from industry, academia, government, and patient advocacy groups can communicate to improve efficiency and success in drug development. The goals of the CPIM are to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 8, 2014.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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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: Alicia Stuart, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4547, Silver Spring, MD 20993–0002, 301–796–3852.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Critical Path Innovation Meetings.'' The draft guidance describes the purpose and scope of a CPIM and how to request such a meeting. A CPIM provides the opportunity to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how the methodology or technology might enhance drug development. During a CPIM, CDER will identify some of the larger gaps in existing knowledge that requesters might consider addressing in the course of their work. The discussions and background information submitted through the CPIM are nonbinding on both FDA and CPIM requesters. The CPIM initiative meets Prescription Drug User Fee Act (PDUFA) V Reauthorization Goal IX.A, ''Enhancing Regulatory Science and Expediting Drug Development'' by ''Promoting Innovation Through Enhanced Communication Between FDA and Sponsors During Drug Development.''

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 CPIMs. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910–0001. The collection of information resulting from formal meetings between interested persons and FDA has been approved under OMB control number 0910–0429.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23970 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–1411]

The Effect of Uniform National Policy on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Standards: Questions and Answers; 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 ''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.'' FDA is issuing these questions and answers to assist industry and State governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013, on State product tracing requirements and on standards, requirements, and regulations with respect to wholesale distributor and third-party logistics provider (3PL) licensing. Title II is also referred to as the Drug Supply Chain Security Act (DSCSA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New

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