

information for certain premarket application reviews. 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 and regulations. This guidance document is issued as a level 1 guidance consistent with GGP's.

This guidance, when used in conjunction with the QS regulation, illustrates an approach for complying with the content requirements for premarket submissions found in section 515(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(c)) and 21 CFR part 814. A manufacturer who chooses to meet application requirements for the QS information in an alternative way may wish to consult with the appropriate office prior to the submission. The FDA staff can help identify areas that might raise particular concerns for CDRH and CBER reviewers or investigators.

III. Comments from the Draft Guidance

In the **Federal Register** of August 3, 1999 (64 FR 42137), "Medical Devices, Draft Guidance on Quality System Regulation Information for Various Premarket Submissions; Availability" was published as a draft level 1 guidance document for comment under GGP's. Six individuals or organizations filed comments on the draft guidance.

Most of the comments requested a better understanding of how FDA used the information previously submitted under the GMP manufacturing section and how the information requested in this guidance would be used. The introduction of the final guidance document explains that CDRH's Office of Compliance (OC) will review the QS information submitted in the premarket application at the same time the Office of Device Evaluation (ODE) reviews the other portions of the application. The appropriate offices in CBER will review the QS information submitted in CBER-regulated premarket submissions. Applicants who use this guidance should be able to focus their submissions on the information CDRH/CBER will need for review. Based on their review, CDRH/CBER will provide inspectional guidance to FDA field staff. Submission of this information can help focus the preapproval inspection process and limit the amount of time field staff will need to spend in the facility.

A few comments questioned the recommendation that manufacturers have design control information available, upon request, for devices subject to 510(k) clearance because it

suggested that such documentation could be requested as part of the determination of substantial equivalence. FDA agrees with the comments and, therefore, has limited the applicability of this guidance document to exclude 510(k) submissions.

A few comments questioned whether the draft guidance document exceeded requirements in the QS regulation. The introduction to the final guidance document explains that the guidance document requests copies of written procedures or lists of items related to the QS regulation. In most cases, these procedures or lists are explicitly required under provisions of the QS regulation. In a few cases, the explanations or lists will facilitate FDA's review of your QS information. In the cases where the information is not explicitly required under statute or regulation (e.g., production flow diagram, list of any standards used, process validation master plan), FDA believes the information is the type you are likely to create and maintain as part of your QS. FDA believes submission of such information as part of your application will reduce or eliminate the need for us to request additional information during our review and preapproval inspection. However, because this is a guidance document, compliance with the recommendation is not required.

The final guidance also incorporates many editorial comments and wording suggestions that were submitted by comments.

IV. Electronic Access

In order to receive the guidance document "Quality System Information for Certain Premarket Application Reviews" 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 (1140) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the document may also do so by 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 access to the Internet. Updated on a regular basis, the CDRH home page includes the "Quality System Information for Certain Premarket Application Reviews," 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>. The guidance entitled "Quality System Information for Certain Premarket Application Reviews" will be available at <http://www.fda.gov/cdrh/comp/guidance/1140.pdf>.

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910-0231) and the regulations governing quality systems (21 CFR part 820, OMB control number 0910-0073).

VI. Comments

Interested parties may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit two copies of any mailed 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: January 10, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1109]

Mercury Compounds in Drugs and Food; List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a