

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0367]

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Certifier R. LEDESMA

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions.” This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics licensing applications (BLAs), investigational new drug applications (INDs), master files, advertising material, and promotional labeling. The submission of these documents in electronic format should improve the agency’s efficiency in processing, archiving, and reviewing them.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and

344

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Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301/594-5411, e-mail: levinr@cder.fda.gov, or

R. Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions.” This draft document provides guidance to industry regarding submission of marketing applications (NDAs, ANDAs, BLAs), INDs, and related submissions (master files, advertising, and promotional labeling) in electronic format based on the International Conference on Harmonisation Electronic Common Technical Document specification.



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 providing applications and related 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 on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

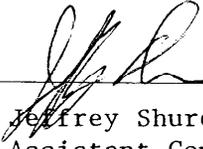
This notice contains no new collections of information. The information requested for human drug and biological products is already covered by the collection of information on postmarketing safety reporting regulations (21 CFR parts 312, 314, and 601) submitted to the Office of Management and Budget (OMB) for review and clearance. This notice announces the availability of a guidance that provides applicants with an alternative mechanism for submitting applications and related submissions to the agency.



IV. Electronic Access

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

Dated: 8/21/03
August 21, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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