

Navigating the FDA's Updated DSCSA Exemptions in 2025:

What's Expected of Trading Partners

On October 9, 2024, the Food and Drug Administration (FDA) adopted a phased approach for compliance with the final enhanced requirements of the [Drug Supply Chain Security Act \(DSCSA\)](#) (known as enhanced, package-level requirements in § 582(g)(1) of the FD&C Act). While the FDA-issued exemptions are available through 2025, the agency does not view these [exemptions](#) as an opportunity for trading partners to delay efforts. Trading partners are urged to continue with their implementation efforts.

Preparing for Updated Enforcement Timeline

The exemptions began on November 27, 2024, and expire for each sector as follows:



**Manufacturers
and Repackagers:**
May 27, 2025



**Wholesale
Distributors:**
August 27, 2025



**Dispensers with 26 or
more full-time employees:**
November 27, 2025¹

The exemptions apply to any product transacted by eligible trading partners that have initiated their systems and processes, as described in § 582(g)(1) of the FD&C Act. This includes electronic DSCSA data connections (which may include portals) with their immediate trading partners.

Further, the exemptions extend to trading partners throughout the pharmaceutical supply chain that subsequently transact and follow the product through the supply chain with each and every transaction and trading partner.

Trading partners that rely on the exemptions do not need to submit a notification or request for a waiver or exemption to the FDA.

If a trading partner does not need to rely on the exemptions or any previously established DSCSA exemption, the FDA advises the trading partner to comply with the fully enhanced, package-level requirements of § 582(g)(1).

¹ Small dispensers (25 or fewer full-times employees) have until November 27, 2026, to fully comply with the DSCSA enhanced distribution security requirements.

Exemption Conditions



Connection or Documentation

For a trading partner to be eligible for the exemptions, it must have completed the following:

- Successfully connected with its immediate trading partners; these "connections" may include portals; or,
- Documented its efforts to establish connections but are not yet fully able to do so.



Trading Partner Notification

As an additional condition, "FDA expects eligible trading partners to communicate their reliance on the exemptions to their trading partners and that such exemptions, where applicable, also extend to transactions of product with trading partners."

Notifications "should occur through a readily accessible resource or communication and should also provide a mechanism by which trading partners can confirm the applicability of the exemptions."



Supporting Compliance Efforts

Given our decades-long experience on DSCSA and traceability issues, HDA can help answer questions. For more information, contact [Kala Shankle](#).

For more information about pharmaceutical traceability visit: www.hda.org/pharmaceutical-traceability/