735(9) of the FD&C Act. Therefore, when a person submits a request for a fee waiver or reduction based on the assertion that the Agency's costs associated with the process for review of animal drug applications for that person will be less than the fees, FDA intends to take into consideration all applications submitted by the entity and its affiliates. The term "process for the review of animal drug applications" is defined in section 739(8) of the FD&C Act, and includes activities related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions. In determining whether the requestor qualifies for a fees exceed costs waiver or reduction, FDA intends to compare the fees paid with the actual and anticipated costs from September 1, 2003, through September 30 of the year for which the request is made.

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To evaluate a waiver request on the basis that fees assessed exceed FDA's costs, FDA will need information that will only be available after the end of the fiscal year for which the request is made, likely by the end of March following the close of the fiscal year.

C. Free Choice Feeds

Section 740(d)(1)(C) of the FD&C Act provides that FDA shall grant a waiver from or a reduction of one or more of the fees where FDA finds that:

the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation)).

Thus, FDA will waive or reduce fees when an application or supplement is intended solely to provide for use of the animal drug in free-choice medicated feed. For the purpose of this provision, FDA intends to define free-choice medicated feeds consistent with 21 CFR 510.455(a) as:

The free-choice administration of animal drugs in feeds involves feeds that are placed in feeding or grazing areas and are not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Such methods of administering drugs include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements ("lick tank" supplements) containing one or more animal drugs.

D. Minor Use or Minor Species

Section 740(d)(1)(D) of the FD&C Act provides that FDA shall grant a waiver from or a reduction of one or more of the fees where FDA finds that:

the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication.

For the purpose of this provision, FDA defines the term "minor use" in 21 CFR 516.3(b): the intended use of a drug in a major species for an indication that occurs infrequently and only in a small number of animals or in limited geographic areas and in only a small number of animals annually.

Likewise, for the purpose of this provision, FDA defines the term "minor species" in 21 CFR 516.3(b): animals, other than humans, that are not major species; that is, animals other than cattle, horses, swine, chickens, turkeys, dogs and cats.

The Agency intends to waive or reduce sponsor and application fees only if the application provides exclusively for a new minor species or minor use indication. The Agency intends to waive or reduce the product fee only if the animal drug product is exclusively labeled for minor species or minor use indications. The Agency intends to waive or reduce the establishment fee only if the establishment manufactures products exclusively for minor species or minor use indications.

E. Small Business

Section 740(d)(1)(E) of the FD&C Act provides that FDA shall grant a waiver from or a reduction of one or more of the fees where FDA finds that:

the sponsor involved is a small business submitting its first animal drug application to [FDA] for review.

A "small business" is one that has fewer than 500 employees, including employees of affiliates. Section 740(d)(3)(A) of the FD&C Act. Because section 740(d)(3)(B) states that FDA shall waive the application fee for the first animal drug application submitted, FDA believes that the provision requires a waiver of the entire application fee rather than a reduction, and that the provision pertains to application fees but not to any other type of animal drug user fee. The waiver applies only to the first animal drug application that the small business or its affiliate submits for review. Section 740(d)(3)(B) of the FD&C Act. FDA believes this means the first application the small business ever submits, regardless of whether it was submitted before or after ADUFA was enacted.

A person who applies for a waiver under this section must certify its qualification for the waiver. Section 704(d)(3)(C) of the FD&C Act. ADUFA requires FDA to periodically publish in the Federal Register a list of persons making such certifications. Section 740(d)(3)(C) of the FD&C Act.

V. Procedures and Timing for Requesting Fee Waivers or Reductions

This section of the guidance document describes the procedures that FDA recommends for submitting a fee waiver or reduction request, and the information that the Agency believes it needs from a person to determine whether it can grant the request for a fee waiver or reduction. Adherence to these procedures will help to minimize time-consuming efforts by the Agency to obtain additional necessary information, and will enable the Agency to grant fee waivers or reductions to qualifying persons in a timely manner. Please note that you must submit a written request to the Agency for a waiver or reduction not later than 180 days after the fee is due.

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Section 740(i) of the FD&C Act. FDA does not intend to consider any requests made later than 180 days after the fee is due.

