

CLIENT ALERT

FDA Postpones DSCSA Provision Enforcement by Three Years

Nov.05.2020

The U.S. Food and Drug Administration (FDA) has again postponed the enforcement of certain requirements under the Drug Supply Chain Security Act (DSCSA), this time by three years.

On October 22, 2020, the FDA issued guidance stating that enforcement of wholesale distributor compliance with the DSCSA's saleable return verification requirement will be postponed until 2023. The FDA guidance states that it "does not intend to take action against wholesale distributors who do not, prior to November 27, 2023, verify the product identifier prior to further distributing returned product as required under the" saleable return verification requirement of the DSCSA. This extension comes just over a year after the FDA's September 2019 guidance, which initially postponed enforcement of the saleable return verification until November 27, 2020.

The FDA has indicated that multiple entities in the supply chain urged FDA to delay enforcement due to concerns with industry-wide readiness for implementation. "Specifically, comments received point out continuing challenges posed by the large volume of saleable returned product, explaining that wholesale distributors still need more time to test verification systems using real-time volumes of saleable returned product with all trading partners involved, as opposed to using small-scale pilot test projects."

Relatedly, the FDA's October 22, 2020 guidance states that, prior to November 27, 2023, the FDA "does not intend to take action against a wholesale distributor for providing a transaction statement to a subsequent purchaser of a product on the basis that such wholesale distributor does not yet have systems and processes in place to comply with the saleable return verification requirements under section 582(c)(4)(D) of the FD&C Act."

The FDA's guidance also delays until November 27, 2023, enforcement against dispensers who do not verify the statutorily-designated portion of product identifiers of suspect product, as well as enforcement of dispenser verification of product when responding to a notification of illegitimate product from FDA or another trading partner.

The FDA expressed its expectation that wholesale distributors and dispensers will use this delay to ensure the necessary systems and processes for compliance with the saleable return verification requirements are in place by November 27, 2023. The additional time provided by this guidance may allow for new technologies and solutions to ensure DSCSA compliance.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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