

DMB

Display Date	8.31.99
Publication Date	9.1.99
Certifier	SW Reese

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Medical Devices; Draft Guidance on Evidence Models for the Least Burdensome Means to Market; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Evidence Models for the Least Burdensome Means to Market." This draft guidance is intended to provide guidance to the medical device industry and FDA reviewers on implementing section 205 of the Food and Drug Administration Modernization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 This draft guidance represents the agency's current thinking on implementing section 205 of FDAMA, and it is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Evidence Models for the Least Burdensome Means to Market" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and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-

NADJ

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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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FDA is announcing the availability of a draft guidance entitled “Evidence Models for the Least Burdensome Means to Market.”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

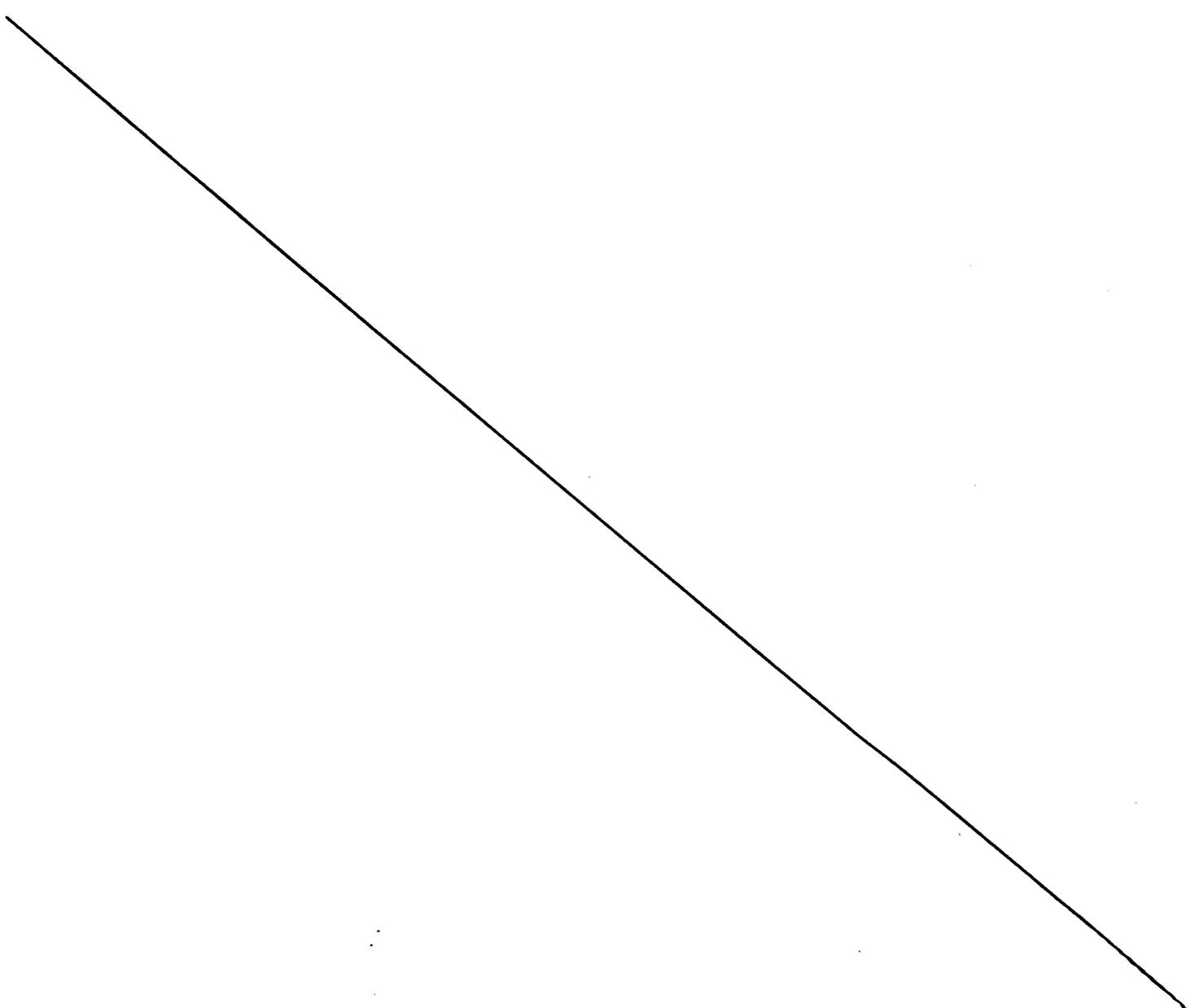
In order to receive the draft guidance document entitled "Evidence Models for the Least Burdensome Means to Market" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch tone telephone. At the first voice prompt press 1 to access DMSA Facts, at 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>".

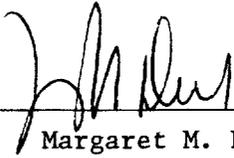
III. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), 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: 8/25/99
August 25, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

