research programs in the Division of Monoclonal Antibodies, Center for Biologics Evaluation and Research (CBER). On February 28, 2003, from 8 a.m. to approximately 4:30 p.m., the committee will discuss safety issues related to the use of retrovirus vectors in gene therapy clinical trials.

Procedure: On February 27, 2003, from 8 a.m. to 5:30 p.m., the meeting is open to the public. 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 February 20, 2003. On February 27, oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. On February 28, oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 20, 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.

Closed Committee Deliberations: On February 27, 2003, from approximately 5:30 p.m. to 6 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of a review of individual research programs in CBER.

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 Gail Dapolito or Rosanna L. Harvey 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 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2374 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Monday, February 24, 2003, from 8:30 a.m. to 5 p.m., and Tuesday, February 25, 2003, from 8:30 a.m. to 5 p.m.

Location: Sheraton College Park Hotel, Salons A, B, and C, 4095 Powder Mill Rd., Beltsville, MD 20705, 301–937–4422.

Contact Person: Sylvia M. Smith, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 24 and 25, 2003, the committee will meet to discuss FDA's action plan for addressing the issue of acrylamide in food and to discuss the findings and recommendations from the Contaminants and Natural Toxicants Subcommittee of the Food Advisory Committee.

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 February 10, 2003. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on February 24, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person on or before February 10, 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 Sylvia Smith 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 24, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–2457 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 12, 2003, from 8:30 a.m. to 5 p.m. and March 13, 2003, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy or Carolyn Jones, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: *REEDYK@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the

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