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Animal Generic Drug User Fees and Fee Waivers and Reductions

Guidance for Industry

This version of the guidance replaces the version made available May 2009. This revision incorporates a new user fee pursuant to the Animal Generic Drug User Fee Amendments of 2023.

Submit comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2009-D-0189.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, and may be viewed on the Internet at https://www.fda.gov/animal-veterinary, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
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Table of Contents

Contains Nonbinding Recommendations

Animal Generic Drug User Fees and Fee Waivers and Reductions

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The Animal Generic Drug User Fee Act (AGDUFA) (Public Law 110-316), originally signed into law in 2008 and reauthorized in 2013 (AGDUFA II), 2018 (AGDUFA III), and 2023 (AGDUFA IV), was designed to enhance the performance of the generic new animal drug review process and enable the FDA to more efficiently ensure that generic new animal drug products are safe and effective. AGDUFA IV amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require the FDA to assess and collect user fees for certain abbreviated new animal drug applications, products, and sponsors. It further requires FDA to assess and collect user fees for certain submissions related to generic new animal drugs. It also authorizes the Agency to grant a waiver from or a reduction of those fees in certain circumstances.

The purpose of this document is to provide guidance on the types of fees the FDA is required to collect under AGDUFA and how to request a waiver or a reduction of these fees. This guidance describes the types of fees; FDA's current thinking on how it implements the generic new animal drug user fee provision of AGDUFA; the type of fee waiver or reduction available; 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.

In general, FDA's guidance documents 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. Types of Fees

A. Abbreviated Application Fee

AGDUFA requires FDA to collect fees from each person who submits certain abbreviated applications for generic new animal drugs on or after July 1, 2008. Section 741(a)(1)(A) of the FD&C Act.

All original abbreviated new animal drug applications submitted under section 512(b)(2) of the FD&C Act are subject to fees. Supplemental abbreviated applications for generic new animal drugs are not subject to application fees under AGDUFA. Sections 741(a)(1)(A) and 741(k)(1) of the FD&C Act.

Exceptions:

- If you submit an abbreviated application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (relating to certain combination animal drugs) on or after October 1, 2013, the application is subject to a fee equal to 50 percent of the amount of the abbreviated application fee. Section 741(a)(1)(C)(ii) of the FD&C Act.

- If you have paid the fee for an abbreviated application 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 submits an application for the same product (i.e., a reactivation), it will not be subject to an application fee. Section 741(a)(1)(C)(i) of the FD&C Act.

An applicant may submit an amendment to an application. At its discretion, the Agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or submission for which FDA has requested a minor amendment. If a pending application is amended with significant changes, the amended application may be considered resubmitted, thereby effectively resetting the clock to the date FDA received the amendment. FDA intends to accept minor changes without considering the amended application as resubmitted.

B. Generic New Animal Drug Product Fee

Under specified circumstances, AGDUFA requires FDA to collect an annual generic new animal drug product fee for each drug product which has been submitted for listing under section 510 of the FD&C Act. Section 741(a)(2) of the FD&C Act. AGDUFA defines the term "generic new 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 abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved." Section 741(k)(6) of the FD&C Act. The product fee is assessed to the person named as the applicant in an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug for a generic new animal drug product that has been submitted for listing and who, after September 1, 2008, had pending with FDA an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug. Section 741(a)(2) of the FD&C Act. Generic new animal drug products that were approved and listed before September 1, 2008, are subject to generic new animal drug product fees once the sponsor has an abbreviated application or supplemental abbreviated application pending after September 1, 2008.

C. Generic New Animal Drug Sponsor Fee

AGDUFA requires FDA to collect generic new animal drug sponsor fees. A generic new animal drug sponsor is defined in section 741(k)(7) of the FD&C Act as either an applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant or a person who has submitted an investigational submission for a generic new animal drug 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, 2008, the person had pending with FDA an abbreviated application for a generic new animal drug, a supplemental abbreviated application for a generic new animal drug, or an investigational submission for a generic new animal drug. Section 741(a)(3) of the FD&C Act.

Each sponsor will pay only one such fee each fiscal year, as follows (section 741(a)(3)(B) of the FD&C Act):

- 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year for an applicant with more than 6 approved abbreviated applications.
- 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year for an applicant with more than 1 and fewer than 7 approved abbreviated applications.
- 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year for an applicant with 1 or fewer approved abbreviated applications.

D. Generic Investigational New Animal Drug (JINAD) File Fee

AGDUFA IV amended the FD&C Act to require FDA to collect a fee for each person that submits a request to establish a generic investigational new animal drug (JINAD) file on or after October 1, 2023. Section 741(a)(4)(A)(i) of the FD&C Act. The term "request to establish a generic investigational new animal drug file" means the submission to FDA of a request to establish a generic investigational new animal drug file to contain investigational submissions for a generic new animal drug. Section 741(k)(12) of the FD&C Act. The fee is due upon submission of the request to establish the JINAD file. Section 741(a)(4)(B)(i) of the FD&C Act.

