



In Effort to Avoid Supply Chain Disruptions, FDA Extends DSCSA Exemptions

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On October 9, the FDA announced that the agency is providing exemptions from the enhanced drug distribution security requirements of section 582 of the Federal Food, Drug and Cosmetic Act (FD&C Act) for eligible trading partners, which were scheduled to take effect on November 27. This exemption applies to drug products transacted by trading partners that have successfully completed (or made documented efforts to complete) data connections with their immediate trading partners, but still face challenges exchanging data.

In August of 2023, FDA announced two compliance policies that explained the agency's approach to applying the drug distribution security requirements mandated under the Drug Supply Chain Security Act (DSCSA), which were to take effect on November 27, 2023. At that time, the FDA provided a one-year "stabilization period" to provide trading partners additional time to comply.

A variety of stakeholders had recently expressed concern that more time was needed for trading partners to establish appropriate data exchange systems, and there was a significant risk of drug supply chain disruptions.

The FDA has now provided additional transition time by extending the deadlines for compliance into 2025. The updated compliance deadline depends on the type of trading partner entity in the supply chain:

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

Trading partners that utilize these exemptions do not need to notify the FDA.

Categories

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