

Committees/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: February 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Pediatric 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 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 Thursday, March 14, 2013 from 8 a.m. to 5:30 p.m.

Location: Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800 or visit the hotel's Web site at <http://www.sheratonsilverpring.com/>.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301-796-0885, email walter.ellenberg@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to

learn about possible modifications before coming to the meeting.

Agenda: On Thursday, March 14, 2013, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Public Law 107-109) and the for Pediatric Research Equity Act (Public Law 108-155) for: ACTEMRA (tocilizumab), ALIMTA (Pemetrexed disodium), CREON (pancrelipase), GADAVIST (gadobutrol), HIZENTRA [Immune Globulin Subcutaneous (Human), 20% Liquid], INOMAX (nitric oxide), INVEGA (paliperidone), KEDBUMIN (albumin human), KYTRIL Injection (granisetron hydrochloride), LAMICTAL XR (lamotrigine), MENACTRA [Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], MOXEZA (moxifloxacin ophthalmic solution 0.5%), NATROBA (spinosad), NEXIUM (esomeprazole magnesium), NEXIUM IV (esomeprazole sodium), UROXATRAL (alfuzosin hydrochloride), and ZENPEP (pancrelipase). Also, there will be an Informational Update on Codeine.

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 meeting 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 March 7, 2013. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 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 February 27, 2013. 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 February 28, 2013.

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 301-796-0885, email walter.ellenberg@fda.hhs.gov, 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: February 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04256 Filed 2-22-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Fecal Microbiota for Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID), are announcing a public workshop entitled "Fecal Microbiota for Transplantation." The purpose of the public workshop is to exchange information with the medical and scientific community about the regulatory and scientific issues associated with fecal microbiota for transplantation (FMT).

Date and Time: The public workshop will be held on May 2 and 3, 2013, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Preregistered participants will receive additional information on security procedures, parking, and public transportation with their email registration confirmation.

Contact Person: Chris Nguyen, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, email: CBERPublicEvents@fda.hhs.gov (subject line: FMT Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Chris Nguyen (see *Contact Person*) or email to CBERPublicEvents@fda.hhs.gov (subject line: FMT Workshop Registration) by April 18, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Chris Nguyen (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Fecal microbiota samples that have been isolated from healthy individuals are being investigated for use in the treatment of *Clostridium difficile* colitis. Published data from case studies and metaanalyses suggest that the use of fecal microbiota to restore gut flora may be an effective therapy in the management of refractory *C. difficile* infection. However, the efficacy of this intervention has not yet been demonstrated in controlled clinical trials. Such controlled trials are needed to demonstrate the safety and effectiveness of FMT products for *C. difficile* infection refractory to conventional therapy. FMT is also being considered as a treatment for inflammatory bowel disease, obesity, and other disorders, and controlled trials are needed in these settings as well.

Clinical studies to evaluate the safety and efficacy of FMT are regulated by FDA. FDA's primary objectives in reviewing an investigational new drug application are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phases 2 and

3, to help insure that the quality of the scientific evaluation of the product is adequate to permit an evaluation of safety and effectiveness. In addition, the complex nature of FMT products presents specific scientific and regulatory challenges.

To facilitate clinical development of FMT, CBER and NIAID are holding this workshop to provide a forum for the exchange of information, knowledge, and experience between CBER, NIAID, and the scientific-medical community.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-04232 Filed 2-22-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Office of Health Assessment and Translation Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments—February 2013; Request for Comments; Notice of a Meeting

SUMMARY: The National Toxicology Program (NTP) requests public comments on the Draft Office of Health Assessment and Translation (OHAT) Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments—February 2013 (available at <http://ntp.niehs.nih.gov/go/38138>). The NTP also plans to release two protocols to illustrate the application of this framework. These documents were prepared by the OHAT, Division of NTP, National Institute of Environmental Health Sciences (NIEHS). The NTP will hold a public web-based, informational meeting during the public-comment period to provide an overview of the framework, describe the contents in the case-study protocols, and respond to questions from the public on any of the documents.

DATES: *Public Comment Submissions:* Deadline is June 11, 2013.

Document Availability: Draft OHAT Approach—February 2013 will be available by February 26, 2013, and case-study protocols should be available on April 2, 2013, at <http://ntp.niehs.nih.gov/go/38673>.

Registration for public, web-based, informational meeting: Deadline is April 16, 2013.

Meeting: April 23, 2013, 12:00–4:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier depending on the number of registered participants and will be cancelled if there are no registered participants by close of business on April 16, 2013. Registrants will receive information by email to access the web-based meeting on or before April 19, 2013.

ADDRESSES: *Agency Web site:* The Draft OHAT Approach—February 2013, protocols, registration for web-based meeting, and public comments are at <http://ntp.niehs.nih.gov/go/38673>.

Public Comment Submissions: Email: andrew.rooney@nih.gov or submit online at <http://ntp.niehs.nih.gov/go/38673>.

TTY users should contact the Federal TTY Relay Service at (800) 877-8330. Requests must be made at least 5 business days in advance of the web-based meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Andrew Rooney, Deputy Director, OHAT, Division of NTP, NIEHS, P.O. Box 12233, K2-04, Research Triangle Park, NC 27709. Phone: 919-541-2999, Fax: 301-480-3299, Email: Andrew.Rooney@nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2154, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The OHAT, Division of NTP, NIEHS, has led an effort for the NTP to develop an approach for carrying out literature-based health assessments that incorporates systematic review methodology. Systematic review and plans for developing the approach were introduced at the NTP Board of Scientific Counselors (BSC) meeting on June 21–22, 2012. A BSC working group reviewed an earlier draft of the approach (then called the draft NTP Approach) at a meeting on August 28–29, 2012, and provided a draft report with recommendations to the BSC at its meeting on December 11, 2012; the report was unanimously accepted by the BSC. Information, presentations, and minutes (when available) from the June and December meetings are available at <http://ntp.niehs.nih.gov/go/9741>.