Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22678 Filed 8–31–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2873]

Medical Devices; Draft Guidance on Evidence Models for the Least Burdensome Means to Market; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Evidence Models for the Least Burdensome Means to Market.'' This draft guidance is intended to provide guidance to the medical device industry and FDA reviewers on implementing section 205 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 205 requires FDA, in consultation with the product sponsor, to consider the ''least burdensome'' means that will allow appropriate premarket development and review of a product without unnecessary delays and expense to manufacturers. This draft guidance represents the agency's current thinking on implementing section 205 of FDAMA, and it is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by November 30, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Evidence Models for the Least Burdensome Means to Market'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Alpert, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Evidence Models for the Least Burdensome Means to Market.'' Section 205 of FDAMA requires FDA, in consultation with the product sponsor, to consider the ''least burdensome'' means that will allow appropriate premarket development and review of a product without unnecessary delays and expense to manufacturers. This draft guidance is designed to help both the Center for Devices and Radiological Health (CDRH) reviewers and the medical device industry apply the new provisions of FDAMA. Through this draft guidance, CDRH intends to establish a general approach for applying the least burdensome provisions that will be applicable to any device application; this draft guidance does not attempt to establish specific clinical data requirements for any particular type of submission.

The focus of this draft guidance is the application of the least burdensome provisions to clinical data requirements because the input from stakeholders has indicated that the regulated industry is most concerned with FDA's interpretation of these provisions with respect to clinical data.

In addition, as this draft guidance was being developed, it became clear that it cannot easily be applied to in vitro diagnostic devices (IVD's) because of the unique clinical data needs associated with establishing IVD performance. The agency is soliciting comments on applying the least burdensome provisions to data requirements for IVD's.

To foster a collaborative approach to the implementation of section 205 of FDAMA, FDA's CDRH hosted a meeting with stakeholders on January 4, 1999, to solicit comments and suggestions regarding the least burdensome approach to medical device development and evaluation. CDRH heard formal presentations at that meeting and also received written comments.

This draft guidance has incorporated, in part, the written proposal dated March 11, 1999, from the ''Least Burdensome Industry Task Force'' convened by the Health Industry Manufacturers Association, comments from the January 4, 1999, stakeholders meeting, and other stakeholder communications.

This draft guidance represents the agency's current thinking on implementing the ''least burdensome'' provisions of section 205 of FDAMA. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive the draft guidance document entitled ''Evidence Models for the Least Burdensome Means to Market'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DMSA Facts, at the second voice prompt press 2, and then enter the document number 1154 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance document entitled ''Evidence Models for the Least Burdensome Means to Market,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

III. Comments

Interested persons may, on or before November 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 brackets in the heading of this document. A copy of the draft guidance and received comments

are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2213]

Draft ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors;'' 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: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors.'' This draft guidance document, when finalized, is intended to provide guidance to blood establishments on invalidating donor test results based on control reagents required by the Clinical Laboratory Improvement Act of 1988 (CLIA). The implementation of additional quality control procedures that involve the use of external control reagents should enhance overall testing accuracy and blood safety.

DATES: Written comments on the draft guidance document may be submitted at any time, however, comments should be submitted by November 30, 1999, 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: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors'' 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 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft 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, 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: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors.'' This draft guidance document would provide recommendations for blood establishments in integrating current CLIA requirements for invalidating donor test results based on CLIA required control reagents. When finalized, this draft guidance document would replace the January 3, 1994, guidance document entitled ''Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors.'' FDA has developed revised recommendations based on discussions held during the public meetings of the Blood Products Advisory Committee (BPAC) on September 26, 1996, and December 13, 1996, and additional discussions among the Centers for Disease Control and Prevention (CDC), Health Care Financing Administration (HCFA), and FDA. At this time, the draft guidance document is being made available for comment purposes only and is not intended for use by the industry. The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This document is being issued as a draft level 1 guidance document consistent with GGP's.

This draft guidance document represents the agency's current thinking with regard to the invalidation of test results based on the CLIA required external control reagents. 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. 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 November 30, 1999, to ensure adequate consideration in preparation of the final 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 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: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the