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]

BILLING CODE 4160–01–P

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 on-line 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.*

The NTP prepared the ''Draft OHAT Approach for Systematic Review and Evidence Integration for Literature-based Health Assessments—February 2013,'' (Draft OHAT Approach—February 2013) taking into consideration input from the BSC working group, the BSC, and the public (available at *http://ntp.niehs.nih.gov/go/38673*). The approach includes seven steps that provide a framework for incorporating systematic review and evidence integration into NTP literature-based health assessments. To assist with determining if additional refinement or revision to the Draft OHAT Approach—February 2013 might be needed, OHAT plans to apply it to two case-study evaluations. One case study will evaluate the association of bisphenol A (BPA) exposure with obesity and the other will examine the association of perflurooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS) exposure with immunotoxicity. Prior to initiating these evaluations, OHAT is developing protocols that include specific elements for how the seven steps in the Draft OHAT Approach—February 2013 would be carried out. The protocols on BPA exposure and obesity and PFOA or PFOS exposure and immunotoxicity should be available on April 2, 2013, at *http://ntp.niehs.nih.gov/go/38673.* Persons interested in the Draft OHAT Approach—February 2013 and the protocols are encouraged to access this Web site to stay abreast of the most current information.

The NTP will carefully consider the public comments on the Draft OHAT Approach—February 2013 and consider what changes, if any, might be needed. The NTP plans to present the Draft OHAT Approach—February 2013 to the NTP BSC at the meeting on June 25–26, 2013 and discuss plans to update the document based on comments. Details about this meeting will be published in the **Federal Register** and posted on the NTP Web site (*http://ntp.niehs.nih.gov/go/165*).

Request for Comments

The NTP invites public comments on the Draft OHAT Approach—February 2013. Two protocols are being released to illustrate application of this framework: BPA exposure and obesity and PFOA or PFOS exposure and immunotoxicity. The deadline for submission of public comments is June 11, 2013. Comments will be posted on the NTP Web site *http://ntp.niehs.nih.gov/go/38668* and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Public comments can be submitted on-line or by email (see **ADDRESSES**, Public Comment Submissions). Persons submitting written comments should include their name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document.

Web-based Informational Meeting

The NTP will hold a public, web-based, informational meeting on April 23, 2013, 12:00–4:00 p.m. EDT to provide an overview of the Draft OHAT Approach—February 2013, describe the contents in the two case-study protocols, and respond to questions from the public on any of the documents. The meeting will be interactive and opportunities will be provided for members of the public to ask NTP staff specific questions that may assist in their review or understanding of the Draft OHAT Approach—February 2013. The deadline for registration for the webinar is April 16 at *http://ntp.niehs.nih.gov/go/38673,* and the event will be cancelled if there are no registered participants by close of business that day. Registrants will receive information by email to access the web-based meeting on or before April 19, 2013.

Background Information on OHAT

OHAT was established to serve as an environmental health resource to the public and regulatory and health agencies (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094430*). This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as ''substances'') cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found at *http://ntp.niehs.nih.gov/go/ohat.*

Dated: February 19, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2013–04254 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Pediatrics Subcommittee.

Date: March 14, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel Bethesda (Formerly Holiday Inn Select) 8120 Wisconsin Avenue Bethesda, MD 20814.

Contact Person: Rita Anand, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of, Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–496–1487, *anandr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 15, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04207 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the