AGDUFA IV also amended the FD&C Act to require FDA to collect a fee for each person's first submission on or after October 1, 2023, to an existing (established prior to October 1, 2023) JINAD file. Section 741(a)(4)(A)(ii) of the FD&C Act. FDA intends to assess a fee only for the first data (or "P") submission to the Bioequivalence (BE) or Chemistry, Manufacturing, and Controls (CMC) technical sections of the JINAD file. The Agency has selected P submissions to the BE or CMC technical sections as the basis for assessing this fee because P submissions to these sections consistently entail the substantial use of FDA review hours during the phased review process. The fee is due upon the first P submission to the JINAD file on or after October 1, 2023. Section 741(a)(4)(B)(ii) of the FD&C Act.

EXCEPTIONS:

- If a person makes a submission to a JINAD file to terminate that file, the person shall not be subject to a fee.
- If a person makes a submission to a JINAD file to transfer that file to a different generic new animal drug sponsor, the person shall not be subject to a fee.

(Section 741(a)(4)(C)).

III. Determining Whether You are Subject to the Generic New Animal Drug Sponsor Fee

Section 741 of the FD&C Act requires FDA to assess and collect generic new animal drug sponsor fees. You are subject to sponsor fees if you: (1) meet the definition of a generic new animal drug sponsor within a fiscal year; and (2) after September 1, 2008, had pending before the Secretary an abbreviated application for a generic new animal drug, a supplemental abbreviated application for a generic new animal drug, or an investigational submission for a generic new animal drug. (Section 741(a)(3) of the FD&C Act). This two-part test is discussed in more detail below.

A. Determining whether you are a generic new animal drug sponsor.

You are a "generic new animal drug sponsor" if you are either:

- An applicant named in an abbreviated application for a generic new animal drug that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary; or

- A person who has submitted an investigational submission for a generic new animal drug that has not been terminated.

(Section 741(k)(7) of the FD&C Act).

Abbreviated application for a generic new animal drug

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

Investigational submission for a generic new animal drug

An "investigational submission for a generic new animal drug" is either:

- The filing of a claim for an investigational exemption under 512(j) for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated 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 the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

(Section 741(k)(8) of the FD&C Act).

FDA will establish a generic investigational new animal drug (JINAD) file no later than at the time a sponsor is required by 21 CFR 511.1(b)(4) to submit a Notice of Claimed Investigational Exemption. Thus, the existence of a JINAD will enable FDA to identify those persons who meet the definition of a generic new animal drug sponsor. The existence of the JINAD 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 a generic investigational product will meet the definition of an "investigational submission for a generic new animal drug." In general, FDA does not consider submissions requesting only administrative actions or asking general questions to be investigational submissions for generic new animal drugs. For example, submissions asking whether a product under development is a new animal drug subject to FDA regulation, or submissions asking about FDA's administrative process for submitting a "Notice of Claimed Investigational Exemption for a New Animal Drug" or submitting an ANADA, by themselves, are not generic investigational animal drug submissions. However, if you wish to discuss generic investigational or submission requirements and provide advance materials that relate to the safety or effectiveness of the generic new animal drug for FDA to review, FDA would likely establish a JINAD file for these materials and you would be considered a generic new animal drug sponsor.

FDA does not intend to consider you a generic new animal drug sponsor if:

- You withdraw all of your ANADAs; and
- All of your JINAD files are either terminated, pursuant to 21 CFR 511.1(d), or are otherwise rendered inactive; or
- All of your applications and files are sold to another party.

Note that if a sponsor withdraws an ANADA for a listed new animal drug and the manufacturer is no longer manufacturing, preparing, propagating, compounding, or processing that drug for commercial distribution, the sponsor must update the listing regarding the discontinuance. 21 CFR 207.30(a)(2).

FDA intends to render inactive a JINAD file if it receives a request from the generic new animal drug sponsor to close the JINAD file and the request states that the sponsor has ceased all investigations and recalled or destroyed all unused supplies of the generic new animal drug. FDA asks that your request to close a JINAD file include a waiver of a right to a hearing.

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

B. Determining whether you have an abbreviated application for a generic new animal drug, a supplemental abbreviated application for a generic new animal drug, or an investigational submission for a generic new animal drug pending before FDA after September 1, 2008.

The terms "abbreviated application for a generic new animal drug" and "investigational submission for a generic new animal drug" are explained above. A "supplemental abbreviated application for a generic new animal drug" is:

- A request to the Secretary to approve a change in an approved abbreviated application.

An application was "pending after September 1, 2008," if:

- It was accepted for filing after September 1, 2008; or
- It was accepted for filing before September 1, 2008, and it is still under review after that date.

Likewise, an investigational submission for a generic new animal drug, also referred to as a JINAD, was "pending after September 1, 2008," if:

- FDA established a JINAD file for the generic new animal drug sponsor after September 1, 2008;
- The generic new animal drug sponsor filed, after September 1, 2008, information to support the approval of a supplemental abbreviated application for a generic new animal drug in the event of its filing; or
- The generic new animal drug sponsor submitted, before September 1, 2008, information to support the approval of an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug in the event of their filing and the submission had not been completely processed prior to September 1, 2008.

