FDA Releases Draft Guidances to Enhance Drug Supply Chain Security

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Healthcare Alert
3.2.18

On March 1, 2018, the U.S. Food and Drug Administration (FDA) issued two new draft guidances which further the FDA's implementation of the Drug Supply Chain Security Act (DSCSA). The DSCSA amended the Federal Food, Drug, and Cosmetic Act (FD&C) by establishing requirements for prescription drug product tracing and verification in the United States. The draft guidances outline steps to be taken in the creation of an electronic, interoperable track and trace system for prescription drugs in the United States. This system will be fully implemented by 2023 and will allow the FDA to help protect consumers from counterfeit, stolen, contaminated, or otherwise harmful drugs.

Standardization of Data and Documentation Practices for Product Tracing

This 23-page draft guidance elaborates on the standards for the interoperable exchange of prescription drug product tracing information as required by the FD&C as amended by the DSCSA. The interoperable exchange of such information is the ability of manufacturers, repackagers, wholesale distributors, and dispensers[1] to exchange product tracing information accurately, efficiently and in a usable format. The purpose of the guidance is to assist all participants in the drug supply chain, by standardizing the product tracing information data that they must provide and maintain. Additionally, the guidance provides recommendations for documentation practices based on the specific type of transaction. These recommendations can be used to meet product tracing obligations.

Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act

This 7-page draft guidance provides the FDA's interpretation of terms used in the definitions of "suspect product" and "illegitimate product" in the DSCSA to help manufacturers, repackagers, wholesale distributors, and dispensers meet their verification obligations, such as providing notice to the FDA. Additionally, the guidance provides the FDA's current understanding of the following terms as used in the DSCSA: "counterfeit," "diverted," "fraudulent transaction," and "unfit for distribution."

The above draft guidance documents were distributed for comment purposes only. Prescription drug manufacturers, repackagers, wholesale distributors, and dispensers are encouraged to view the Standardization of Data and Documentation Practices for Product Tracing and Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act in their entirety and to submit any comments or suggestions on or before May 1, 2018 and April 2, 2018, respectively.

If you have questions or need additional information, contact Kate Woods (215.864.6376; woodscj@whiteandwilliams.com; 215.864.6376) or Jason Premus (premusj@whiteandwilliams.com; 215.864.6399).

[1] The DSCSA generally defines "dispensers" a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities.