Program; *Use:* Section 109(a) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. 109–432) amended section 1833(t) of the Social Security Act by adding a new subsection (17) that affects the payment rate update applicable to Outpatient Prospective Payment System (OPPS) payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. Section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for quality measures selected by the Secretary in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act will incur a reduction in their annual payment update (APU) factor to the hospital outpatient department fee schedule by 2.0 percentage points. Sections 1833(t)(17)(C)(i) and (ii) of the Act require the Secretary to develop measures appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings. Such measures must reflect consensus among affected parties and, to the extent feasible and practicable, must be set forth by one or more national consensus building entities. The Secretary also has the authority to replace measures or indicators as appropriate and requires the Secretary to establish procedures for making the data submitted available to the public. Such procedures must provide the hospitals the opportunity to review such data prior to public release. Our program established under these amendments is referred to as the Hospital Outpatient Quality Reporting (OQR) Program.

Hospital OQR Program payment determinations are made based on OQR quality measure data reported and supporting forms submitted by hospitals as specified through rulemaking. To reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken to employ existing data and data collection systems. The complete list of measures and data collection forms are organized by type of data collected and data collection mechanism.

The Medicare program has a responsibility to ensure that Medicare beneficiaries receive the health care services of appropriately high quality that are comparable to that received by those under other payers. The Hospital OQR Program seeks to encourage care that is both efficient and of high quality in the hospital outpatient setting through collaboration with the hospital community to develop and implement quality measures that are fully and specifically reflective of the quality of hospital outpatient services. *Form Number:* CMS–10250 (OCN: 0938–1109); *Frequency:* Occasionally; *Affected Public:* Private sector—For-profit and not for institutions; *Number of Respondents:* 3,200; *Total Annual Responses:* 3,200; *Total Annual Hours:* 949,590. (For policy questions regarding this collection contact Anita Bhatia at 410–786–7236.)

Dated: August 16, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–20400 Filed 8–20–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

The Food and Drug Administration/ European Medicines Agency Orphan Product Designation and Grant Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting entitled ''The Food and Drug Administration/European Medicines Agency Orphan Product Designation and Grant Workshop.'' This 1-day workshop is intended to provide valuable information about the FDA and European Medicines Agency (EMA) Orphan Drug Designation programs, the FDA Humanitarian Use Device (HUD) Designation program, and the FDA Orphan Products Grant program to participants representing pharmaceutical, biotechnology, and device companies, as well as academics.

Date and Time: The meeting will be held on October 4, 2013, from 8:30 a.m. to 4 p.m.

Location: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Eleanor Dixon-Terry, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5279, Silver Spring, MD 20993–0002, 301–796–8660, FAX: 301–847–8621, *Eleanor.Dixon-Terry@fda.hhs.gov.*

Registration: Interested participants may register for this meeting at the following Web site: *https://events-support.com/events/FDA_Orphan_Workshop.* If you need sign language interpretation during this meeting, please contact Eleanor Dixon-Terry at *Eleanor.Dixon-Terry@fda.hhs.gov* by September 20, 2013.

Attendance: Online registration for the workshop will be limited to 240 participants for the morning session, of which approximately 50 teams (up to 150 participants) may register for the one-on-one sessions. There will be no registration fee for the workshop.

For participants who cannot attend the morning meetings, simultaneous live interactive Webcasts will be made available. Participants may access the drug and biologics Webcast by visiting the following site: *https://collaboration.fda.gov/odd100413/.* The medical devices Webcast can be accessed by visiting: *https://collaboration.fda.gov/hudd100413/.*

SUPPLEMENTARY INFORMATION: The FDA/EMA Orphan Product Designation and Grant Workshop is being conducted in partnership with the European Organisation for Rare Diseases, Genetic Alliance, and the National Organization for Rare Disorders.

The morning program includes two simultaneous sessions. The first will provide an overview of the FDA and EMA Orphan Drug Designation programs, respectively, while the second will provide an overview of the FDA HUD Designation Program and Pediatric Device Consortia Grant Program. Both morning sessions will also cover the Orphan Products Grant Program as they relate to drugs, biologics, and devices. Both of these morning sessions will also be available by Webcast.

The afternoon session (no Webcast), provides an opportunity for appropriately registered participants to have one-on-one meetings with FDA staff members onsite, to discuss the specifics on how to apply for an orphan product grant, a HUD designation, or orphan drug designation. It also provides for videoconference sessions with EMA staff representatives on EMA orphan drug designation. Participants requesting one-on-one meetings are expected to bring information for at

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 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: *whiteld@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