ATTACHMENT F
July 12, 1993

INTERIM GUIDANCE

APPLICABILITY OF USER FEES TO: (1) APPLICATIONS WITHDRAWN BEFORE FILING DECISION, OR (2) APPLICATIONS THE AGENCY HAS REFUSED TO FILE AND THAT ARE RESUBMITTED OR FILED OVER PROTEST

I. BACKGROUND

The Prescription Drug User Fee Act of 1992 (User Fee Act) provides that 50% of the user fee for each application or supplement[1] is due upon submission of the application or supplement.[2] The User Fee Act provides that if FDA does not file an application, it shall return one-half the amount paid at the time the application was submitted (i.e., 25% of the total application fee).[3] The User Fee Act provides that withdrawal of an application after the application is filed is an action that ordinarily causes the remaining 50% of the fee to be due unless all or part of the fee is waived ". . .because no substantial work was performed on such application or supplement after it was filed."[4]

Under normal administrative practices, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) evaluate original applications and supplements for fileability upon receipt and generally reach a decision either to file or to refuse to file the application within 60 days of its submission (See 21 CFR 314.101 and 21 CFR 601.2 and 601.3). The circumstances under which FDA would refuse to file an application are described in more detail in the documents "New Drug Evaluation Guidance Document: Refusal to File" and "Center for Biologics Evaluation and Research: Refusal to File (RTF) Guidance for Product License Applications (PLAs) and Establishment License Applications (ELAs)."

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[1] In this policy, "supplement" is intended also to refer to PLA amendments.

[2] Section 736(a)(1)(B)(i), 21 U.S.C. §379h(a)(1)(B)(i).

[3] Section 736(a)(1)(D), 21 U.S.C. §379h(a)(1)(D).

[4] Section 736(a)(1)(B)(ii), 21 U.S.C. §379h(a)(1)(B)(ii).

If FDA refuses to file the application, the applicant may correct the deficiencies and resubmit the application, or ask that the unamended application be filed over protest.[5]

When evaluations of fileability are made, there is often close communication between FDA review staff and applicants. During the communication, FDA staff may explicitly inform applicants that an RTF notification is or may be forthcoming or describe substantial deficiencies such that the applicant may infer that FDA currently intends to send a "refuse to file" letter to the applicant. In such cases, some applicants have withdrawn their applications before receiving an RTF letter from FDA.

The User Fee Act does not specify what fee is due if the application is withdrawn before FDA issues an RTF letter, or the application is filed over protest in its original state or with an amendment. The purpose of this interim guidance document is to describe how FDA intends to assess user fees if an application is filed over protest or withdrawn before a decision is made on its fileability.

This document is not a proposed rule or a rule. It is not binding on either FDA or sponsors, and does not create or confer any rights, privileges, or benefits for or on any person. It does, however, describe FDA's present intentions regarding how FDA intends to assess user fees if an application is filed over protest or withdrawn before a decision is made on its fileability.[6]

II. INTERIM GUIDANCE

FDA intends to assess user fees for applications withdrawn before filing, refused for filing and resubmitted, or filed over protest. If FDA refuses to file an application or it is withdrawn before filing, the agency will refund one-half of the fee submitted with the application (25% of the total fee due).

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[5] Under the CDER regulations in 21 CFR 314.101, the applicant also may amend the application and ask that it be filed over protest. This type of request to file over protest will be handled the same for user fee purposes as if an unamended application was filed over protest. At the time a refuse to file action is taken, the user fee review clock stops. It starts anew with a resubmission. If a sponsor requests that the application be filed over protest, the original user fee review clock will be reactivated minus the time between the refuse to file action and the receipt of the request to file over protest (whether the application is amended or unamended).

[6] FDA is currently considering proposing a rule governing these issues.

If the application is subsequently resubmitted or the sponsor requests that the application be filed over protest, the following principles will apply:

a. If, after withdrawing the application, the applicant resubmits the unamended application, or amends and resubmits the application, the agency will treat the resubmission as a new original application and it should be accompanied by the fees applicable to a new submission.

b. If the applicant decides to file the application over protest, the filing of the application over protest will be regarded by the agency as a new original application for user fee purposes. Therefore, it should be accompanied by the fees applicable to a new submission.

The purpose of the provision in the statute providing for a refund of only 25% of the application fee in the event of a refusal to file is twofold: 1) to encourage higher quality submissions, and 2) to reimburse FDA for the work it has performed to determine whether the application was fileable. Retention of 25% of the fee when an application that would have been refused for filing is withdrawn in anticipation of such a decision, or filed over protest after such a decision, is consistent with Congressional intent in drafting the refund provision. In each case, retention of 25% of the fee will encourage the submission of higher quality applications and compensate the agency for the work required to determine whether the application was fileable.