professionals. In May 2011, FDA convened a joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee to discuss the use of acetaminophen in children. Shortly before the meeting, the Consumer Healthcare Products Association (CHPA) proposed to voluntarily phase out all of the existing single-ingredient concentrated drop formulations of the OTC, pediatric, oral, liquid acetaminophen drug products and market only the 160 mg/5 mL. At the Advisory Committee meeting, FDA took note of CHPA's voluntary transition to a single concentration of pediatric oral liquid acetaminophen.

In response to CHPA's voluntary transition to a single concentration of OTC oral liquid acetaminophen products, FDA published a Drug Safety Communication on December 22, 2011, to inform the public of the 160 mg/5 mL concentration now marketed for children ages 2 to 3 years and to recommend that end users of the product read the Drug Facts label to identify the concentration of the oral liquid acetaminophen, dosage, and directions for use.

FDA issued the draft guidance on October 8, 2014 (79 FR 60854), to address ongoing concerns about the potential for acetaminophen overdose associated with these products and to encourage safer use. Comments on the draft guidance were considered while finalizing this guidance, which has been revised and clarified in some respects.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on addressing safety achieved through drug product design and labeling to minimize medication errors. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information found in FDA regulations. The collection of information is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information referenced in this guidance that pertain to the format and content requirements for OTC drug product labeling (§ 201.66) have been approved under OMB control number 0910–0340. The labeling requirements in § 201.326 are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA. Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19178 Filed 8–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Open Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public, 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 also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

Date: November 4, 2015.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: Strategic Discussion of NCI's Clinical and Translational Research Programs.

Place: National Institutes of Health, Building 31, C-Wing, 6th Floor, Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Room 6W136, Rockville, MD 20850, 240–276–6173, *prindivs@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm, where an agenda and any additional information for the meeting will be posted when available.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 31, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19193 Filed 8–4–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30 Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD/OPERA)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection