

Dear All,

FDA is issuing an [exemption](#) from the enhanced drug distribution security requirements of section 582 of the FD&C Act for eligible trading partners. This exemption applies to any product transacted by eligible trading partners, which are trading partners who have successfully completed or made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data.

This exemption is part of the agency's broader efforts to avoid supply chain disruptions and ensure patients will not face delays in receiving the medicines they need.

FDA is committed to ensuring patient access to medicines and avoiding supply chain disruptions while continuing significant progress toward full implementation of Drug Supply Chain Security Act (DSCSA) requirements.

While much progress has been made, including establishing electronic system data connections, this exemption is intended to support continued implementation of DSCSA without disrupting patient access to their medications .

The duration of the exemption varies depending on the eligible trading partners:

- Manufacturers and Repackagers: May 27, 2025
- Wholesale Distributors: August 27, 2025
- Dispensers with 26 or more full-time employees: November 27, 2025

Trading partners who utilize these exemptions do not need to notify FDA. Please share this information with stakeholders that may be interested in this information.

Regards,
Leigh



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Director

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