considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated June 2014.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on the use of nanomaterials in food for animals. 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 571.1 and 21 CFR 571.6 have been approved under 0910–0546.

IV. 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*.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov*.

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19179 Filed 8–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1473]

Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen.'' The guidance is intended to help drug manufacturers, packagers, and labelers minimize the risk to consumers of acetaminophen-related liver damage associated with the use of nonprescription, also known as over-the-counter or OTC, pediatric oral liquid acetaminophen drug products. This guidance provides recommendations regarding acetaminophen concentration, container labels, carton labeling, and packaging of such products, as well as for any associated delivery devices. FDA's recommendations are designed to encourage safer use of these products by minimizing the potential for acetaminophen overdosing due to medication errors or accidental ingestion.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alice Tu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4325, Silver Spring, MD 20993–0002, 301–796–7586.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen.'' Acetaminophen is marketed in many OTC drug products as a pain reliever and fever reducer. Most OTC acetaminophen products are marketed under FDA's ongoing rulemaking to establish a final monograph for OTC internal analgesic, antipyretic, and antirheumatic (IAAA) drug products. These products must conform to the conditions described in FDA's Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter (OTC) Human Use (the IAAA TFM) [1] and FDA's general regulations for OTC drug marketing (21 CFR 330.1) and labeling (21 CFR 330.10 and part 201). They also must be labeled with acetaminophen-related warnings and other information as specified in 21 CFR 201.326. However, OTC pediatric oral liquid drug products containing acetaminophen have been associated with overdoses due to medication errors that resulted in serious adverse events, including severe liver damage and death. In particular, there have been reports of overdose attributed to confusion between concentrated acetaminophen drops (80 milligrams (mg)/0.8 milliliters (mL) and 80 mg/mL) and acetaminophen oral liquid (160 mg/5 mL).

This guidance document is part of FDA's ongoing initiative to reduce the risk of acetaminophen-related liver injury associated with all OTC and prescription acetaminophen-containing products. As part of that initiative, in June 2009, three FDA committees, the Drug Safety and Risk Management Advisory Committee, the Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee, met jointly to consider a range of risk reduction measures. Among other measures, these Advisory Committees recommended moving to a single, standardized acetaminophen concentration for OTC pediatric oral liquid drug products because the availability of multiple concentrations causes confusion and errors among both consumers and health care

[1] ''Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph,'' 53 FR 46204 (November 16, 1988). Available at *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/UCM078460.pdf.*

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