

The DSCSA Stabilization Period—under which FDA indicated that it would not enforce the enhanced traceability requirements of the DSCSA—**expired November 26, 2024.**

Learn more at: <https://www.fda.gov/media/171592/download>

However, FDA has established **new flexibilities.**

If you employ **25 or fewer** full-time employees* licensed as pharmacists or qualified as pharmacy technicians

* A full-time employee is one who is employed on average at least 30 hours per week, or 130 hours per month; the number of employees is aggregated across all jointly owned/commonly controlled pharmacies.

- ✓ You **are exempt** from the requirement to receive and maintain package-level transaction information until **November 26, 2026.****

OTHER DSCSA OBLIGATIONS, SUCH AS CONFIRMATION OF SUPPLIERS' AUTHORIZED STATUS AND IMPLEMENTATION OF SYSTEMS AND PROCESSES TO DETECT, INVESTIGATE, AND RESPOND TO SUSPICIOUS PRODUCTS CONTINUE TO APPLY.

- ✓ This exemption is **automatic**; you do not need to apply for it.
- ✓ It is **recommended** that you communicate to your suppliers that you intend to rely on this exemption.

Learn more at: <https://www.fda.gov/media/179256/download?attachment>

If you employ **26 or more** full-time employees* licensed as pharmacists or qualified as pharmacy technicians

* A full-time employee is one who is employed on average at least 30 hours per week, or 130 hours per month; the number of employees is aggregated across all jointly owned/commonly controlled pharmacies.

- ✓ You **may be exempt** from the requirement to receive and maintain package-level transaction information until **November 26, 2025.****
- ✓ To qualify for this exemption, you **must**:
 1. Document that you have completed data connections with your suppliers or have made efforts to do so.
 2. Communicate to your suppliers that intend to rely on this exemption.
- ✓ If you qualify, this exemption is **automatic**; you do not need to apply for it.

OTHER DSCSA OBLIGATIONS, SUCH AS CONFIRMATION OF SUPPLIERS' AUTHORIZED STATUS AND IMPLEMENTATION OF SYSTEMS AND PROCESSES TO DETECT, INVESTIGATE, AND RESPOND TO SUSPICIOUS PRODUCTS CONTINUE TO APPLY.

Learn more at: <https://www.fda.gov/media/182584/download?attachment>

If you do not qualify for either exemption, you may pursue a company-specific waiver or exemption. Information on requesting waivers or exemptions is available at <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-waivers-exceptions-and-exemptions>

**Additional considerations and requirements apply if you further sell/distribute product to an unaffiliated third-party