#183

Guidance for Industry

Animal Drug User Fees: Fees Exceed Costs Waiver/Reduction

FINAL GUIDANCE

This guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver/reduction provision.

Comments and suggestions regarding the document should be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov/. All comments should be identified with the Docket No. 2006D-0301.

For questions regarding this document, contact Steven Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855, 240-276-8300, e-mail: steven.vaughn@fda.hhs.gov.

Additional copies of this 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/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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GUIDANCE FOR INDUSTRY

Animal Drug User Fees: Fees Exceed Costs Waiver/Reduction[1]

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

Enacted on November 18, 2003, the Animal Drug User Fee Act (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.

FDA issued Guidance for Industry #170 to provide guidance on the types of fees the Food and Drug Administration (FDA) is authorized to collect under ADUFA and how to request waivers and reductions from these fees. This guidance further explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision. Procedures may be updated in the future to reflect changes in Agency processes or changes in the law.

Please note that you must submit a written request to the Agency for a waiver/reduction, including under the fees exceed costs waiver provision, no later than 180 days after the fee is due (section 740(i) of FD&C Act). See Guidance #170 Section V for additional information about the procedures and timing for requesting fee waivers and reductions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes 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. Standard Costs

To determine eligibility for a fee waiver or reduction under section 740(d)(1)(B) of the FD&C Act, FDA must determine the anticipated present and future costs in conducting the process for the review of animal drug applications for the person requesting the waiver. 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

[1] This guidance has been prepared by the Office of New Animal Drug Evaluation in the Center for Veterinary Medicine at the Food and Drug Administration.

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. Section 740(d)(2) of the FD&C Act states that in making this finding the Secretary may use standard costs.

Standard costs for various components of the animal drug review process for each fiscal year are developed by FDA.

A. Standard Costs Calculation

FDA developed standard costs to represent anticipated present and future costs to complete a review of an application or phased review of an application. Three general categories of review of animal drug applications/submissions exist: Investigational New Animal Drug Submission, New Animal Drug Application, and Supplemental New Animal Drug Application. FDA's cost analysis, however, clearly showed great variation within these categories in certain cases. Therefore, standard costs per unit were developed for eight categories. These eight categories are outlined below:

Submission Type
Investigational New Animal Drug (INAD) - Environmental
INAD - Non-Food Animal Safety and Efficacy
INAD – Food Animal Safety and Efficacy
INAD – Manufacturing
INAD – Human Food Safety
Administrative New Animal Drug Application (NADA)*
Supplemental NADA – with Safety and/or Efficacy Review
Supplemental NADA – Other without Safety and/or Efficacy Review

* Administrative NADA – this includes NADAs with minor review work.

B. Anticipated Costs

Investigational New Animal Drug Submissions (INADs) - INAD submissions included in each of the sub-processes above represent technical sections that normally would be completed prior to the submission of an NADA. When the sponsor submits an investigational animal drug submission after September 1, 2003, FDA intends to anticipate that all required technical sections will be submitted in the future as well as the NADA, thus the standard costs is the total costs for review of all the technical sections expected to be submitted and the NADA itself. For information on what constitutes an "investigational animal drug submission," please refer to Guidance for Industry #173, Animal Drug Sponsor Fees under the Animal Drug User Fee Act (ADUFA).

C. Applying Standard Costs to the Person Applying for the Waiver

After receiving a timely-submitted fees exceed costs waiver request, which is due no later than 180 days after the fee is due, FDA compiles a complete list of the submissions pending on or received since September 1, 2003 that meet the definition of "animal drug application", 'investigational animal drug submission" or "supplemental new animal drug application" as contained in the Act.

