

least one candidate orphan drug or device that holds promise for the treatment of a rare disease or condition in order to discuss the processes for putting together an application. In addition, participants in the HUD or orphan drug designation one-on-one sessions are highly encouraged to come prepared with a working draft submission of their particular promising therapy in order to maximize the utility of the one-on-one meetings.

Dated: August 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-20371 Filed 8-20-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monographs for ortho-Toluidine and Pentachlorophenol and By-Products of Its Synthesis; Availability of Its Documents; Request for Comments; Notice of Meeting

SUMMARY: The notice announces a meeting to peer review the Draft Report on Carcinogens (RoC) Monographs for ortho-Toluidine and Pentachlorophenol and By-products of its Synthesis (hereafter referred to as “pentachlorophenol”). These documents were prepared by the Office of the Report on Carcinogens (ORoC), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS).

DATES: *Meeting:* October 7, 2013, 8:30 a.m. to approximately 5:00 p.m. Eastern Daylight Time (EDT) and October 8, 2013, from 8:30 a.m. until adjournment, approximately 11:30 a.m.

Document Availability: Draft monographs will be available by August 28, 2013, at <http://ntp.niehs.nih.gov/go/38853>.

Public Comments Submissions:

Deadline is September 25, 2013.

Pre-Registration for Meeting and/or Oral Comments: Deadline is September 30, 2013.

ADDRESSES: *Meeting Location:* Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Agency Meeting Web page: The draft monographs, draft agenda, registration, and other meeting materials will be posted at <http://ntp.niehs.nih.gov/go/38853>.

Webcast: The meeting will be available via webcast at <http://>

www.niehs.nih.gov/news/video/index.cfm.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, NTP Designated Federal Official, Office of Liaison, Policy and Review, DNTP, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709. Phone: (919) 541-9834, Fax: (301) 480-3272, Email: whiteltd@niehs.nih.gov. Hand Delivery/Courier: 530 Davis Drive, Room 2136, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: The Report on Carcinogens (RoC) is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called “substances”) in our environment that pose a cancer hazard for people in the United States. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services.

The NTP follows an established, four-part process for preparation of the RoC (<http://ntp.niehs.nih.gov/go/rocprocess>). A RoC Monograph is prepared for each candidate substance selected for review for the RoC. Pentachlorophenol and ortho-toluidine were selected as candidate substances following solicitation of public comment, review by the NTP Board of Scientific Counselors on June 21–22, 2012, and approved by the NTP Director (<http://ntp.niehs.nih.gov/go/9741>). A draft RoC monograph consists of a (1) cancer evaluation component that reviews all information that may bear on a listing decision, assesses its quality and sufficiency for reaching a listing decision, applies the RoC listing criteria to the relevant scientific information, and recommends a listing status for the candidate substance in the RoC and (2) a substance profile that contains the NTP’s preliminary listing recommendation and a summary of the scientific evidence considered key to reaching that recommendation. This meeting is planned for peer review of the draft RoC Monographs for ortho-toluidine and pentachlorophenol.

ortho-Toluidine (CASRN 95-53-4) is an arylamine used (directly or as an intermediate) to manufacture herbicides, dyes, pigments, and rubber chemicals. It is currently listed as reasonably anticipated to be a human carcinogen in the 12th RoC. Additional information about the review of ortho-toluidine for the RoC is available at <http://ntp.niehs.nih.gov/go/37898>.

Pentachlorophenol (CASRN 87-86-5) is a general biocide that has been used extensively as a fungicide, bactericide, herbicide, and insecticide by agriculture and other industries. In 1987, over-the-

counter use was banned and other uses restricted. Currently, pentachlorophenol is defined in the United States as a ‘heavy duty’ wood preservative that is used primarily in the treatment of utility poles and cross arms. The candidate substance is defined as “pentachlorophenol and by-products of its synthesis.” During synthesis of pentachlorophenol, several additional chlorinated molecules are formed as by-products. In addition, biomonitoring studies have found that people who are exposed to pentachlorophenol or pentachlorophenol-containing products are always exposed to the combination of pentachlorophenol and its by-products. Additional information about the review of pentachlorophenol for the RoC is available at <http://ntp.niehs.nih.gov/go/37897>.

Meeting and Registration: The meeting is open to the public with time set aside for oral public comment; attendance at the NIEHS is limited only by the space available. The meeting is scheduled for October 7, 2013, 8:30 a.m. to approximately 5:00 p.m. EDT and October 8, 2013, from 8:30 a.m. until adjournment, approximately 11:30 a.m. Two days are set aside for the meeting; however, it may adjourn sooner if the panel completes its peer review of the draft monographs. Pre-registration to attend the meeting and/or provide oral comments is by September 30, 2013, at <http://ntp.niehs.nih.gov/go/38853>. Visitor and security information is available at <http://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (919) 541-4363 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

The preliminary agenda and draft monographs should be posted on the NTP Web site (<http://ntp.niehs.nih.gov/go/38853>) by August 28, 2013. Additional information will be posted when available or may be requested in hardcopy, see **FOR FURTHER INFORMATION CONTACT**. Following the meeting, a report of the peer review will be prepared and made available on the NTP Web site. Registered attendees are encouraged to access the meeting Web page to stay abreast of the most current information regarding the meeting.

Request for Comments: The NTP invites written and oral public comments on the draft monographs. The deadline for submission of written comments is September 25, 2013, to enable review by the peer-review panel

and NTP staff prior to the meeting. Pre-registration to provide oral comments is by September 30, 2013, at <http://ntp.niehs.nih.gov/go/38853>. Public comments and any other correspondence on the draft monographs should be sent to the **FOR FURTHER INFORMATION CONTACT**. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP Web site, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft monographs. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The lines will be open from 8:30 a.m. until approximately 5:00 p.m. EDT on October 7 and from 8:30 a.m. EDT until adjournment on October 8, and oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. Each organization is allowed one time slot per monograph. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair. Persons wishing to make an oral presentation are asked to register online at <http://ntp.niehs.nih.gov/go/38853> by September 30, 2013, and if possible, to send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of speakers who register on-site.

Background Information on the RoC: Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. The 12th RoC, the latest edition, was published on June 10, 2011 (available at <http://ntp.niehs.nih.gov/go/roc12>). The 13th RoC is under development. For each listed substance, the RoC contains a substance profile, which provides information on: Cancer studies that support the listing—including those in humans, animals, and studies on possible mechanisms of action—information about potential sources of

exposure to humans, and current Federal regulations to limit exposures.

Background Information on NTP Peer Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current *curriculum vitae* to the **FOR FURTHER INFORMATION CONTACT**. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 14, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2013–19928 Filed 8–20–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special

Emphasis Panel Expedited Review of Biorepository Project.

Date: September 12, 2013.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-1446, eckertt1@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 15, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–20343 Filed 8–20–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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