part 312). Part 312 must be followed in the preparation of any IND or eIND application.

This draft guidance document represents the agency's current thinking with regard to the eIND applications for biological products. 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 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. Request for Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by July 31, 1998, to ensure adequate consideration in preparation of the final 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 A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: May 22, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14313 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0316]

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;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA)/ Establishment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 for Evaluation and Research.'' The draft guidance document, when finalized, is intended to provide information regarding the electronic submission of a Biologic License Application (BLA), or a Product License Application/ Establishment License Application (PLA/ELA) to the Center for Biologics Evaluation and Research (CBER). This draft guidance document is part of CBER's continuing 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, however, comments should be submitted by July 31, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''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'' 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 the office in processing your requests. The draft guidance 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. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''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.'' This draft guidance document, when finalized, is intended to provide a degree of uniformity to future electronically submitted license 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. This draft guidance document, when finalized, is intended to supersede the guidance manual entitled ''Computer Assisted Product License Application (CAPLA) Guidance Manual'' as announced in the **Federal Register** of March 21, 1996 (61 FR 11644).

This draft guidance document represents the agency's current thinking with regard to the 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. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this draft guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document

is intended to provide information and does not set forth requirements.

II. Request for Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by July 31, 1998, to ensure adequate consideration in preparation of the final guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance 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 draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: May 22, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0315]

Draft ''Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research.'' The draft guidance document, when finalized, is intended to provide instructions to manufacturers regarding the submission of the electronic protocols to the Center for Biologics Evaluation and Research (CBER). This draft guidance document is part of CBER's continuing 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, however, comments should be submitted by July 31, 1998, to ensure their adequate consideration in preparation of the final guidance document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research'' 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 the office in processing your requests. The draft guidance 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. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research.'' Under 21 CFR 610.2(a), samples of any lot of licensed product, together with the protocols showing results of applicable tests, may at any time be required to be submitted to CBER for review and confirmatory testing. This draft guidance document, when finalized, is intended to assist those manufacturers who choose to submit the required protocols electronically.

This draft guidance document represents the agency's current thinking with regard to the submission of electronic lot release protocols. 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 draft guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document is intended to provide information and does not set forth requirements.

II. Request for Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by July 31, 1998, to ensure adequate consideration in preparation of the final guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance 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

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Dated: May 22, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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