Applications/submissions not meeting this definition are not included in the list. Then FDA assigns a standard cost to each qualifying submission. FDA intends to include costs for reviewing applications submitted by affiliates of the waiver requestor (see Guidance #170, section IV.B.). As explained in the previous section, if FDA receives an INAD submission, it intends to use this as a basis for anticipating that other required components have been/will be submitted, culminating in the submission of a new animal drug application for either a food-producing or a non-food-producing animal. The sum of all of these standard costs for each separate INAD/NADA represent FDA's estimate of its cost associated with reviewing applications submitted by the waiver requestor and its affiliates. An example of this calculation is provided in Attachment 1 (Some special considerations apply to applications pending [received prior to September 1, 2003] on September 1, 2003, and to investigational new drug submissions submitted prior to September 1, 2003. These are explained separately below.)

As stated in Guidance #170, section IV.B. 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. Without this affiliate information a firm's request for a waiver of fees under the fees exceeds the costs provision of the Animal Drug User Fee Act will likely be denied because we will not have complete information in order to process the request.

The Act defines affiliate to mean "a business entity that has a relationship with a second business entity if, directly or indirectly – (A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has the power to control, both of the business entities." See section 735(9) of the FD&C Act.

D. Waiver Determination

From its records FDA will calculate the total of all ADUFA fees (application, product, sponsor, establishment) paid or payable by the applicant and by each of its affiliates, since the beginning of ADUFA on September 1, 2003 (excluding fees previously waived or refunded). If the anticipated present and future costs exceed total fees paid, then the waiver request will be denied. See section 740(d)(1)(B) of the FD&C Act. If fees paid exceed the anticipated present and future costs, then FDA intends to refund the amount of fees paid in excess of standard costs. 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 requests would the Agency review the fees exceed costs request.

E. Special Considerations

For any submission received after September 1, 2003, the estimated incurred costs associated with the submission will be 100 percent of the standard costs for that category of submission in the fiscal year it was submitted. By applying 100% of these costs, whether or not action on the application is completed, FDA is complying with the statutory direction to include "future costs" in its cost estimation.

For submissions submitted prior to September 1, 2003, some review may still be on-going on or after September 1, 2003. Based on CVM's estimates of the average length of various review processes, fractional standard costs have been developed to represent the portion of the review still going on after

September 1, 2003. The following table shows the percent of standard costs that FDA intends to apply to each submission sub-process, based on the year the initial submission was received. For example, in the chart below, for a waiver request submitted in FY 2004, if an INAD HFS submission was received in 1996, an estimated 6.3% of the work still remains to be completed in FY 2004.

Fiscal Year of Receipt of First Submission of the Sub-process	INAD Envir.	INAD NF S&E	INAD Food S&E	INAD Mfg	INAD HFS	Administrative NADA	Supp. S&E	Supp. Other
FY 96					6.3%			
FY 97					18.8%			
FY 98					31.3%			
FY 99					43.8%			
FY 00					56.3%			
FY 01		16.7%	16.7%		68.8%			
FY 02		50%	50%	25%	81.3%			
FY 03	50%	83.3%	83.3%	75%	93.4%	50%	50%	50%
FY 04	100%	100%	100%	100%	100%	100%	100%	100%

For INAD Human Food Safety (HFS), FDA has adopted the assumption that an average INAD HFS review spans 8 years; for INAD Safety and Efficacy (S&E) submission (whether Food or Non-Food (NF)), FDA has adopted the assumption that on average the review span is 3 years; for INAD Manufacturing (Mfg) FDA has adopted the assumption that on average the review span is 2 years; and for INAD Environmental, NADA's, and Supplementals FDA has adopted the assumption that the average span for review is 1 year. For submissions submitted prior to these time spans no costs are allocated.

