DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy

Guidance for Industry

This guidance is for immediate implementation.

This guidance is for immediate implementation. FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 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 Number FDA-2015-D-2270.

For questions regarding this document, contact CDER Office of Compliance at 301-796-3130 or drugtrackandtrace@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

July 2015
Procedural

DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm
and/or
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-7800
Email: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Office of Regulatory Affairs

July 2015
Procedural

Contains Nonbinding Recommendations

TABLE OF CONTENTS

Contains Nonbinding Recommendations

DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance addresses the readiness of dispensers in the pharmaceutical distribution supply chain to comply with the provisions in section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(d)(1)) related to the exchange of transaction information, transaction history, and transaction statements (product tracing information). For dispensers, requirements for the tracing of products through the pharmaceutical distribution supply chain under section 582(d)(1) of the FD&C Act go into effect on July 1, 2015.[2]

This guidance announces the FDA's intention with regard to enforcement of the product tracing information requirements under section 582(d)(1) of the FD&C Act. As described below, FDA does not intend to take action against dispensers who, prior to November 1, 2015, (1) accept ownership of product without receiving product tracing information, prior to or at the time of a transaction, as required by section 582(d)(1)(A)(i) of the FD&C Act, or (2) do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act. Section IV of this guidance provides further detail about the scope of this compliance policy and FDA's expectations for dispensers and trading partners involved in transactions with dispensers.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] "Dispenser" is defined in section 581(3) of the FD&C Act (21 U.S.C. 360eee(3)).

II. BACKGROUND

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) was signed into law. Section 202 of the DSCSA, which adds new sections 581 and 582 to the FD&C Act, 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, which will identify and trace certain prescription drugs as they are distributed within the United States. This system will enhance FDA's ability to help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.

Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers and repackagers) are required under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to provide the subsequent purchaser with product tracing information when engaging in transactions involving certain prescription drugs. Trading partners are also required to capture the product tracing information and maintain the applicable information for not less than 6 years after the date of the transaction.

FDA, in consultation with other appropriate Federal officials and pharmaceutical distribution supply chain stakeholders, published a draft guidance as required under section 582(a)(2)(A) of the FD&C Act, entitled "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information." This draft guidance established initial standards for the interoperable exchange of the product tracing information related to each transaction of certain human, finished, prescription drugs covered by the statute, in paper or electronic format, through the extension and/or use of current systems and processes.

III. SCOPE OF THIS GUIDANCE

This guidance applies to dispensers engaged in transactions[3] involving "products" as defined under section 581(13) of the FD&C Act.

IV. PRODUCT TRACING REQUIREMENTS FOR DISPENSERS – COMPLIANCE POLICY

The product tracing requirements in sections 582(d)(1) of the FD&C Act take effect for dispensers on July 1, 2015. However, some dispensers have expressed concern that electronic systems used to exchange, capture, and maintain product tracing information will not be operational by this effective date. Although the DSCSA allows product tracing information to be exchanged through paper in certain circumstances,[4] FDA understands that many dispensers

[3] "Transaction" is defined in section 581(24) of the FD&C Act.

[4] See the draft guidance for industry *DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information*." For the most recent version of a guidance, check the FDA Drugs guidance Web page at

intend to utilize electronic systems to capture and maintain product tracing information. Thus, FDA recognizes that some dispensers may need additional time beyond July 1, 2015, to work with trading partners to ensure that the product tracing information required by section 582 is captured and maintained by dispensers.

FDA does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving the product tracing information, as required by section 582(d)(1)(A)(i) of the FD&C Act. This compliance policy does not extend to the requirements under section 582(b)(1), (c)(1), and (e)(1) that other trading partners (manufacturers, wholesale distributors, and repackagers) provide product tracing information to dispensers. In addition, this compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by section 582(d)(1)(A)(ii). If a dispenser has not received product tracing information prior to or at the time it takes ownership of a product, FDA recommends that the dispenser work with the previous owner to receive this information. FDA believes that product tracing information serves as an important tool for dispensers to meet their obligation under section 582(d)(4) to identify suspect product, quarantine the product, and investigate whether that product is illegitimate.[5]

Prior to November 1, 2015, FDA also does not intend to take action against dispensers who do not capture and maintain the product tracing information, as required by section 582(d)(1)(A)(iii) of the FD&C Act.

This compliance policy does not extend to other requirements of the FD&C Act, including those in section 582, such as verification related to suspect and illegitimate product (including quarantine, investigation, notification and recordkeeping) and requirements related to engaging in transactions only with authorized trading partners.

---

http://www.fda.gov/RegulatoryInformation/Guidances/default.htm. This draft guidance, when finalized, will represent FDA's current thinking on this topic.

[5] See the draft guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*. This draft guidance, when finalized, will represent FDA's current thinking on this topic.