4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1981]

The Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information." The draft guidance addresses the drug supply chain security provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which requires the Secretary of the Department of Health and Human Services to establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format. Specifically, the guidance establishes standards for how transaction information, transaction history, and transaction statements should be exchanged among trading partners through the extension and/or use of current systems and processes.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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

On November 27, 2013, the Drug Supply Chain Security Act (Title II of Public Law 113-54) was signed into law. Section 202 of the Drug Supply Chain Security Act (DSCSA), which adds new sections 581 and 582 to the FD&C Act (21 U.S.C. 360eee and 360eee-1), sets forth new definitions and requirements related to product tracing. The DSCSA outlines critical steps

to build an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States.

Starting in 2015, certain trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) are required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to capture, maintain, and provide the subsequent purchaser with transaction information, transaction history, and a transaction statement (product tracing information) for certain prescription drug products. Manufacturers, wholesale distributors, and repackagers must meet these requirements by January 1, 2015; dispensers must meet them by July 1, 2015. In addition, each manufacturer, wholesale distributor, dispenser, and repackager must comply with all applicable requirements in the event they meet the definition of more than one trading partner under section 582(a)(1), but trading partners are not required to duplicate requirements. Section 582(a)(2)(A) of the FD&C Act directs FDA to establish initial standards to facilitate the interoperable exchange of transaction information, transaction history, and transaction statements between trading partners.

FDA obtained stakeholder input on the development of the initial standards for the interoperable exchange of product tracing information, in paper and electronic formats, through a public docket established in February 2014, as required under section 582(a)(2)(B), and a public workshop that was held May 8 and 9, 2014. The public workshop provided a forum for FDA to obtain input from stakeholders in the pharmaceutical distribution supply chain on how trading partners can best comply with the requirements for the interoperable exchange of product tracing information beginning in 2015, using currently available standards or practices. Comments to the public dockets and from the workshop were considered in the development of this guidance,

and will be considered in developing additional guidance to further elaborate on the standards for the interoperable exchange of product tracing information.

This initial draft guidance establishes standards to help trading partners comply with the requirements of sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to provide the subsequent trading partners with product tracing information, in paper or electronic format, through the extension and/or use of current systems and processes. Under these provisions, trading partners are also required to capture and maintain the applicable product tracing information for not less than 6 years after the date of the transaction. Implementation of these provisions will help further improve the security of the pharmaceutical distribution supply chain and increase confidence in the safety and authenticity of human prescription drugs. FDA intends to issue additional guidance to facilitate the interoperable exchange of product tracing information through standardization of data and documentation practices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is marked as a "draft" consistent with its description in section 582(a)(2)(A) of the FD&C Act. Under section 582(h)(4) of the FD&C Act, FDA intends to eventually "update . . ., as necessary and appropriate, and finalize" this document to reflect standards for interoperable data exchange at the package level. Because the DSCSA clearly intends for stakeholders to rely upon this guidance document before finalization, however, FDA is immediately implementing this document under 21 CFR 10.115(g)(2). As a result, it reflects FDA's current thinking on this topic and is intended to provide guidance to stakeholders as they implement the DSCSA. Guidance documents generally do not create or confer any rights for or on any person and do 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. 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). 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 modifications to those previously approved collections of information found in FDA regulations or guidances.

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/Guidances/default.htm, or http://www.regulations.gov.

Dated: November 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-28085 Filed 11/26/2014 at 8:45 am; Publication Date: 11/28/2014]