

Publications

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FDA Issues Exemptions from November 27, 2024 Compliance Deadline for Updated DSCSA Requirements

On Wednesday, the Food and Drug Administration (FDA) issued a statement granting additional exemptions from its November 27, 2024 deadline for compliance with certain product transaction requirements. The exemptions followed concerns from the stakeholders across the pharmaceutical supply chain about their ability to fully comply with the new requirements without significant impact on product distribution timelines. The new compliance deadlines vary for manufacturers, repackagers, wholesale distributors and dispensers.

Background

The FDA originally announced these compliance policies in August of 2023, that explained their planned enforcement policies surrounded three key requirements of the Drug Supply Chain Security Act (DSCSA), which incorporated new requirements into the Food, Drug, and Cosmetic Act (FD&C Act):

1. Enhanced drug distribution security requirements across the drug supply chain;
2. Updated verification requirements for saleable returns applicable to wholesale distributors; and
3. Increased verification requirements for dispensers regarding suspect or illegitimate product.

These policies established a “stabilization period” until November 27, 2024, to allow time for the implementation and testing of new processes.

New Exemptions

The FDA’s new guidance emphasized that many pharmaceutical supply chain participants had begun implementation of electronic transaction systems. A significant number of commenters, however, were concerned with their ability to comply with the November 27, 2024 deadline due to ongoing challenges involving missing or incorrect electronic DSCSA transaction information. These trading partners also feared that issues with their updated systems could significantly delay product distribution, including products already experiencing shortages.

Related People

- Mark S. Armstrong
- Laura D. Pone

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In response, on October 9, 2024, the FDA issued new exemptions, applicable to manufacturers, repackagers, wholesale distributors and dispensers. The FDA emphasized in its new guidance that the exemptions apply only to product transacted by eligible trading partners who have initiated systems and processes for compliance, including electronic DSCSA data connections. These exemptions then flow down to any trading partners in the pharmaceutical distribution chain who transact the product. “Eligible trading partners” must have already initiated systems and processes, including successful completion of data connections with their immediate trading partners (or those who have documented initiation of their efforts to establish connections).

The FDA will not require any notification or request for waiver or exemption in order for distribution supply chain partners to be eligible.

The FDA created three separate exemptions for different trading partners, including (i) Manufacturers and Repackagers, (ii) Wholesale Distributors and (iii) Dispensers. Under each of the three exceptions, the trading partners may continue to:

- Rely on current methods for providing, capturing and maintaining transaction information and transaction statements for products introduced into the supply chain;
- Exchange transaction information that does not incorporate package-level product identifiers for each transaction;
- Rely on current package-level product verification methods;
- Use current methods to respond to product transaction information and statement requests from federal and state officials (including, where applicable, if they themselves introduced the product into commerce);
- Continue to use current methods to accept saleable returns of products.

Eligible Wholesale Distributors are also not required to verify the predict identifier, including the standardized numerical identifier, when receiving saleable returned product before further distribution.

The primary difference in the trading partner exemption is the duration. The exemptions for eligible Manufacturers and Repackagers are in place until May 27, 2025, exemptions for eligible Wholesale Distributors are in place until August 27, 2025, and exemptions for eligible Dispensers are in place until November 27, 2025.

Trading partners must communicate their reliance on the exemptions to their immediate trading partners and incorporate a mechanism that allows all parties to confirm the applicability of the exemptions. The FDA reiterated that these updated exemptions should not be viewed as a justification to delay efforts for compliance and that all drug distribution supply chain partners should continue to use their best efforts to implement the new requirements.

If trading partners are not eligible for the exemption described above and do not qualify for either the Small Business Dispenser exemption issued in July 2024 or a different, previously established exemption, they will be expected to comply with all requirements of section 582(g)(1) of the FD&C Act as of November 27, 2024.

If you have questions about the DSCSA’s transaction requirements or your eligibility to qualify for an exemption, please contact:

- Mark Armstrong: marmstrong@polsinelli.com
- Laura D. Pone: lpone@polsinelli.com

