Hampshire Ave., 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100, *drugtrackandtrace@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers.'' On November 27, 2013, the DSCSA (Title II of Pub. L.113–54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA adds sections 581 through 585 as Subchapter H of the FD&C Act. These sections establish definitions (section 581), requirements for supply chain participants (section 582), standards for and licensing of wholesale drug distributors (section 583) and 3PL providers (section 584), and a Uniform National Policy (section 585).

The DSCSA establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to provide, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and 3PL providers. Section 585 of the FD&C Act sets forth a Uniform National Policy, preempting States and political subdivisions of states from establishing or continuing in effect certain standards and requirements. FDA is issuing this guidance to: (1) Help industry and States understand the immediate effects of the law and (2) clarify section 585's effect on State product tracing requirements and on standards, requirements, and regulations with respect to wholesale distributor and 3PL licensing.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the effect of section 585 of the FD&C Act on drug product tracing and wholesale drug distributor and 3PL provider licensing and requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. 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*.

IV. Electronic Access

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

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23972 Filed 10–7–14; 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 Liquid Drug Products Containing Acetaminophen; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Over-the-Counter Pediatric Liquid Drug Products Containing Acetaminophen.'' The draft 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 (OTC), acetaminophen-containing pediatric liquid drug products. This guidance provides recommendations for acetaminophen concentration, container labels and carton labeling, packaging of such products, and recommendations regarding 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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 8, 2014.

ADDRESSES: Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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 draft guidance for industry entitled ''Over-the-Counter Pediatric Liquid Drug Products Containing Acetaminophen.'' Acetaminophen is

marketed in many OTC drug products as a pain reliever and fever reducer. A majority of OTC acetaminophen products are currently marketed under the conditions stated in FDA's tentative final monograph for internal analgesic, antipyretic, and antirheumatic drug products for over-the-counter human use (the IAAA TFM).[1] In addition to the drug labeling requirements described in section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352) and Title 21 of the Code of Federal Regulations (CFR), part 201, OTC acetaminophen products must also be labeled with liver injury warnings and other required information under § 201.326 (21 CFR 201.326). The Agency allows acetaminophen to be marketed without approval of a new drug application (see generally section 505 of the FD&C Act (21 U.S.C. 355) and 21 CFR part 314), in accordance with the IAAA TFM, and when the required acetaminophen-related warnings and other labeling requirements in § 201.326 are met. However, OTC pediatric 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 many 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 draft 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, the Advisory Committees recommended moving to a single, standardized acetaminophen concentration for OTC pediatric liquid drug products because the availability of multiple concentrations causes confusion and errors among both consumers and health care 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) voluntarily proposed to phase out all of the existing concentrated drop formulations of the OTC, single-ingredient, oral, liquid acetaminophen drug products for pediatric use 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 liquid acetaminophen. Among other recommendations, the Advisory Committees recommended the use of a flow restrictor or another feature designed to prevent excessive dosing, use of a safety dosing syringe to reduce accidental ingestion by children, and marking dosage delivery devices in milliliters only.[2]

In response to CHPA's voluntary transition to a single concentration of OTC 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 liquid acetaminophen, dosage, and directions for use.

FDA is issuing this guidance to address ongoing concerns about the potential for acetaminophen overdose associated with these products and to promote their safe use.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on addressing safety achieved through drug product design and labeling to minimize medication errors. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach 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 draft guidance includes information collection provisions that are 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 draft 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 the Office of Management and Budget 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)). In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

IV. Electronic Access

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

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23973 Filed 10–7–14; 8:45 am]

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[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*.

[2] Summary Minutes of the Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee, held May 17–18, 2011, are available at *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM264147.pdf*.