
Guidance for Industry

Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Financial Management
June 1999
User Fees**

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Table of Contents

I.	INTRODUCTION	1
II.	BACKGROUND	1
III.	PROCEDURES	1
	A. Developing Standard Costs	1
	B. Applying Standard Costs to the Person Requesting the Waiver	3
	C. Determining the Waiver	3
	D. Special Considerations	4
	Attachment 1 — Sample Cost Calculation	6

GUIDANCE FOR INDUSTRY¹

Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act

I. INTRODUCTION

This document is intended to provide guidance to industry on the procedures adopted by the Food and Drug Administration (FDA) to determine eligibility for waivers or refunds of user fees collected under the Prescription Drug User Fee Act (PDUFA), as amended, on the basis that fees paid exceed the costs the FDA incurred in reviewing submissions (21 U.S.C. 379h(d)(1)(C)). This guidance provides substantially the same information as that provided in FDA's Supplement to Attachment G, *Draft Interim Guidance Document for Waivers of and Reductions in User Fees* (February 1, 1995), but it has been updated to reflect statutory changes effected by the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

II. BACKGROUND

As amended, PDUFA modifies the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and requires FDA to collect user fees from certain applicants. It also authorizes the Agency to grant a waiver or reduction of fees when the Agency finds that the fees to be paid will exceed "the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person. . . ." (the fees-exceed-the-costs waiver) (21 U.S.C. 379h(d)(1)(C)) [21 U.S.C. 379h(d)(3) prior to the passage of the Modernization Act].

To qualify for consideration of a waiver of fees due on or after October 1, 1997, an applicant must submit a written request for a fees-exceed-the-cost waiver, refund, or reduction no later than 180 days after the fee is due (21 U.S.C. 379h(I)). Waivers of fees due on or before September 30, 1997, were to have been requested in writing on or before November 21, 1998 (section 103(h) of the Modernization Act).

III. PROCEDURES

A. Developing Standard Costs

¹ This guidance has been prepared by the Office of Financial Management in the Office of Management and Systems at the Food and Drug Administration, with input from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. This guidance represents the Agency's current thinking on the fees-exceed-the-costs waiver provision under the Prescription Drug User Fee Act of 1992 as amended by the Food and Drug Administration Modernization Act of 1997. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

To determine eligibility for a fees-exceed-the-costs waiver or reduction, FDA needs to determine the anticipated present and future costs FDA has incurred or expects to incur in conducting the process for the review of human drug applications for the person requesting the waiver. In making this finding, the Secretary may use standard costs (21 U.S.C. 379h(d)(2)) [21 U.S. C. 379h(d) prior to the passage of the Modernization Act].

Standard costs for fiscal year (FY) 1993 were developed by Arthur Andersen & Co (Arthur Andersen). The report entitled "Standard Costs for the Process for the Review of Human Drug Applications As Required Under the Prescription User Fee Act" provides an explanation of how Arthur Andersen derived the costs.²

FDA has developed standard costs for subsequent years using the methodology applied by Arthur Andersen with updated expenditure and review workload data for each subsequent year. In determining standard costs, FDA first allocates the full costs of the process for the review of human drug applications among major types of submissions that require FDA review, as defined by the FD&C Act. These categories are identified at the left-hand side of the table below, with the standard costs for FY 1993 through FY 1998 shown for each submission type.

Estimates Made Pursuant to Section 736(d)(2) of the FD&C Act

Standard Costs (in thousands of dollars)

Submission Type	FY93	FY94	FY95	FY96	FY97	FY98
<i>CDER Application</i>						
IND	\$70	\$79	\$98	\$97	\$84	\$94
NDA with Clinical Data-NME	\$887	\$1,004	\$1,243	\$1,233	\$1,065	\$1,194
NDA with Clinical Data-Non-NME	\$298	\$337	\$417	\$414	\$358	\$401
NDA w/out Clinical Data	\$127	\$144	\$178	\$177	\$152	\$171
Supplement with Clinical Data	\$151	\$171	\$212	\$210	\$181	\$203
Supplement w/out Clinical Data	\$6	\$7	\$8	\$8	\$7	\$8
<i>CBER Applications</i>						
IND	\$184	\$230	\$234	\$266	\$204	\$173
BLA						\$1,118
PLA	\$1,078	\$1,345	\$1,369	\$1,560	\$1,194	\$1,016
ELA	\$177	\$221	\$225	\$256	\$196	\$167
Supplement with Clinical Data	\$561	\$700	\$713	\$812	\$622	\$529
Supplement w/out Clinical Data	\$34	\$42	\$43	\$49	\$38	\$32

² This report may be obtained from the National Technical Information Service; PB Number 94121894; (Tel) 703-605-6000.

B. Applying Standard Costs to the Person Requesting the Waiver

After receiving a timely submitted fees-exceed-the-costs waiver request, FDA compiles a complete list of the applicant's submissions pending on or received since September 1, 1992, that meet the definition of *human drug application* or *supplement* as contained in PDUFA (21 U.S.C. 379g(1) and (2)). Submissions not meeting these definitions are not included in the list. Then FDA assigns a standard cost to each qualifying submission. The sum of all of these costs represents FDA's initial estimate of its costs associated with reviewing applications submitted by the waiver applicant. An example of this calculation is provided in Attachment 1. (Some special considerations apply to applications (INDs) pending on September 1, 1992, and to investigational new drug applications submitted since September 1, 1988. These are explained separately below.)

