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**REVIEW MANAGEMENT**

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**REFUSAL TO ACCEPT APPLICATION FOR FILING  
FROM APPLICANTS IN ARREARS**

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**PURPOSE**

- To establish Center policy concerning refusal to accept applications for filing because the applicant is in arrears with respect to user fees owed the federal government. The policies established by this document are intended to standardize Center procedures for recognizing and processing applications submitted by applicants subject to user fees and for communicating to such applicants that their application(s)<sup>1</sup> have not been accepted by the Center for filing.
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**REFERENCE**

- Prescription Drug User Fee Act of 1992, Sec. 736(e), Effect of Failure to Pay Fees  
  
A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.
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**DEFINITIONS**

- **Refusal to accept for filing.** "Refusal to accept for filing" is NOT the same as "refusal to file" defined under 21 CFR 314.101. Refusal to accept for filing means that the application is not accepted by the Food and Drug Administration for purposes of reviewing the application to determine its initial suitability for filing. The Prescription Drug User Fee Act of 1992 defines this action as mandatory in situations in which an applicant is determined to be in arrears for ANY user fees owed the federal government.
  - **Being in arrears for any user fees.** An applicant will be determined to be in arrears for any prescription drug user fee owed the federal government if that
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applicant has not paid all fees by the payment due date to the satisfaction of the FDA Office of Financial Management (OFM). All fees include product fees, establishment fees, and application fees previously billed.

- An applicant will also be determined to be in arrears for user fees for a particular application if OFM has not received confirmation that an application fee has been received by the designated bank within five days of the date the application is received by FDA.
- OFM will maintain an active listing of all such applicants and payments of application fees, as well as a listing of applicants who are in arrears for establishment, product, and application fees previously billed that have not been paid, which will serve as the reference for determining whether an applicant is in arrears.

**POLICY**

- It is the general policy of the Center for Drug Evaluation and Research that human drug applications and supplements will be accepted for filing only from applicants who have paid all prescription drug user fees owed. This includes all such fees owed for the submitted application and all such fees (application, product, and establishment user fees) previously owed the federal government.
- When OFM determines that an applicant is in arrears for such owed fees, the reviewing division to which an application is submitted shall refuse to accept the application for filing.
- The one exception to this policy is when FDA determines that an application was inappropriately bundled and needs to be separated into more than one application. In these cases, the unbundled applications will be placed into review status if the submission was accompanied by the appropriate fee for a single application. OFM will separately invoice the applicant for any additional fees determined to be due.

**PROCEDURES**

- When a new application subject to prescription drug user fees is received by a review division, the responsible CSO (Consumer Safety Officer)/Project Manager (PM) shall determine immediately 1) whether OFM has classified the applicant as being in arrears; or 2) whether OFM has received confirmation that the appropriate application fee was submitted to the Bank. Mechanisms for communicating this information between OFM and the CSOs/PMs will change with time. Individual procedures for such communication will be issued from time to time as communication mechanisms change.
- If the CSO/PM determines that OFM has classified the applicant as being in arrears or that receipt of the appropriate application fee has not been confirmed by OFM within five days of receipt of the application, the CSO/PM shall notify

all members of the review team by E-mail that the applicant is in arrears and that the application will not be accepted for filing.

- The CSO/PM shall notify the applicant by telephone that the application is not being accepted for filing because of non-payment of fees and then prepare a "Refuse to Accept for Filing" letter for signature by the Division Director. (A form letter has been provided to the CSO's.) This letter will inform the applicant that the application has not been accepted for filing because OFM has determined either that the applicant is in arrears for previously billed fees, or appropriate fees for the application were not submitted, and that initial review of the application will not begin until payment of all fees due is made and confirmed by OFM.
- The reviewing division document room shall enter the Code "UN" in COMIS to signify the fact that the division refused to accept the application for filing because OFM had determined that the applicant was in arrears. Neither the regulatory review clock nor the user fee review clock will start under these circumstances.
- Normally, the application material should be held in the Document Room until OFM determines that the applicant is no longer in arrears or the appropriate application fee has been submitted. OFM will advise the Divisions when payment is made such that the applicant is no longer in arrears. When the responsible CSO/PM receives this notification, the CSO/PM shall determine which applications have not been accepted for filing because of the applicant's arrears status and shall place the applications in review status. The CSO/PM shall prepare a letter notifying the applicant that the application(s) has been accepted for determination of the application's suitability for filing **as of the date OFM notified the review Division that the applicant was no longer in arrears.** (A form letter has been provided to the CSO's). This will normally be the same day that OFM received confirmation from the bank that the fees have been paid.
- Through the same E-mail that notifies the CSO's/PM's, OFM will notify the Document Room contractor task leaders that the applicant is no longer in arrears. The contractor will file the E-mail in the appropriate application jackets to document the clock date.
- The Division Document room will update NDE/COMIS to change the status of each of the applicant's submissions to "pending." The date of OFM's E-mail to the Division CSO's/PM's and the Document Room contractor that payment had been made shall be entered in NDE/COMIS as the "clock" date of the application. The 60-day clock for determining whether the application will be refused for filing shall commence on this "clock" date. The "clock" date will start both the user fee and regulatory clocks.

**NOTE**

"Application" includes supplements to applications.