Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 123, e-mail: *mea@cdrh.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512518. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 11, 2005, the committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. Subsequently, on October 11 and 12, 2005, the committee will discuss and make recommendations on the classification of the following unclassified dental devices:

- Root canal cleanser, product code KJJ, intended to cleanse a root canal after endodontic instrumentation;
- Retraction cord, product code MVL, intended for temporary retraction and hemostasis of the gingival margin;
- Root apex locator, product code LQY, intended to measure the length of the root canal;
- Dental mouthguards, product code MQC, intended to provide protection against bruxism, teeth clenching, and grinding;
- Artificial saliva, product code LFD, intended for the relief of chronic and temporary xerostomia;
- Oral wound dressing, product code MGQ, intended to provide pain relief from aphthous ulcers, canker sores, and minor oral lesions; and
- Electrical anesthesia, product code LWM, intended, through the application of electrical current, to provide analgesia or anesthesia during dental procedures.

Also, on October 12, 2005, the committee will discuss and make recommendations regarding the over-the-counter (OTC) use of dental mouthguards.Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*. More information regarding product code classification can be accessed by visiting *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm* or by contact person. Material for the October 11 and 12 sessions will be posted on October 7, 2005.

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 October 3, 2005. On October 11, 2005 and October 12, 2005, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 3, 2005, 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 AnnMarie Williams, Conference Management Staff, 301–594–1283, ext. 113, 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: September 6, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–18363 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Nonprescription Drugs 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 October 20, 2005, from 8 a.m. to 5:30 p.m., and on October 21, 2005, from 8 a.m. to 12 noon.

Location: Holiday Inn Washington Silver Spring, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301–589–0800.

Contact Person: Darrell Lyons, Center for Drug Evaluation and Research (HFD–021), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6760, FAX: 301–827–6778, e-mail: *lyonsd@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the benefits and risks of antiseptic products marketed for consumer use (e.g., antibacterial hand-washes and body-washes). The discussion will include topics such as the efficacy of antiseptics intended for use by consumers and potential risks to the individual and the general population from using these products. The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to NDAC).

Procedure: On October 20, 2005, 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 October 13, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 20, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 2005, 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 October 21, 2005, from 8 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 LaNise Giles at 301–827–7001, 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: September 8, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–18366 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs 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: Pediatric Oncology Subcommittee of the Oncologic Drugs 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 October 20, 2005, from 8 a.m. to 5 p.m.

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

Contact Person: Victoria Ferretti-Aceto, 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, FAX: 301–827–6776, e-mail: *ferrettiv@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will do the following: (1) Present the structure and function of the Office of Oncology Drug Products in CDER, (2) discuss issues involved with the conduct of certain pediatric postmarketing studies for products approved for oncologic indications, (3) review status of studies for specific off-patent drugs for pediatric oncology, and (4) consider other off-patent oncology drugs for which pediatric studies are needed, as mandated by the Best Pharmaceuticals for Children Act. When available, background materials for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Oncologic Drugs Advisory Committee; Pediatric Subcommittee.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 13, 2005. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:15 p.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 2005, 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 Victoria Ferretti-Aceto 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: September 6, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–18330 Filed 9–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0348]

Draft Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; 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 ''Procedures for Handling Post-Approval Studies Imposed by PMA Order.'' The draft guidance is designed to assist the Center for Devices and Radiological Health (CDRH) and sponsors to meet their responsibilities to track post-approval studies (sometimes called Condition of Approval Studies) that are mandated for market approval of medical devices.

DATES: Submit written or electronic comments on this draft guidance by November 14, 2005.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Procedures for Handling Post-Approval Studies Imposed by PMA Order'' 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Steven H. Chasin, Office of Surveillance and Biometrics, Division of Postmarket Surveillance, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3674