4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-2254]

The Drug Supply Chain Security Act Implementation: Product Tracing Requirements--Compliance Policy; 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 guidance for industry entitled "DSCSA Implementation: Product Tracing Requirements--Compliance Policy." This guidance announces FDA's intention with regard to enforcement of certain product tracing requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Supply Chain Security Act (DSCSA). FDA does not intend to enforce these requirements against manufacturers, wholesale distributors, and repackagers who do not, prior to May 1, 2015, provide or capture the transaction information, transaction history, and transaction statement required by the FD&C Act (product tracing information) for transaction of certain human, finished prescription drugs that are covered in the statute.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For information about enforcement dates, please see the SUPPLEMENTARY INFORMATION section.

ADDRESSES: All responses to this notice should be identified with Docket No. FDA-2014-D-2254 and directed to the office listed in the FOR FURTHER INFORMATION CONTACT section of this document.

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 guidance for industry entitled "DSCSA Implementation: Product Tracing Requirements--Compliance Policy." This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance has been implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate. (§ 10.115(g)(2)). This guidance document provides information pertaining to statutory requirements that will take effect on January 1, 2015, regarding the provisions to provide and capture product tracing information under section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act (21 U.S.C. 360eee-1(b)(1), (c)(1), and (e)(1)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices. (§ 10.115(g)(3)).

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. Section 202 of the DSCSA added sections 581 and 582 to the FD&C Act, which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) will be required under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act, to exchange product tracing information when engaging in transactions involving

certain prescription drugs. Manufacturers, wholesale distributors, and repackagers must meet these requirements by January 1, 2015; dispensers must meet these requirements by July 1, 2015.

Although the product tracing requirements under section 582(b), (c), and (e) of the FD&C Act go into effect for manufacturers, wholesale distributors, and repackagers on January 1, 2015, some trading partners have expressed concern that unforeseen complications with the exchange of the required information may result in disruptions in the pharmaceutical supply chain, and ultimately could impact patients' access to needed prescription drugs. FDA recognizes that some manufacturers, wholesale distributors, and repackagers may need time beyond January 1, 2015, to work with trading partners to ensure that all the proper product tracing information is provided and captured. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA does not intend to take action against trading partners who do not, prior to May 1, 2015, provide or capture the product tracing information required by section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act. This compliance policy is limited to the requirements that trading partners provide and capture product tracing information; it does not extend to other requirements in section 582 of the FD&C Act, such as verification of suspect and illegitimate products (including quarantine, investigation, notification, and recordkeeping) or the requirement to engage only in transactions with authorized trading partners.

II. Comments

This guidance is for immediate implementation. FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments 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. You should identify all comments with Docket No. FDA-2014-D-2254.

III. 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: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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