A. Procedures Applicable To All Requests for Waivers or Reductions

1. Submitting a Waiver or Reduction Request

Because waivers and reductions apply to specific fees due for a specific application or fiscal year, new requests should be submitted for each application or fiscal year. The request must be submitted in writing. Section 704(i) of the FD&C Act. Requests for fee waivers and reductions, other than those made on the basis that fees exceed costs, will be reviewed and granted or denied by FDA's Center for Veterinary Medicine (CVM) ADUFA Waiver Officer. Requests for waivers made on the basis that fees exceed costs will be reviewed and granted or denied by the Director of FDA's Office of Financial Management. To facilitate timely review and processing, these requests should contain the following information:

- a. The name and address of the entity requesting the waiver or reduction (requestor), including the company name and address if the requestor is an agent for the company.
- b. The name, telephone number, and e-mail address of a contact person.
- c. The specific fee or fees for which a waiver or reduction is requested, including:
 - i. *For application or supplement fees:*
 - a) the number of the NADA or supplemental NADA for which a waiver or reduction is being requested;
 - b) the trade and established names of animal drug products covered by the application; and
 - c) the date the application or supplement was submitted.
 - ii. *For product fees:*
 - a) the trade and established names of the animal drug product, its applicable National Drug Code (NDC) number, and the number of the NADA or supplemental NADA under which the product was approved;
 - b) the name of the person holding the approved application for the animal drug product;
 - c) the specific strength or potency of the product and its final dosage form; and

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- d) the product fee invoice number and invoice date, if available. A photocopy of FDA's invoice to the person may be submitted to provide this information, though you should clearly state for which specific animal drug product the fee waiver or reduction is requested.
- iii. *For establishment fees:*
- a) the name, address, and FEI/CFN number of the establishment for which the waiver or reduction is requested;
 - b) the establishment number as listed on the fee invoice, and the invoice number and date, if available. A copy of the invoice is acceptable.
- iv. *For sponsor fees:*
- a) the name and address of the animal drug sponsor requesting the waiver or reduction;
 - b) the invoice number and invoice date if available. A copy of the invoice is acceptable.
- d. If payment has been made, the date on which payment was made;
 - e. The particular grounds on which the waiver or reduction is requested (i.e., one or more of the provisions specified in section IV above); and
 - f. Information and analyses showing why the requestor believes it qualifies for the waiver or reduction.

If submitting a fee waiver or reduction request in advance of the date the fees are due, you should provide any new or updated information as soon as it becomes available.

A request for a fee waiver or reduction should be sent to:

ADUFA Waiver Officer
Office of New Animal Drug Evaluation, HFV-100
7500 Standish Place
Rockville, MD 20855

FDA will send a written acknowledgement of receipt of the waiver or reduction request to the requestor. The acknowledgement letter will include the date on which the waiver or reduction request was received, and will request any additional information the FDA believes, at the time, will be necessary to evaluate the request. The Waiver Officer will evaluate the fees exceed costs waiver or reduction request and forward the recommendation to the Director of the Office of Financial Management.

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2. Timing of a Fee Waiver Or Reduction Request

If you plan to request a waiver or reduction and wish to minimize the likelihood that you will have to pay the fee and then wait for a refund, FDA encourages you to submit your requests at least 90 days before the fees are due. For animal drug application and supplemental animal drug application fees, this would be 90 days before the expected submission of the application or supplement. For sponsor, product, and establishment fees, this would normally be by November 1 of each fiscal year because after FY 2004 these fees are due on or before January 31 of the fiscal year. This recommendation does not apply to "Fees Exceed Costs" waivers and reductions since FDA expects that it will not be able to make a decision on them until after the associated fees are due.

3. The Waiver Officer's or Office of Financial Management Director's Review of the Request

The Waiver Officer will review the waiver or reduction request and consult with relevant Agency officials as appropriate. The Waiver Officer may request additional information from, or a meeting with, the requestor during the review period. The Agency expects to notify the requestor of the Waiver Officer's decision and the reasons for it within 90 days of the receipt of a waiver or reduction request, except for Fees Exceed Costs waiver or reduction requests, which will not be decided by the Director of FDA's Office of Financial Management until approximately 6 months after the end of the fiscal year for which the waiver or reduction is requested. These time periods may vary depending on, among other things, the number of fee waiver or reduction requests submitted and whether the request contains sufficient supporting information.

4. Requesting Reconsideration of a Decision

If the Waiver Officer, or Director of FDA's Office of Financial Management in the case of fees exceed costs requests, fully or partially denies your request for a fee waiver or reduction, you may request reconsideration of that decision. FDA encourages persons to make such requests for reconsideration promptly, and suggests that they be made within 15 days of receiving the decision. A request for reconsideration should state the person's reasons for believing that the decision is in error, and should include any additional information necessary to support the person's position. The Waiver Officer or Office of Financial Management Director will issue a decision upon reconsideration, setting forth the reasons for it. A request for reconsideration is decided by the original decision maker, and is different from a request for review, which is described in the next two sections. You may, but are not required to, request reconsideration of the initial decision by the Waiver Officer or Office of Financial Management Director before seeking review of that decision.

