4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0725]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions; Content and Format of Abbreviated New Drug Applications; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Content and Format of Abbreviated New Drug Applications." The guidance document is intended to assist applicants in preparing complete and high-quality original abbreviated new drug applications (ANDAs) for submission to FDA under the Federal Food, Drug, and Cosmetic Act. The guidance summarizes the statutory and regulatory requirements for ANDAs, references existing guidance documents, and incorporates additional recommendations on the content and format of ANDA submissions. This guidance describes the Common Technical Document format for human pharmaceutical product applications and specifies the information to be submitted in each section of the application.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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, Food and Drug Administration, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, email: elizabeth.giaquinto@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7268, 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--Content and Format of Abbreviated New Drug Applications." On July 9, 2012, the Generic Drug User Fee Amendments (GDUFA) was signed into law by the President to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter.

Among these obligations is FDA's commitment to performance metrics for the review of original ANDAs. For example, FDA has committed to review and act on 90 percent of original ANDA submissions within 10 months from the date of submission in Year 5 of the program, which begins on October 1, 2016.

In an effort to increase the number of original ANDAs that the Agency can receive upon initial submission and to decrease the number of review cycles required to approve an application for marketing, FDA prepared this guidance on improving the quality of original ANDA submissions. FDA is committed to providing comprehensive assistance in the early stages of the application process to ensure that an original ANDA contains all information necessary for FDA to complete its review in one review cycle.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "ANDA Submissions--Content and Format of Abbreviated New Drug Applications." 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 in 21 CFR 314.94 have been approved under 0910-0001. The collection of information in Form FDA 356h has been approved under 0910-0338. The collection of information for Form FDA 3674 has been approved under 0910-0616. The

collection of information for Form FDA 3794 has been approved under 0910-0727. The collection of information for Form FDA 3454 has been approved under 0910-0393. The collection of information for Form FDA 3455 has been approved under 0910-0396. The collection information for 21 CFR part 11, Electronic Records, has been approved under 0910-0303.

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/default.htm, or http://www.regulations.gov.

Dated: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-13641 Filed 06/11/2014 at 8:45 am; Publication Date: 06/12/2014]