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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98 D-0964]

**Draft “Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product;” Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice,

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ‘Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological *In Vitro* Diagnostic Product, ’ The draft guidance document, when finalized, is intended to assist applicants in the preparation of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h, for biological in vitro diagnostic products. This action is part of FDA’s continuing effort to achieve the objectives of the President’s “Reinventing Government” initiatives and FDA Modernization Act of 1997, and it is intended to reduce unnecessary burdens for industry without diminishing public health protection.

**DATES:** Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 days after date of publication in the Federal Register*), to ensure their adequate consideration in preparation of the final document.

**ADDRESSES:** Submit written requests for single copies of “Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological *In Vitro* Diagnostic Product” 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. 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 See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

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

**FOR FURTHER INFORMATION CONTACT:** Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0373.

**SUPPLEMENTARY INFORMATION:**

**L Background**

FDA is announcing the availability of a draft document entitled ‘ ‘Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological *In Vitro* Diagnostic Product’. This draft document, when finalized, is intended to provide general information for the content and format of the CMC section and establishment description section of the BLA for biological in vitro diagnostic products. This draft document is intended for use by those firms which manufacture any licensed in vitro diagnostic product used to screen donor blood, determine donor suitability, test for retroviral infection, or determine transfusion compatibility (e.g., blood grouping and typing reagents). This draft document is not intended to cover those in vitro diagnostic products used to test for endotoxins, such as limulus amoebocyte lysate (LAL), or those products for which a premarket application (PMA) or a 510(k) must be submitted.

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a new harmonized Form FDA 356h entitled ‘ ‘Application to Market a New Drug, Biologic,

or an Antibiotic for Human Use.” The new harmonized form is intended to be used by applicants for all drug and biological products. The new harmonized form, when fully implemented, will allow biological product manufacturers to submit a single application, the BLA, instead of two separate license application submissions, a product license application (PLA), and an establishment license application (ELA).

This draft guidance document represents the agency’s current thinking on content and format of the CMC information and establishment description information for biological in vitro diagnostic 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 [o 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

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written comments to the Dockets Management Branch (address above) regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted (*insert date 60 days after date of publication in the Federal Register*), to ensure their adequate consideration in preparation of the final 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 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 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: November 2, 1998  
November 2, 1998



William K. Hubbard  
Associate Commissioner  
for Policy Coordination

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