You should send the request for reconsideration to:

CVM ADUFA Waiver Officer
Office of New Animal Drug Evaluation, HFV-100
7500 Standish Place

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Rockville, MD 20855

5. Requesting Review of the ADUFA Waiver Officer's Decision

If the ADUFA Waiver Officer denies your waiver or reduction request or denies your request for reconsideration, you may seek review by CVM's ADUFA Appeals Officer. Please note that this does not apply to fees exceed costs waiver or reduction requests. Your request for review should contain a copy of the Waiver Officer's original decision; the Waiver Officer's decision upon reconsideration, if any; and the reasons you believe the decisions are in error. The review will be based on information in the administrative file, which includes information and analyses already submitted to the Agency, as provided by 21 CFR 10.75(d).

The request for review should be sent to:

CVM ADUFA Appeals Officer (HFV-1)
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

After reviewing the request, the CVM ADUFA Appeals Officer will issue a written decision.

6. Requesting Review of the CVM ADUFA Appeals Officer's Decision or the Office of Financial Management Director's Decision

If the Director of the Office of Financial Management denies your fees exceed costs waiver or reduction request or denies your request for reconsideration, you may seek review by FDA's User Fee Appeals Officer. You may likewise seek review by FDA's User Fee Appeals Officer if the CVM ADUFA Appeals Officer upholds the ADUFA Waiver Officer's decision. Your request for review should contain a copy of the original decision, any decisions upon reconsideration or review, and the reasons you believe those decisions are in error. The review will be based only on information in the administrative file, which includes information and analyses already submitted to the Agency, as provided by 21 CFR 10.75(d).

The request for review should be sent to:

The FDA User Fee Appeals Officer (HF-3)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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After reviewing the request, FDA's User Fee Appeals Officer will issue a written decision.

B. Additional Procedures for Small Business Waiver Requests

1. Submitting the Waiver Request

In addition to the information requested in section V (A)(1) of this document, a request for a small business waiver must contain a certification that the requestor qualifies for the waiver. Section 740(d)(3)(C) of the FD&C Act. For this, we recommend that a responsible officer of the entity certify:

- a) that the entity has fewer than 500 employees, including employees of affiliates; and
- b) that this is the first animal drug application the entity or any one of its affiliates has submitted to FDA for review.

2. FDA's Review of the Waiver Request

In evaluating whether the entity meets the size criteria for the small business waiver, FDA intends to ask the Small Business Administration (SBA) to make a formal size determination under 13 CFR 121.1001(b)(6). The requestor will have to respond to information requested by the SBA in this process. If the requestor wishes to appeal SBA's determination, it should follow the procedures in 13 CFR 121.1101.

The Agency encourages requestors to time their small business waiver requests carefully to reduce the potential that the information provided as the basis of the request is no longer current when the animal drug application is submitted.

C. Additional Procedures for Significant Barrier to Innovation Waiver or Reduction Requests

In addition to the information requested in section V(A)(1) of this document, a request for a fee waiver or reduction on the basis that the fee would present a significant barrier to innovation should contain the following information:

1. a statement of what the innovation is relating to the animal drug product for which the waiver is being requested, or other animal drug products or technologies the requestor is pursuing);
2. an explanation of why the requestor believes it is innovative;

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3. an analysis of why the fee or fees would present a significant barrier to the requestor's ability to develop, manufacture, or market the innovative product or technology; and
4. if the request is based on limited resources:
 - a. an estimate of the total fees that the requestor, including its affiliates, would be required to pay in the fiscal year; and
 - b. the annual gross revenues and all other resources available to the requestor, including its affiliates.

D. Additional Procedures for Fees Exceed Costs Waiver or Reduction Requests

In addition to the information requested in section V(A)(1) of this document, a request for a fee waiver or reduction on the basis of fees exceeding costs should include a list of affiliates, as defined in section 735(9) of the FD&C Act. The information will be used to estimate the fees paid and the anticipated costs. For each affiliate on the list, you should include the name, address, and phone number of the affiliate's counsel or head of regulatory affairs so that FDA may contact the affiliate if necessary in reviewing the request.

If a waiver or reduction is also requested under other provisions of ADUFA, then FDA intends to evaluate the other waiver or reduction requests first. Only if it denies the other waiver or reduction request(s) would the Agency review the fees exceed costs request.