

**POLICY AND PROCEDURES**

**OFFICE OF MANAGEMENT**

**Refusal to Accept Applications for Filing From Applicants in Arrears**

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**PURPOSE**

- This MAPP establishes:
  - The Center for Drug Evaluation and Research (CDER) policy concerning refusal to accept applications for filing because the applicant and/or its affiliates are in arrears with respect to user fees owed the Federal government.
  - Standard procedures in CDER for recognizing and processing applications submitted by applicants subject to user fees, and for communicating to applicants that their applications<sup>1</sup> have not been accepted by CDER for filing.

**POLICY**

- It is the general policy of CDER that human drug applications and supplements will be accepted for filing only from applicants (including their affiliates) who have paid all prescription drug user fees owed. These fees include all such fees owed for the submitted application and all such fees (application, product, or establishment user fees) previously owed the Federal government.

<sup>1</sup> For the purposes of this MAPP, the term *application* refers to new drug applications and biologics license applications that are human drug applications (as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) and supplements to these human drug applications.

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- An applicant will be determined to be in arrears for any prescription drug user fee owed the Federal government if that applicant or its affiliate has not paid all fees by the payment due date to the satisfaction of the Office of Financial Management (OFM). All fees include product fees and establishment fees previously assessed.

An applicant also will 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 5 calendar days of the date the application is received by the Food and Drug Administration (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, or application fees previously assessed that have not been paid, which will serve as the reference for determining whether an applicant is in arrears.

- When OFM determines that an applicant is in arrears for such owed fees, the review division to which an application is submitted shall refuse to accept the application for filing.
- The one exception to this policy is when the 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 to be unbundled was accompanied by the appropriate fee for a single application. OFM will separately invoice the applicant for any additional fees determined to be due regardless of when it was discovered that the application was inappropriately bundled.<sup>2</sup>

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## PROCEDURES

- When a review division receives a new application, the responsible consumer safety officer (CSO)/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 designated bank. Mechanisms for communicating this information between OFM and the CSOs/PMs will change with time. Individual procedures for such communication will be issued 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 5 calendar days of receipt of the application, the CSO/PM shall

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<sup>2</sup> It is incumbent on the applicant to ensure that the submission is appropriately bundled and the appropriate fees are assessed for all user-fee-liable applications and supplements.

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- notify all members of the review team (e.g., by email) 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 nonpayment of fees and then prepare the applicable *Unacceptable for Filing* letter (available on the CDER Standard Templates Web site) for signature by the division director. This letter will inform the applicant that the application has not been accepted for filing because OFM has determined either that the applicant or its affiliate is in arrears for previously billed fees, or that the FDA was not notified of receipt of the appropriate fees for the application within 5 calendar days of the receipt of the submission and that initial review of the application will not begin until payment of all fees due is made and confirmed by OFM.
  - When the applicable *Unacceptable for Filing* letter is issued, the appropriate person will update the electronic database to indicate the division refused to accept the application for filing because OFM had determined that the applicant was in arrears for previously billed fees, or the appropriate application fees were not submitted. Neither the regulatory review clock nor the user fee review clock will start under these circumstances. 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 notify the review division (e.g., by email) when the appropriate application fee has been submitted, or payment has been made such that the applicant is no longer in arrears. When the responsible CSO/PM is notified, the CSO/PM shall use established procedures to notify the review team, the Document Room, and other offices or individuals, as appropriate, that the application is now acceptable for determination of filing, and is to be placed in review status.
  - In cases when an inappropriate payment is received (e.g., the incorrect fiscal year payment is submitted), the CSO/PM should contact the user fee staff for further processing instructions.
  - The CSO/PM shall prepare an *Acknowledgment of Receipt of Fees* letter (available on the CDER Standard Templates Web site) notifying the applicant that the application has been accepted for determination of the application's suitability for filing as of the date OFM received confirmation from the designated bank that the appropriate fees have been paid.
  - After notification from the CSO/PM, the Document Room will enter the appropriate decision date (*clock* date) into the electronic database, and will update the electronic database to change the status of the submission to *pending*. The

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decision date will start both the user fee and regulatory clocks, including the 60-day clock for determining whether the application will be filed.

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## REFERENCES

- Federal Food, Drug, and Cosmetic Act (FD&C Act):
  - Sections 735 and 736 — Fees Relating to Drugs
  - Section 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.”
- CDER standard templates (e.g., letters, forms) can be found on the CDER Standard Templates Web site at <http://inside.fda.gov:9003/ProgramsInitiatives/Drugs/ProjectManagement/ucm039716.htm>

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## DEFINITIONS

- **Affiliate** — Under section 735(9) of the FD&C Act, this term means a business entity that has a relationship with a second business entity if, directly or indirectly: (1) one business entity controls, or has the power to control, the other business entity; or (2) a third party controls, or has the power to control, both of the business entities.
- **Applicant** — Any person<sup>3</sup> who submits an application<sup>4</sup> or an amendment or supplement to an application to obtain FDA approval of a new drug or an antibiotic drug (21 CFR 314.3(b)) and any person who owns an approved application; or any legal person or entity who submits an application to obtain a biologics license under section 351 of the Public Health Service Act or who holds the biologics license and assumes responsibility for compliance with the applicable product and establishment standards (21 CFR 600.3(t)).

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<sup>3</sup> For the purposes of this MAPP, the term *person* includes affiliates. See the Food and Drug Administration Modernization Act of 1997, Public Law 105-115, section 103(h) (November 21, 1997).

<sup>4</sup> Abbreviated applications are **not** *human drug applications* as defined in the user fee provisions of the FD&C Act (see section 735(1)).

- **Refusal to accept for filing** — This term 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 FDA for purposes of reviewing the application to determine its initial suitability for filing. The FD&C Act defines refusal to accept for filing as mandatory in situations in which an applicant is determined to be in arrears for **any** user fees owed the Federal government.
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#### EFFECTIVE DATE

This MAPP is effective upon date of publication.