Drugs

Medical Product Activities During the Federal Government Shutdown

(*update October 4, 2013*)

This document summarizes the anticipated scope of FDA's activities beginning on October 1, 2013, and continuing until the date of enactment of an FY 2014 appropriation or Continuing Resolution for FDA (the "lapse period"). Please note that FDA's anticipated activities are subject to resource constraints on the Agency due to the lapse in appropriations and may change in the event of a protracted lapse period.

Overview

- During the lapse period, FDA activities related to medical products generally will be limited to the following:
    - Emergency work involving the safety of human life or the protection of property;
    - Criminal law enforcement work; and
    - Activities funded by carryover user fee balances, including user fee balances under the Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Amendments (GDUFA), and the Medical Device User Fee Amendments (MDUFA).
- Carryover user fee balances will be spent on activities for which the fees are authorized under PDUFA, GDUFA, or MDUFA, as applicable.
- FDA will not have legal authority to accept user fees assessed for FY 2014 until an FY 2014 appropriation or Continuing Resolution for FDA is enacted. This means that FDA will not be able to accept any regulatory submissions for FY 2014 that require a fee payment and that are submitted during the lapse period.
- We do not anticipate that the lapse in appropriations will affect our routine product review process for submissions within the scope of the PDUFA or GDUFA programs, provided that applicable fees were paid before October 1, 2013. We cannot predict whether we will experience delays in these programs in the event of a protracted lapse in appropriations.
- Due to resource constraints, certain review activities for products within the scope of the MDUFA program may be suspended during the lapse period.
- Generally, scheduled advisory committee meetings regarding the approval of, or postmarketing safety issues regarding, products within the scope of the PDUFA, GDUFA, or MDUFA programs may go forward during the lapse period, subject to . Other advisory committee meetings that can be conducted with carryover user fee balances will be handled on a case-by-case basis.

PDUFA

- During the lapse period, FDA will not accept PDUFA applications or supplements that require payment of a fee (e.g., New Drug Applications (NDAs) or certain Biologics License Applications (BLAs)), unless the FY 2014 fee was paid prior to October 1, 2013. FDA expects to continue to review PDUFA applications and supplements for which all applicable user fees were received prior to October 1.
    - For example, for an application or supplement that requires a fee, if the FY 2014 fee was received on September 30, 2013, FDA expects to review the application, even if the application or supplement itself is submitted during the lapse period.

- However, if an application or supplement was received on September 30, 2013 and the fee was received on October 1, then FDA will not review the submission, because it cannot accept the fee.

- During the lapse period, FDA will accept new regulatory submissions for which no fee is required, if the product is within the scope of the PDUFA program. These types of submissions include, for example:
  - Investigational new drugs applications (INDs)
  - Annual reports
  - Supplements to NDAs and BLAs for which clinical data with respect to safety or effectiveness are not required for approval (this includes most manufacturing and labeling supplements)
  - NDAs or BLAs that only have orphan designated indications, or a supplement for an orphan designated indication
  - Submissions that fall within the exemption for previously filed applications or supplements
  - Applications for which FDA has waived the application fee (e.g., small business waiver)
  - General correspondence

- Sponsors who have not yet paid PDUFA product or establishment fees for FY 2014 should not remit payment during the lapse period, because FDA cannot accept the fees. Sponsors will not be in arrears for FY 2014 product or establishment fees during the lapse period. The due date for these fees will be the first business day after enactment of an appropriation for FY 2014 or a Continuing Resolution for FDA.

GDUFA

- During the lapse period, FDA will not accept generic drug submissions that require payment of a fee (e.g., Abbreviated New Drug Applications (ANDAs), prior approval supplements to approved ANDAs). FDA expects to continue reviewing GDUFA applications and supplements that were submitted on or before September 30, provided that all applicable fees are paid within 20 calendar days of the due date. (FDA can continue to receive FY 2013 fees, but not FY 2014 fees, during the lapse period).
- During the lapse period, FDA will accept generic drug submissions for which no fee is required, if the product is within the scope of the GDUFA program. These types of submissions include, for example:
  - Changes Being Effected (CBE) supplements
  - Amendments
  - Annual reports
  - Applications for positron emission tomography drugs
  - General correspondence

- Sponsors who have not yet paid GDUFA facility fees for FY 2014 should not remit payment during the lapse period because FDA cannot accept the fees. Sponsors will not be in arrears for FY 2014 GDUFA facility fees during the lapse period. The due date for the facility fee is the first business day after enactment of an appropriation for FY 2014 or a Continuing Resolution for FDA.
- During the lapse period, FDA will accept Drug Master Files (DMFs), including Type II Active Pharmaceutical Ingredient (API) DMFs, intended to be referenced in generic drug applications.
- FDA will not conduct initial completeness assessments on Type II API DMFs for which the fee

has not been paid and these new DMFs will not be placed on the Available for Reference List.