FDA next identifies affiliates of the person applying for the waiver or reduction of fees, and makes similar calculations for each of these affiliates. In section 103(h) of the Modernization Act, Congress confirmed that the term *person* includes any affiliate of the party submitting the waiver application.

An affiliate is defined in PDUFA as “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” (21 U.S.C. 379g(9)). Accordingly, FDA's costs for reviewing applications also include costs of reviewing applications of any entity that FDA determines was an affiliate of the party submitting the waiver application on or after September 1, 1992. Although FDA communicates with the waiver applicant about potential affiliates, the Agency makes an independent determination about who is affiliated with the waiver applicant. FDA may also seek outside assistance in resolving affiliate relationship questions.

After completing the affiliates analysis, the Agency totals the costs estimated for the waiver applicant and for all of its affiliates to estimate its full costs associated with the review work for the waiver applicant.

C. Determining the Waiver

From its records FDA calculates the total of all user fees (application, product, and establishment) that have been paid or are payable by the applicant and its affiliates since September 1, 1992 (excluding fees previously waived or refunded). FDA then compares the two amounts — total costs versus total fees paid. If total costs exceed fees paid, the waiver will be denied. If fees paid exceed the costs, then FDA will waive the amount that exceeds the fees paid, up to the full amount of the waiver that was requested in writing.

D. Special Considerations

For any submission received after September 1, 1992, the estimated incurred costs will be 100 percent of the standard costs for that category of submission in the fiscal year it was submitted. By charging 100 percent 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.

1. *Submissions (Other Than INDs) Pending on September 1, 1992*

For submissions (other than INDs) that were in pending status on September 1, 1992, FDA has adopted the Arthur Andersen assumption that 50 percent of the work on the submission was completed before September 1, 1992, and the remaining 50 percent of the work was completed after that date. Therefore, for a submission received before September 1, 1992, the estimated incurred cost should be 50 percent of the total FY 1993 standard cost for that category of submission. An exception to this is old submissions with no recent activity. If a submission was originally submitted before September 1, 1982, received a not approvable or approvable letter before September 1, 1987, and has not been amended since that date, it will not be counted as a pending application for the cost estimate. If FDA issued a not approvable or approvable letter before September 1, 1992, and if the sponsor has not amended the application or supplement with a complete response, the sponsor may withdraw such application or supplement and it will not be included in the cost calculation. Note, however, if the application is resubmitted after withdrawal, the resubmission will be reassessed appropriate application fees under PDUFA, as amended.

2. *INDs Pending on September 1, 1992*

FDA has adopted the assumption that an average IND review spans 5 years.

For INDs pending on September 1, 1992:

- no costs are allocated if the IND was submitted before September 1, 1988
- costs are prorated if the IND was submitted after September 1, 1988, but before September 1, 1992

FDA has prorated the estimated incurred cost on a yearly basis. Thus, the standard incurred cost allocated to each IND depends on the date it was submitted, as shown below:

Date of IND Submission	Years of Cost Applied	% of Standard Cost
From 9/1/88 to 9/30/89	1	20% of FY 1993 Standard Cost
From 10/1/89 to 9/30/90	2	40% of FY 1993 Standard Cost
From 10/1/90 to 9/30/91	3	60% of FY 1993 Standard Cost
From 10/1/91 to 9/30/92	4	80% of FY 1993 Standard Cost
From 10/1/92 to Present	5	100% of Standard Cost for Fiscal Year of Submission

The cost for a withdrawn IND is calculated as a fraction of the standard IND cost for the fiscal year in which it was submitted. This calculation is based on the assumption that the average IND review spans 5 years (60 months). The numerator of that fraction is the number of months that elapsed from receipt of the IND until it was withdrawn, and the denominator is 60. Costs will not be prorated for IND submissions that are not withdrawn and are at FDA for less than 5 years.

Attachment 1 — Sample Cost Calculation

Hypothetical Firm A

Year	Submission Type	Standard Cost	Number of Submissions	Estimated FDA Cost
*pre-1993	Manufacturing Supplement—CDER	\$6,000	.5	\$3,000
1993	Manufacturing Supplement—CDER	\$6,000	3	\$18,000
1993	Manufacturing Supplement—CBER	\$34,000	1	\$34,000
1995	New Drug Application—New Molecular Entity	\$1,243,000	1	\$1,243,000
1996	Investigational New Drug Application—CBER	\$266,000	2	\$532,000
1996	Supplement with Clinical Data—CDER	\$210,000	1	\$210,000
1997	Product License Application—CBER	\$1,194,000	1	\$1,194,000
1997	Establishment License Application—CBER	\$622,000	1	\$622,000
Total				\$3,856,000

* Submissions (other than INDs) pending on September 1, 1992, are assigned 50 percent of the 1993 standard cost.