4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0901]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions--Prior Approval Supplements Under the Generic Drug User Fee Amendments of 2012; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Prior Approval Supplements Under GDUFA." The Generic Drug User Fee Amendments of 2012 (GDUFA) enables FDA to assess user fees to fund critical and measurable improvements to FDA's generic drugs program. This draft guidance is intended to assist applicants preparing to submit to FDA prior approval supplements (PASs) and amendments to PASs for abbreviated new drug applications (ANDAs). It describes FDA's performance metric goals for PASs and clarifies how FDA will handle a PAS and amendments to a PAS for an ANDA subject to the GDUFA performance metric goals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin Chacko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1673, Silver Spring, MD 20993-0002, 240-402-7924 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Prior Approval Supplements Under GDUFA." On July 9, 2012, the President signed GDUFA (Pub. L. 112-144, Title III) into law. GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry to address a growing number of regulatory challenges. GDUFA aims to ensure timely access to safe, high-quality, low-cost generic drugs. GDUFA enables FDA to assess user fees to fund critical and measurable improvements to FDA's generic drugs program and to bring greater predictability and timeliness to the review of generic drug applications.

GDUFA requires that FDA and human generic drug manufacturers meet certain commitments. In the GDUFA Commitment Letter, FDA committed to review and act on a certain percentage of PASs within a specified time period from the date of submission for receipts in fiscal years (FY) 2015-2017. The percentage of PASs that FDA has committed to review and act on varies for each fiscal year, and the deadlines for review depend on whether a PAS requires an inspection.

This draft guidance describes the performance metric goals that FDA agreed to in the Commitment Letter and clarifies how FDA will review a PAS and amendments to a PAS for an ANDA subject to the GDUFA performance metric goals. The GDUFA performance metrics described in this draft guidance only apply to ANDA applicants that submit a PAS on or after October 1, 2014. These performance metrics do not apply to new drug applications (NDAs), biologics license applications (BLAs), supplements filed for NDAs or BLAs, or changes being effected (CBE) supplements and annual report filings to NDAs, BLAs, or ANDAs.

Elsewhere in this issue of the Federal Register, FDA is publishing another draft guidance entitled "ANDA Submissions--Amendments and Easily Correctable Deficiencies Under GDUFA," which explains how the GDUFA performance metric goals apply to amendments made to ANDAs and to PASs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent the Agency's current thinking on how GDUFA relates to prior approval supplements for ANDAs. 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 and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information for supplements and amendments in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collection of information for manufacturer registration in 21 CFR part 207 has been approved under OMB control number 0910-0045. The collection of information for manufacturer compliance with current good manufacturing practices in 21 CFR part 211 has been approved under OMB control number 0910-0139.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidance/default.htm, or http://www.regulations.gov.

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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