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, May 16, 2011, from 8 a.m. to 3 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel's telephone number is 301–589–5200.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, Bldg. 32, rm. 5154, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0885, e-mail: *Walter.Ellenberg@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 16, 2011, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 110–85) for Bepreve (bepotastine besliate), Besivance (besifloxacin hydrochloride), Cetraxal (ciprofloxacin hydrochloride), Patanase Spray (olopatadine hydrochloride), Astepro Spray (azelastine hydrocholoride), Crestor (rosuvastatin calcium), Welchol (colesevelam hydrochloride), Intuniv (guanfacine), Lexapro (escitalopram oxalate), Actonel (risedronate), Hiberix [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)], and Valcyte (valganciclovir). The committee will also receive further followup on Topical Calcineurin Inhibitors: Elidel (pimecrolimus) and Protopic (tacrolimus).

The Pediatric Advisory Committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on May 11, 2011, regarding the Institutional Review Board process for clinical investigations that involve both an FDA regulated product and research involving children as subjects that is conducted or supported by HHS. The announcement of the May 11, 2011, Pediatric Ethics Subcommittee of the Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

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 on or before May 2, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before April 25, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 26, 2011.

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 Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9150 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0184]

Pediatric Ethics Subcommittee; 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 Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA and certain Department of Health and Human Services regulatory issues.

DATES: The meeting will be held on Wednesday, May 11, 2011, from 8 a.m. to 3 p.m.

FDA is opening a docket to allow for additional public comments to be submitted to the Agency on the issues before the Pediatric Ethics Subcommittee. Submit either electronic or written comments by May 5, 2011.

ADDRESSES: The meeting will be held at the North Marriott Hotel & Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993–0002, 301–796–0885, or by *e-mail: Walter.Ellenberg@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the

Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 11, 2011, the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss the general topic of the ethics of administering subtherapeutic doses of investigational products to children for the purpose of determining, for example, drug metabolism, disposition, and targeting (*e.g.,* exploratory investigational new drug (IND) studies). In this context, the subcommittee will also discuss the referral of such protocols by an Institutional Review Board for review by a Federal panel under 21 CFR 50.54.

The subcommittee's recommendations will then be presented to the FDA Pediatric Advisory Committee on Monday, May 16, 2011. The announcement of the May 16, 2011, Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

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 on or before April 28, 2011. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on May 11, 2011. Those desiring to make formal oral presentations should notify the contact person 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 on or before April 20, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 21, 2011.

Comments: FDA is opening a docket to allow for additional public comments to be submitted to the Agency on issues before the Pediatric Ethics Subcommittee beginning April 15, 2011, and closing May 5, 2011. All comments received on or before May 5, 2011, will be provided to the committee members. All comments received after May 5, 2011, will be taken into consideration by the Agency. Interested persons are encouraged to use the docket to submit either electronic or written comments regarding this meeting (*see* **ADDRESSES**). Submit electronic comments to *http://www.regulations.gov*. Submit written comments to Division of Dockets Management (*see* **ADDRESSES**). It is necessary to submit only one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets management between 9 a.m. and 4 p.m. Monday through Friday.

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FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9149 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Food Reporting Comparison Study (FORCS) and Food and Eating Assessment Study (FEAST) (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Food Reporting Comparison Study (FORCS) and Food and Eating Assessment Study (FEAST) (NCI*). Type of Information Collection Request:* Extension. *Need and Use of Information Collection:* The title of this collection was previously, "24-hour Dietary Recall Method Comparison and the National Cancer Institute (NCI) Observational Feeding Studies." The objective of the two studies is to compare the performance of the newly developed computerized Automated Self-Administered 24-Hour Recall (ASA24) approach to collecting 24 hour recall (24HR) data with the current standard, the interviewer-administered Automated Multiple Pass Method (AMPM). The ultimate goal is to determine to what extent the new automated instrument can be used instead of the more expensive interviewer-administered instrument in the collection of dietary intake data. *Frequency of Response:* Twice. *Affected Public:* Individuals. *Type of Respondents:* For the FORCS study, approximately 1,200 adult members from three health maintenance organization plans (in Minnesota, California, and Michigan) between ages 20 and 70 years. For the FEAST study, approximately 90 adult residents from the Washington, DC metropolitan area between ages 20 and 70 years. The annual reporting burden is estimated at 866 hours (see table below). This amounts to an estimated 2,598 burden hours over the 3-year data collection period with a total cost to the respondents of $54,293. There are no Capital costs, Operating costs, and/or Maintenance Costs to report.