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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98D–0316 and 98D–0317]

"Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)]"; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)].'' The guidance document provides information regarding the electronic submission of license applications, i.e., BLA, PLA/ELA, NDA, and supplements and amendments to those applications intended for submission to Center for Biologics Evaluation and Research (CBER). This guidance document is part of CBER's effort to develop an efficient process for electronic submissions of regulatory information relating to the development and marketing of biological products. Submissions in electronic format are voluntary.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA),

NAD-2

Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)]'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 400N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)].'' This guidance document is intended to provide a degree of uniformity for electronically submitted biologics marketing applications to assure timely review, archiving, and retrieval processes for agency reviewers, and to describe those electronic formats that CBER is currently able to support for review and archive purposes. The guidance announced in this notice finalizes the two draft guidances entitled ''Draft Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA)/Establishment License Application (ELA) to the Center for Biologics Evaluation and Research,'' and ''Draft 'Guidance for Industry:

Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's) and Data to the Center for Biologics Evaluation and Research,''' which were announced in the **Federal Register** of June 1, 1998 (63 FR 29741 and 29739, respectively). In the **Federal Register** of January 28, 1999 (64 FR 4433), FDA announced the availability of a document entitled ''Guidance for Industry on General Considerations for Providing Regulatory Submissions in Electronic Format'' which provided a list of guidance documents that are under development regarding electronic submissions, and guidance on general issues relevant to all electronic submissions.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records; electronic signatures final rule, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). FDA also established public docket number 92S–0251 to provide a permanent location for a list of the agency units that are prepared to receive electronic submissions and the specific types of regulatory records that can be accepted in electronic format (62 FR 13467, March 20, 1997). CBER will identify in this public docket any submission type that can be reviewed and archived in an electronic format as they become available. This public docket can be accessed on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm.

This guidance document represents the agency's current thinking with regard to regulatory 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch 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 http://www.fda.gov/cber/guidelines.htm.

Dated: 11-5-99
November 5, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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