In addition, as discussed above, for INAD submissions FDA assumes that the remaining required technical sections and the NADA itself will be submitted in the future and thus will incur the full costs of them. For example, under this guidance if prior to September 1, 2003 a firm has submitted for a food animal approval the INAD Human Food Safety, INAD Food Animal S&E and INAD Manufacturing technical sections, FDA will apply the pro-rata charge based on the year those submissions were received (see chart above). However, FDA also assumes that the remaining required technical sections – INAD Environmental and Administrative NADA– will be submitted in the future thus they would be applied the full costs of those technical sections. (See example in Attachment 1)

See Attachment 1 – Sample Cost Calculation Hypothetical Firm A

Attachment 1 – Sample Cost Calculation
Hypothetical Firm A

ADUFA Fees Exceed Cost Summary

(In thousands)

INAD-Human Food Safety

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	standard cost
1996	6.3%		0.00		
1997	18.8%	1	.188		
1998	31.3%		0.00		
1999	43.8%		0.00		
2000	56.3%		0.00		
2001	68.8%		0.00		
2002	81.3%		0.00		
2003	93.4%		0.00		
Prior to FY 04		1	.188	1012.50	190.35
2004	100.0%		0.00	1012.50	0.00
Future Cost			0.00	1012.50	0.00
Cumulative Cost					190.35

INAD-Safety and Efficacy Food Animals

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	standard cost
2001	16.7%	1	.167		
2002	50.0%		0.00		
2003	83.3%		0.00		
Prior to FY 04		1	.167	948.70	158.44
2004	100.0%		0.00	948.70	0.00
Future Cost			0.00	948.70	0.00
Cumulative Cost					158.44

INAD-Safety and Efficacy Non Food Animals

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	standard cost
2001	16.7%	0	0.00		
2002	50.0%		0.00		
2003	83.3%		0.00		
Prior to FY 04		0	0.00	937.90	0.00
2004	100.0%		0.00	937.90	0.00
Future Cost			0.00	937.90	0.00
Cumulative Cost					0.00

INAD-Environmental

fiscal year	% of work remaining	applications/submissions received	current work units	standard cost/unit	standard cost
2003	50.0%		0.00		
Prior to FY 04			0.00	26.80	0.00
2004	100.0%		0.00	26.80	0.00
Future Cost		1	1.00	26.80	26.80
Cumulative Cost					26.80

INAD-Manufacturing

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	Standard Cost
2002	25.0%	1	0.25		
2003	75.0%		0.00		
Prior to FY 04		1	0.25	213.80	53.45
2004	100.0%		0.00	213.80	0.00
Future Cost			0.00	213.80	0.00
Cumulative Cost					53.45

Administrative NADA (this includes NADA's with minor review work)

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	standard cost
2003	50.0%		0.00		
Prior to FY 04			0.00	170.90	0.00
2004	100.0%		0.00	170.90	0.00
Future Cost		1	**1.00**	170.90	170.90
Cumulative Cost					170.90

Supplement-Safety and Efficacy

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	Standard Cost
2003	50.0%		0.00		
Prior to FY 04			0.00	93.20	0.00
2004	100.0%		0.00	93.20	0.00
Future Cost			0.00	93.20	0.00
Cumulative Cost					0.00

Supplement-Other

fiscal year	% of work remaining	applications/ submissions received	current work units	standard cost/unit	standard cost
2003	50.0%		0.00		
Prior to FY 04			0.00	15.10	0.00
2004	100.0%		0.00	15.10	0.00
Future Cost			0.00	15.10	0.00
Cumulative cost					0.00

Fees Paid

Fiscal Year	Sponsor	Product	Establishment	Application	Total
2004	15.45	0	23.95	0	39.40
Cumulative Fees Paid	15.45	0	23.95	0	39.40

Total ADUFA

Fiscal Year	total cost	fees paid	fees less cost	
Previous to FY 2004	402.23			
2004	0	39.40		
Future Cost	197.70			
Cumulative Cost	599.93	39.40	560.53	**No Refund**

In the above example, if the total of all fees paid by Firm A and its affiliates exceeded $599,930 then FDA would refund the amount of fees paid in excess of $599,930. Since in this example the fees paid by Firm A are less than the total cost, Firm's A waiver request will be denied.

The standard costs for each year will be published on CVM's web page.