4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0077 (formerly 2007D-0213)]

Guidance for Industry; Providing Regulatory Submissions in Electronic Format--Receipt Date; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Receipt Date." This guidance describes how FDA will assign receipt dates to certain submissions provided in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This document finalizes the guidance of the same name, which was issued in June 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the documents 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 (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the documents.

Submit electronic comments on the 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: Edward Hallissey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1139, Silver Spring, MD 20993, 301-796-0420; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 5515 Security Lane, rm. 5130, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Receipt Date." This guidance describes how FDA will assign receipt dates to certain submissions provided in electronic format or in physical media to CDER and CBER.

When CDER or CBER receives a submission, the receipt date may be used to determine important regulatory milestones, such as FDA's 30-day safety review cycle for an investigative new drug (IND) application. The guidance provides clarity regarding when items submitted electronically are deemed received by FDA for purposes of such milestones. Prior to issuance of this final guidance, certain submissions received through the electronic submission gateway (ESG) after 4:30 p.m. were deemed to be received on the following business day. With this final guidance, we are generally eliminating this 4:30 p.m. cut-off for submissions received through the ESG Monday through Friday. However, certain submissions received through the ESG on a weekend, Federal holiday, or on a day when the FDA office that will review the submission is

otherwise not open for business, will be assigned a receipt date corresponding to the next business day.

Occasionally, submissions in electronic format have technical deficiencies that prevent FDA from opening, processing, or archiving the submission. The guidance explains that FDA considers a technically deficient electronic submission to be not received (i.e., not present at the Agency and not under review) until all technical deficiencies are resolved.

On June 5, 2007 (72 FR 31079), FDA announced the availability of the draft version of this guidance. The public comment period closed on August 6, 2007. Several comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Those changes clarified the draft guidance and updated the document to reflect legislative provisions adopted since the draft was issued. More specifically, the final guidance generally eliminates the 4:30 p.m. cut-off for submissions received through the ESG Monday through Friday. It also provides guidance on FDA's interpretation of a provision in the Generic Drug User Fee Amendments of 2012 (GDUFA) concerning the date of submission for Type II drug master files, Abbreviated New Drug Applications (ANDAs), and amendments and supplements to ANDAs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on determining the receipt date for certain submissions in electronic format or in physical media. 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

The guidance refers to 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 guidance pertains to sponsors and applicants making regulatory submissions to FDA in electronic format for INDs, pre-market applications, including new drug applications (NDAs), ANDAs, biologics license applications (BLAs), and amendments and supplements to these applications, master files (MFs), postapproval studies (whether submitted as supplements to approved applications or otherwise), submissions related to products marketed without an approved application, and adverse event reports. The information collection discussed in the guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910-0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910-0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910-0338.

III. Comments

Interested persons may submit either electronic comments to http://www.regulations.gov or written comments regarding this document 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/DevelopmentApprovalProcess/FormsSubmissionRequirements/Electr

onicSubmissions/ucm253101.htm, http://www.regulations.gov, or http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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