

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date	5/1/02 @ 12:40
Publication Date	5/3/02
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[Docket No. 01D-0202]

Medical Devices: Draft "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles." In this draft guidance, FDA sets forth its interpretation of the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) that require FDA to take into account the least burdensome means for applicants to demonstrate a device's effectiveness or substantial equivalence. This guidance is neither final nor is it in effect at this time.

DATES: Submit written comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles" to the Division of Small Manufacturers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 two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments on this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in

brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ-403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Background

A central purpose of FDAMA was to ensure the timely availability of safe and effective new products that would benefit the American public. While Congress wanted to reduce unnecessary burdens associated with the premarket clearance and approval processes, Congress did not intend to lower the statutory thresholds for substantial equivalence or reasonable assurance of safety and effectiveness. To help achieve this goal, Congress added section 513(a)(3)(D)(ii) and (i)(1)(D) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c).

These two paragraphs (a)(3)(D)(ii) and (i)(1)(D) of section 513 of the law contain what are commonly referred to as the “least burdensome provisions” of the act. During the last year, FDA has been working with the Least Burdensome Industry Task Force to develop an interpretation of the least burdensome provisions that would accurately capture Congress’ intent and that could be implemented consistently by FDA and industry. This draft guidance, in addition to the other guidances developed by the agency, is a part of that process. As presented in this draft guidance, FDA has chosen to apply the least burdensome concept beyond the two statutory provisions in which the language actually appears. FDA considers the least burdensome concept to be one that could affect almost all premarket regulatory activities, including presubmission meetings with industry, premarket submissions, and the development of guidance documents and regulations.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the least burdensome provisions of the act. 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 statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a Level 1 guidance in accordance with the GGP regulations.

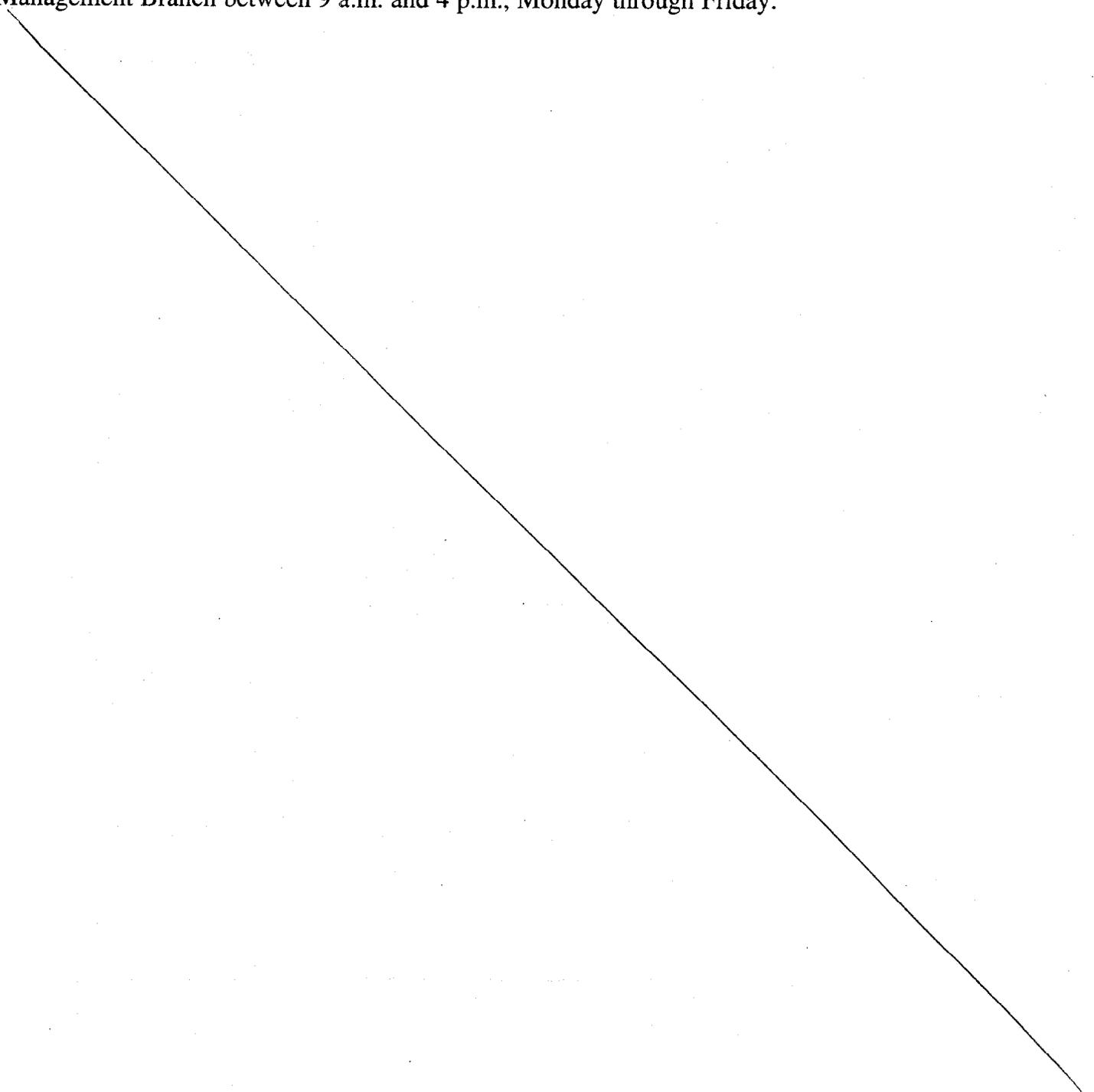
III. Electronic Access

In order to receive "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1332) followed by the pound sign (#). 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 Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 4/30/01
April 30, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

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[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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