- If a generic drug application references, for the first time after October 1, 2013, a Type II API DMF for which the fee has not been paid, then FDA will notify the applicant that the fee must be paid within 20 calendar days. If the fee is not paid within 20 calendar days of that notice, FDA will not receive the application. At this time, FDA has not determined what approach it will take if the 20 calendar day period expires during the lapse period.

- Type II API DMF fees should not be submitted during the lapse period because FDA cannot accept the fees. Fees that are due during the lapse period may be paid as soon as the lapse period ends.

BsUFA

- FDA does not expect to have access to BsUFA funding during the lapse period. Accordingly, FDA does not expect to perform any activities with respect to biosimilars, except for emergency work involving the safety of human life or the protection of property.
- FDA will suspend review of any pending regulatory submissions (e.g., INDs, IND amendments, biosimilar initial advisory meeting and Biosimilar Product Development (BPD) meeting requests), unless the submission is:
  - An emergency IND; or
  - An IND amendment that relates to the safety of human subjects (e.g., an IND safety report).
- The 30-day review clock for any pending, non-emergency BsUFA INDs will be suspended during the lapse period. The clock will resume when the lapse period is over.
- If a sponsor sends FDA a new regulatory submission for a biosimilar during the lapse period, FDA will not consider the submission to have been received by the agency during the lapse period. The only new BsUFA submissions that FDA will consider "received" (and proceed to review) during the lapse period are:
  - New emergency INDs; and
  - New IND amendments that relate to the safety of human subjects (during the lapse period, FDA will screen incoming IND amendments to determine if they are in this category).
- For non-emergency BsUFA INDs submitted during the lapse period, the 30-day review clock will not start until the lapse period is over.

CDER's Non-PDUFA, Non-GDUFA Drugs

- Certain drugs regulated by CDER are not within the scope of the PDUFA program; accordingly, PDUFA carryover funding is not available to carry out activities with respect to these products. These drugs include:
  - Over the Counter (OTC) drugs not associated with an NDA, ANDA or supplement (e.g., OTC monograph drugs);
  - Large volume parenteral drug products approved before September 1, 1992; and
  - Drugs that are not for commercial distribution and are sponsored by State or Federal government entities.
- During the lapse period, FDA will not perform any activities with respect to these products except for emergency work involving the safety of human life or the protection of property.

FDA will suspend review of any pending regulatory submissions (e.g., NDAs, ANDA, BLAs, and supplements).

CBER's Non-PDUFA, Non-MDUFA Biologics

- Certain biological drug products regulated by CBER are not within the scope of PDUFA. These include whole blood, blood components for transfusion, and allergenic extract products. Accordingly, PDUFA carryover funding is not available to carry out activities with respect to these products. During the lapse period, FDA will not perform any activities with respect to these products except for emergency work involving the safety of human life or the protection of property.
- FDA will suspend review of any pending regulatory submissions (e.g., INDs, IND amendments, NDAs, BLAs, supplements), unless the submission is:
    - An emergency IND; or
    - An IND amendment that relates to the safety of human subjects (e.g., an IND safety report).
- The 30-day review clock for any pending, non-emergency IND will be suspended during the lapse period. The clock will resume when the lapse period is over.
- If a sponsor sends FDA a new IND or IND amendment during the lapse period, FDA will not consider it to have been received by the agency during the lapse period. The only new INDs and IND amendments for these products that FDA will consider "received" (and proceed to review) during the lapse period are:
    - New emergency INDs; and
    - New IND amendments that relate to the safety of human subjects (during the lapse period, FDA will screen incoming IND amendments to determine if they are in this category).
- If a sponsor sends FDA a non-emergency IND during the lapse period, the 30-day review clock will not start until the lapse period is over.

MDUFA Products Regulated by CDRH and CBER

- FDA expects to continue reviewing regulatory submissions received prior to October 1, 2013. However, the Agency may suspend work on certain submission types during the lapse period due to resource constraints.
- FDA will not accept new regulatory submissions that require fee payment. These include:
    - Premarket Approvals (PMAs);
    - Product Development Protocols (PDPs);
    - Premarket Reports (PMRs);
    - original BLAs and BLA efficacy supplements for medical devices reviewed by CBER;
    - some PMA and PDP supplements (e.g., panel-track, 180-day, real-time, 30-day notice);
    - 510(k)s;
    - 513(g)s;
    - annual reports for PMAs, PDPs, and PMRs; and
    - registration information submitted under section 510 by a device establishment subject to a registration fee.
- FDA can accept and review new regulatory submissions for which no fee is required. However, the Agency may suspend work on certain submission types during the lapse period

due to resource constraints. Non-fee paying submissions include, for example:

- Humanitarian Device Exemptions (HDEs) (originals, supplements and reports)
- Investigational Device Exemptions (IDEs) (originals, supplements and reports)
- De novos
- Pre-submissions
- Special CBE supplements
- Site change supplements
- Trade name change supplements
- Post-Approval Studies (PAS) labeling or protocol change supplements
- PAS reports
- Submissions for pediatric only indications
- The first PMA submitted by a small business with gross receipts or sales of $30 million or less

Page Last Updated: 10/04/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page: