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FDA 2018 Year in Review: Drug Supply Chain Security Act

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Developments in 2018

In 2018, FDA issued two final and five draft guidance documents to further implement and clarify certain aspects of Title II of the Drug Quality Security Act—the Drug Supply Chain Security Act (DSCSA). DSCSA was enacted by Congress on November 27, 2013, and it provides steps to build a system to identify and trace certain prescription drugs as they are distributed in the United States and to improve detection and removal of potentially harmful drugs from the drug supply chain. The effective compliance date applicable to manufacturers and repackagers for product identifier requirements was November 27, 2018. The effective compliance dates applicable to wholesalers and dispensers for authentication and verification requirements are November 27, 2019, and November 27, 2020, respectively. The deadline for complete unit level traceability is November 27, 2023.

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Section 582 of the FDCA, added by section 202 of DSCSA, requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier that is encoded with the product's standardized numerical identifier, lot number, and expiration date.

FDA finalized two guidance documents related to the DSCSA. In the first guidance, Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy Guidance for Industry, regarding the implementation of the product identifier requirements, FDA stated its intention not to take action against manufacturers that did not affix or imprint a product identifier to each package and homogenous case of product before November 27, 2018 (representing a one-year delay in enforcement of the requirement). In the second guidance, Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier, FDA specified whether and under what circumstances such packages and homogenous cases of product that are not labeled with a product identifier and are in the pharmaceutical distribution supply chain at the time of the effective date shall be subject to the grandfathering exemption from certain requirements. The effective date, as mentioned, was extended to November 27, 2018, for manufacturers. The original effective date of November 27, 2018, remained the same for repackagers.

To further clarify the product identifier requirements under section 582 of the FDCA, FDA issued the Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers draft guidance.

FDA also issued the Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry which outlines the process for submitting requests to FDA for waivers, exceptions or exemptions to the requirements related to the traceability and security of prescription drugs. Section 582 also requires that manufacturers, wholesale distributors, dispensers and repackagers have verification systems in place to comply with tracing and verification requirements. The draft guidance further clarifies relevant terms for verification requirements under section 582. Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act draft guidance provides the industry with the agency's interpretation of the requirements regarding verification systems, recommendations for a robust verification system, recommendations for submitting cleared product notifications,

and a discussion of the statutory requirements for verification. The Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs,

A related draft guidance, Standardization of Data and Documentation Practices for Product Tracing, provides insight to industry on how to standardize the data contained in the product tracing information and how to understand the data elements that should be included in the product tracing information.

Looking Ahead to 2019

The effective compliance date applicable to manufacturers and repackagers for product identifier requirements was November 28, 2018. In 2019, industry can expect FDA to take action against noncompliant entities. The effective compliance date for wholesalers will be November 27, 2019, so wholesalers should be certain to make all necessary changes prior to that date.

Read more on FDA 2018 Year in Review.