

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier L. CLAWSON
DDM

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Receipt Date; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Receipt Date.” This draft guidance provides information on what FDA will consider to be the receipt date for certain submissions provided in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The receipt date of these submissions has a number of important regulatory implications. Under the draft guidance, FDA will not consider a submission to be received until it has passed a technical validation check to ensure that the submission can be opened, processed, and archived.

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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (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. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Gary Gensinger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1112, Silver Spring, MD 20993-0002, 301-796-0589; or

Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM-25), 11400 Rockville Pike, Rockville, MD 20852, 301-827-5132.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Receipt Date.” This draft guidance provides information on what FDA will consider to be the receipt date for submissions provided in electronic format to CDER and CBER. When FDA receives a submission, the receipt date is used to determine important regulatory milestones (e.g., 30-day safety review cycle for an

investigational new drug application, review performance goal date for a new drug application or biologics license application). Occasionally, however, submissions in electronic format have technical deficiencies that prevent FDA from being able to open, process, and archive them. When this occurs, FDA's review cannot begin until these technical deficiencies are corrected. To encourage sponsors to ensure that electronic submissions are free of technical deficiencies that can delay FDA review of the submission, FDA is changing its policy on the receipt date for submissions provided in an electronic format. The guidance provides that FDA will not consider a submission to be received until it has passed a technical validation check to ensure that the submission can be opened, processed, and archived.

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 determining the receipt date for submissions in electronic format. 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.

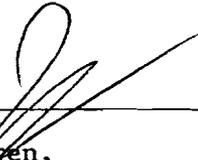
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 5/26/07
May 26, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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