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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2212]

Medical Devices; Draft Guidance on Quality Systems Regulation Information for Various Premarket Submissions; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance on Quality System Regulation Information for Various PreMarket Submissions." This draft guidance is intended to assist medical device manufacturers with information they should include in premarket approval applications (PMA) and product development protocols (PDP) to demonstrate that the submissions are in compliance with the revised quality system (QS) regulation. This draft guidance document also describes the information that should be maintained at the manufacturing facility for premarket notifications (510(k)'s). This draft guidance document represents the agency's current thinking on the QS regulation information for various premarket submissions. This guidance 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DATES: Written comments concerning this draft guidance must be submitted by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Draft Guidance on Quality System Regulation Information for Various PreMarket Submissions" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and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.

Submit written comments on the draft guidance to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Collin L. Figueroa, Center for Devices and Radiological Health (HFZ-341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4654.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Draft Guidance on Quality System Regulation Information for Various PreMarket Submissions.” This draft guidance document is intended to describe for manufacturers one means of complying with the requirements of the QS regulation in 21 CFR part 820 and the requirement for design controls and manufacturing information in various premarket submissions.

II. Significance of Guidance

When used by the premarket applicant in conjunction with the QS regulation, this draft guidance document illustrates an approach to comply with the content requirements for PMA and PDP submissions in section 515(c) of the Food, Drug, and Cosmetic Act (the act) (21 USC 360e(c)) and 21 CFR part 814. This document also describes the information that should be maintained at the manufacturing facility for premarket notifications submitted under section 510(k) of the act (21 U.S.C. 360(k)). The guidance document entitled “The 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications” (63 FR 25865, May 11, 1998) describes the type of design control information to be submitted in special 510(k)’s for device modifications.

This guidance document 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 document is issued as a Level 1 guidance consistent with GGPs.

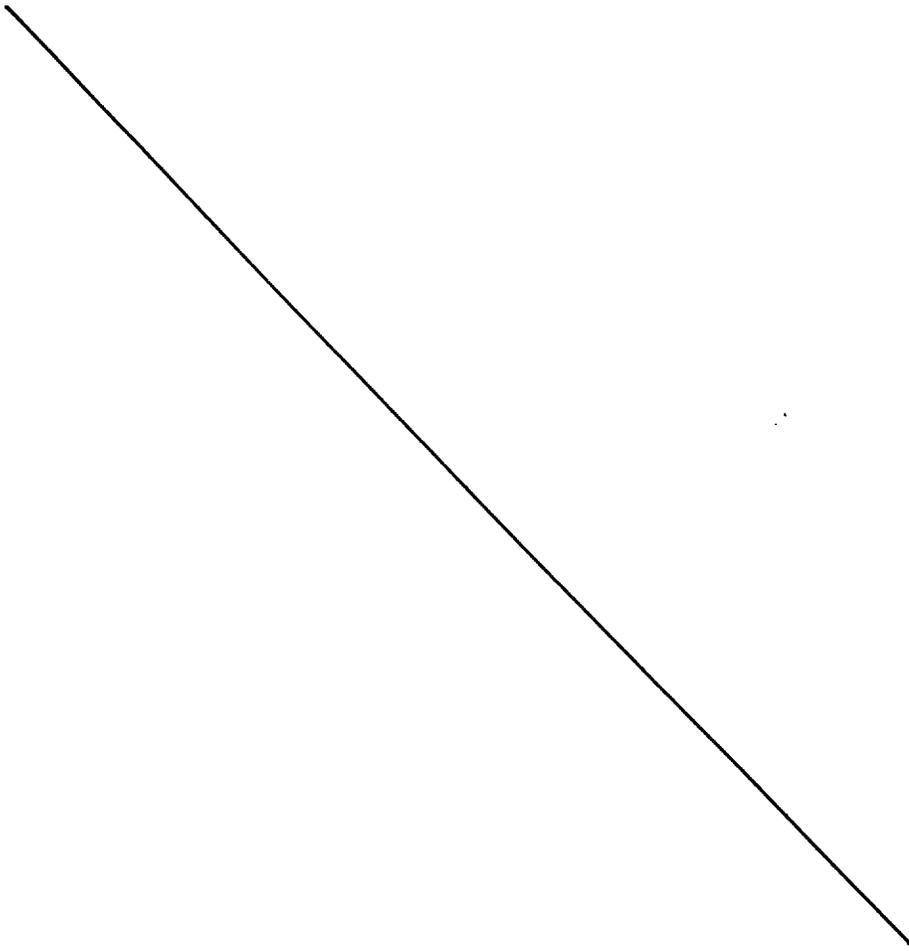
III. Electronic Access

In order to receive the "Draft Guidance Document on Quality System Regulation Information for Various PreMarket Submissions" 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 second voice prompt press 2, and then enter the document number (1140) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft document 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 WWW. Updated on a regular basis, the CDRH home page includes the "Guidance on Quality System Regulation Information for Various PreMarket Submissions," 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>".

IV. 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 that individuals may submit one copy. Comments are to 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: 7/20/99

July 20, 1999

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jen Windsor

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