Thus, FDA will not consider a JINAD file to be pending after September 1, 2008, if the sponsor established the file prior to that date but there is no data or information pending for review as of that date and the sponsor 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 information in support of the approval of the generic new animal drug, such as a request to terminate the JINAD file, to be an investigational submission for a generic new animal drug.

IV. Fee Waiver or Reduction

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

Minor Use or Minor Species

Section 741(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 generic new animal drug 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 in only 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 the JINAD file fee only if the JINAD file is for a generic new animal drug intended exclusively for a minor species or minor use indication. The Agency intends to waive or reduce application fees only if the application is for a generic new animal drug intended exclusively for a minor species or minor use indication. The Agency intends to waive sponsor fees only if the sponsor's approved and pending applications are exclusively for minor species or minor use indications. The Agency intends to waive or reduce the product fee only if the animal drug product is labeled exclusively for a minor species or minor use indication.

V. Procedures and Timing for Requesting Waivers or Reductions of Fees

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 requests you submit 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 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 no later than 180 days after the fee is due. Section 741(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

To qualify for consideration for a waiver or reduction of any fee, a person must submit a written request for the waiver or reduction not later than 180 days after the fee is due. Section 741(i) of the FD&C Act. Requests for fee waivers and reductions will be reviewed and granted or denied by FDA's Center for Veterinary Medicine (CVM) AGDUFA Waiver Officer. 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:

d. ***For abbreviated application fee*:**

1) the number of the ANADA (if available) for which a waiver or reduction is being requested;

2) the trade and established names of animal drug products covered by the application; and

3) the date the application is to be/was submitted.

e. ***For one-time JINAD file fee:***

1) The established name of the animal drug product(s) covered by the file

2) The Reference Listed New Animal Drug products(s) covered by the file

3) The number of the JINAD file (if available) for which a waiver or reduction is being requested; and

4) the date the JINAD file is to be/was opened.

f. ***For generic new animal drug product fee(s):***

1) the trade and established names of the generic new animal drug product, its applicable National Drug Code (NDC) number, and the number of the ANADA or supplemental ANADA under which the product was approved;

2) the name of the person holding the approved application for the generic new animal drug product;

3) the specific strength or potency of the product and its final dosage form; and

4) 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 generic new animal drug product the fee waiver or reduction is requested.

g. ***For generic new animal drug sponsor fee:***

1) the name and address of the generic new animal drug sponsor requesting the waiver or reduction;

2) the invoice number and invoice date if available. A copy of the invoice is acceptable.

h. If payment has been made, the date on which payment was made;

i. The particular grounds on which the waiver or reduction is requested (i.e., the provision specified in section IV above); and

j. 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 written request for a fee waiver or reduction can either be: (1) a paper submission sent to:

Food & Drug Administration
Center for Veterinary Medicine
Document Control Unit (HFV-199)
MPN 2, E150
Attention: AGDUFA Waiver Officer
12225 Wilkins Avenue

or (2) an electronic submission via eSubmitter.[1]

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 the application fee, this would be 90 days before the expected submission of the application. For sponsor and

[1] CVM eSubmitter Resource Center | FDA

product fees, this would normally be by November 1st of each fiscal year because after FY 2009 these fees are due on or before January 31st of the fiscal year.

The Waiver Officer'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. 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.

Requesting Reconsideration of a Decision

If the Waiver Officer 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 will issue a decision on 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 before seeking review of that decision.

You should send the written request for reconsideration as either a paper submission to:

Food & Drug Administration
Center for Veterinary Medicine
Document Control Unit (HFV-199)
MPN 2, E150
Attention: AGDUFA Waiver Officer
12225 Wilkins Avenue
Rockville, MD 20852

or as an electronic submission via eSubmitter.

Requesting Review of the AGDUFA Waiver Officer's Decision

If the AGDUFA Waiver Officer denies your waiver or reduction request or denies your request for reconsideration, you may seek review by CVM's AGDUFA Appeals Officer. Your request for review should contain a copy of the Waiver Officer's original decision; the Waiver Officer's decision on 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.

You should send the written request for review as either a paper submission to:

Food & Drug Administration
Center for Veterinary Medicine
Document Control Unit (HFV-199)
MPN 2, E150
Attention: ADUFA Waiver Officer
12225 Wilkins Avenue
Rockville, MD 20852

or as an electronic submission via eSubmitter.

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

Requesting Review of the CVM AGDUFA Appeals Officer's Decision

If the CVM AGDUFA Appeals Officer upholds the AGDUFA Waiver Officer's decision, you may seek review by FDA's User Fee Appeals Officer. Your request for review should contain a copy of the original decision, any decisions on 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.

The written request for review should be sent to

The Office of the Chief Scientist
FDA White Oak Campus - Building 1
10903 New Hampshire Ave
Silver Spring, MD 20993

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

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

An abbreviated application for a generic new animal drug, an investigational submission for a generic new animal drug, or a request to establish a JINAD file submitted by a person subject to fees under section 741(a) of the FD&C Act shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under section 741 of the FD&C Act by 30 days after the date upon which they are due. Section 741(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 741(i) of the FD&C Act.