DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0298]

Guidance for Industry on General/Specific Intended Use; Draft; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Industry on General/Specific Intended Use.'' This draft guidance is not final or in effect at this time. The purpose of this draft guidance is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a premarket approval application (PMA). The draft guidance is intended to help manufacturers answer the following questions: Under what circumstances is a device with a new, specific indication for use likely to be found to be substantially equivalent to a device legally marketed for a general indication for use? Conversely, when does a specific indication for use become a new intended use that requires submission of a PMA to establish the safety and effectiveness of the device?

DATES: Written comments concerning this draft guidance must be submitted by June 22, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance entitled ''Guidance for Industry on General/Specific Intended Use'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and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 Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Daniel G. Schultz, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–5072.

SUPPLEMENTARY INFORMATION:

I. Background

Congress indicated that FDA should provide additional guidance on the approach that the agency takes when evaluating whether a new indication for use, which appears to fall within the scope of the intended use of a legally marketed predicate device, is a new intended use that would require a PMA. This guidance is issued in accordance with new section 513(i)(1)(F) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(i)(1)(F)), which was added by section 206 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115).

II. Significance of Guidance

This draft guidance represents the agency's current thinking on general/specific intended use. 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.

III. Electronic Access

In order to receive copies of the draft guidance entitled ''Guidance for Industry on General/Specific Intended Use'' 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 DSMA Facts, at the second voice prompt press 2, and then enter the document number 499 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 entitled ''Guidance for Industry on General/Specific Intended Use,'' 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.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before June 22, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 12, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–13798 Filed 5–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0312]

Draft Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997; 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, ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997''. Elsewhere in this issue of the **Federal Register**, FDA has published criteria to accredit or deny accreditation to applicants who request to become Accredited Persons. To the extent this guidance discusses recommendations and procedures that have not been incorporated into the criteria established in the **Federal Register** notice, this guidance is not final nor is it in effect at this time. This guidance will assist those who are interested in participating in the Third Party Program, either as persons accredited to perform 510(k) reviews (Accredited Persons) or as applicants pursuing clearance of 510(k) submissions consistent with the FDA Modernization Act of 1997 (FDAMA), as well as FDA staff responsible for implementing the program.

DATES: Written comments concerning this guidance must be received by June 22, 1998.

ADDRESSES: Written comments concerning this guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. If you do not have access to the World Wide Web (WWW), submit written requests for single copies of the guidance document entitled, ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997'' on a 3.5'' disk, to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, 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.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

On August 1, 1996, FDA established the Third Party Review Pilot Program, a voluntary pilot program, to assess the feasibility of using third party reviewers to improve the efficiency of the agency's review of 510(k)s for selected low-to-moderate risk devices. Under the pilot program, persons required to submit 510(k)s for the eligible devices were permitted to contract with an FDA Recognized Third Party and submit a 510(k) directly to the third party for review. Persons who did not wish to participate in the pilot continued to submit 510(k)s directly to FDA.

Under FDAMA, this pilot program has been codified and expanded and FDA is required to establish and publish criteria to accredit or deny accreditation to persons who request to perform third party reviews. Those criteria are published elsewhere in this issue of the **Federal Register** in accordance with section 210(b) of FDAMA. This guidance document contains additional information regarding applications for accreditation of third party reviewers, as well as additional information about the agency's plans for implementation of the third party review program. FDA will begin to accept applications from prospective accredited persons beginning July 20, 1998. FDA will review those applications in 60 days and approved Accredited Persons may begin to submit reviews of 510(k)s on November 21, 1998. Because Accredited Persons must participate in training prior to submitting recommendations, applicants who wish to attend the initial training that will be held October 14 through 16, 1998, should submit their applications at least 60 days in advance of that date.

II. Significance of Guidance

This guidance document represents the agency's current thinking on implementation of the third party review program. 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 guidance document is issued as a draft Level 1 guidance consistent with GGP's.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may also do so using the 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 ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997,'' device safety alerts, access to **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.

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IV. Comments

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Dated: May 19, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13800 Filed 5–20–98; 8:45 am]

BILLING CODE 4160–01–F