Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 12, 2003, the committee will: (1) Receive a final report from the Process Analytical Technology Subcommittee and provide direction to the Manufacturing Subcommittee; (2) receive an update on sterile products produced by aseptic processing; (3) discuss and provide direction for future subcommittees: Biopharmaceutics Subcommittee and Microbiology Subcommittee; (4) discuss and provide comments on topical dermatological drug product nomenclature; and (5) discuss and provide comments on topical dermatological bioequivalence, methods development. On March 13, 2003, the committee will: (1) Discuss and provide direction for future subcommittee: Pharmacology/Toxicology Subcommittee; (2) receive an update on the Office of Pharmaceutical Science research projects; (3) discuss and provide comments on dose content uniformity, parametric interval test for aerosol products; (4) discuss and provide comments on levothyroxine bioequivalence; and (5) discuss and provide comments on comparability protocols.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 3, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2 p.m. on March 12, 2003, and 11:30 a.m. to 12 noon on March 13, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 3, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carolyn Jones at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 27, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2459 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2212]

Medical Devices; Final Guidance on Quality System Information for Certain Premarket Application Reviews; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Quality System Information for Certain Premarket Application Reviews.'' This guidance has been prepared by the Center for Devices and Radiological Health (CDRH), in coordination with the Center for Biologics Evaluation and Research (CBER), to assist medical device manufacturers in preparing and maintaining the quality system (QS) information required in certain premarket submissions.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5″ diskette of the final guidance document entitled ''Quality System Information for Certain Premarket Application Reviews'' to the Division of Small Manufacturers, International and Consumer 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.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648, or Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

This level 1 guidance entitled ''Quality System Information for Certain Premarket Application Reviews'' provides guidance to manufacturers who prepare and maintain QS information that should be included in premarket approval applications (PMA), PMA supplements, product development protocols (PDP), humanitarian device exemptions (HDE), and modular review submissions. This QS information guidance is meant to assist applicants in providing the information in a clear format for efficient review and timely decisions.

CDRH first published a guidance document entitled ''Guidance for Preparation of PMA Manufacturing Information'' on March 22, 1991, that was modified in 1992. The 1992 document was incorporated into the ''Regulatory Requirements for Medical Devices: A Workshop Manual.'' Feedback from industry and FDA reviewers, as well as revisions to the regulation in 1996, prompted this revision to the guidance.

This guidance entitled ''Quality System Information for Certain Premarket Application Reviews'' replaces the 1991 and 1992 guidance documents concerning the kind of good manufacturing practice (GMP) information that should be submitted in premarket submissions before an inspection is conducted as part of the premarket approval process. The document should be used for PMA, PMA supplements, PDP, HDE, and modular review applications. The information identified in this guidance addresses the current GMP requirements found in the quality system regulation (see 21 CFR part 820).

Applicants who use this guidance should be able to focus their submissions on the information CDRH and CBER need to review. Based on their review, CDRH and CBER will provide to FDA field staff inspectional guidance to plan the premarket approval inspection. This should reduce the amount of time the investigator will need to conduct the onsite inspection.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on QS

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 GGPs.

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 GGPs. 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.

[FR Doc. 03–2375 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

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