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New FDA Guidances to Help Pharmaceutical Supply Chain Partners Comply With the DSCSA's Move to Electronic Tracking

By Matthew E. Brown

The Drug Supply Chain Security Act (DSCSA), enacted in 2013, requires entities in the pharmaceutical supply chain to implement security measures to prevent the introduction of counterfeit and illegitimate drugs into the market. One of these measures is the requirement to track the movement of prescription drugs electronically at the package level.

For the last decade, trading partners — which are primarily manufacturers, wholesale distributors, dispensers, and repackagers — have satisfied their tracking obligations largely via paper format. Starting on November 27, 2023, however, the DSCSA will require trading partners to provide, receive and maintain documentation about products and ownership only electronically. FDA is providing a one-year stabilization period to give trading partners additional time to implement these electronic tracing requirements (November 27, 2023, and end on November 27, 2024).

During the stabilization period, trading partners will need to implement, troubleshoot, and mature their electronic interoperable systems while simultaneously being permitted to continue providing documentation about products and ownership in paper format. Trading partners will also need to finalize building and validating interoperable systems and processes, manage products and data, and ensure continuity of the supply chain and product availability to patients during this stabilization period.

The two new guidelines are:

- Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act – Compliance Policies: This guidance describes the FDA's compliance policies regarding enforcement of the enhanced drug distribution security requirements under section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies: This guidance describes the FDA's compliance policies regarding enforcement of the requirements for wholesale distributors and dispensers to verify a product's product identifier in certain circumstances under sections 582(c)(4) and 582(d)(4) of the FD&C Act.

The FDA also announced a final guidance, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act, which provides updated information on the requirements for electronic tracing of prescription drugs at the package level. Links to all guidance documents can be found via the following links:

- *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act – Compliance Policies*
- *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies*
- *Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act*

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