Waivers and Exemptions Beyond the Stabilization Period

FDA Grants Exemption to Connected Trading Partners

More Information:

DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners (/browser?url=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F182584%2Fdownload%3Fattachment&traceToken=1728502377;rivhs_hosted;hsu&clickId=C04BB373-0A24-431A-BFCF-E9980ACE33C7)

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.

FDA Grants Exemptions to Small Dispensers

More Information:

Exemptions from certain requirements under section 582 of the FD&C Act for small dispensers (/browser?url=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F179256%2Fdownload%3Fattachment&traceToken=1728502377;rivhs_hosted;hsu&clickId=C04BB373-0A24-431A-BFCF-E9980ACE33C7)

FDA is issuing exemptions from certain requirements of section 582 of the FD&C Act to small dispensers (pharmacies), and where applicable their trading partners, until November 27, 2026. This provides small dispensers additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act (DSCSA).

A dispenser is considered a small dispenser, for the purposes of these exemptions, if, as of November 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians. Pharmacies must make their own determination of whether they meet the definition of a small dispenser.

FDA urges small dispensers to continue their efforts to implement the necessary measures to comply with the enhanced drug distribution security requirements. Small dispensers and their trading partners who utilize these exemptions do not need to submit anything to FDA or inform the agency.

Requesting a Waiver or Exemption Beyond the Stabilization Period

Trading partners that do not qualify for the exemptions above and are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act by November 27, 2024, may request a waiver, exception, or exemption from those requirements. The agency will make every effort to respond to the waiver, exception, or exemption request by November 27, 2024.

A trading partner's obligation to comply with enhanced drug distribution security requirements by November 27, 2024, will not be paused or extended upon submission of a request or while FDA's response is pending. The agency expects the trading partner to continue their efforts to meet the requirements until FDA has approved or denied the request.

What to Include in Your Request

A trading partner's request should include the information recommended in the Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (/browser?url=https%3A%2F%2Fwww.fda.gov%2Fregulatory-information%2Fsearch-fda-guidance-documents%2Fwaivers-exceptions-and-exemptions-requirements-section-582-federal-food-drug-and-cosmetic-act&traceToken=1728502377;rivhs_hosted;https:/www.fda.gov/drugs/drug-su&clickId=C04BB373-0A24-431A-BFCF-E9980ACE33C7) guidance. For example, this guidance recommends that each request include:

- a detailed statement describing the reason(s) justifying the request
- pertinent and applicable supporting documentation
- any special circumstances of a product and/or transaction

The agency has received numerous waiver and exemption requests that have included the following information, which has been useful to address the information recommended in the guidance:

- Steps that have been completed to implement the section 582 requirements for which the waiver or exemption is being sought
- Explanation detailing why additional time is needed
- Steps that will be taken to fully implement requirements
- Number of full-time employees employed by the trading partner seeking the waiver or exemption
- Identity of the manufacturer who holds the approved application(s) for the product(s) involved, if a co-licensed partner or affiliate submits a waiver or exemption request

Submitting Your Request

Trading partners should submit their requests to the agency as follows:

- CDER-regulated products: All requests should be submitted through CDER NextGen (/browser?url=https%3A%2F%2Fcdernextgenportal.fda.gov%2FLogin_CDER%3Fec%3D302%26startURL%3D%252Fs%252F&traceTok su&clickId=C04BB373-0A24-431A-BFCF-E9980ACE33C7).

- CBER-regulated products: Requests associated with a biologics license application (BLA), new drug application (NDA) or abbreviated new drug application (ANDA) that CBER reviews, should be submitted in eCTD format through FDA's Electronic Submissions Gateway as product correspondence to the application. Send requests not associated with a BLA, NDA or ANDA to DSCSA-CBER-WEER@fda.hhs.gov (mailto:DSCSA-CBER-WEER@fda.hhs.gov).

Visit our waivers, exceptions and exemptions (/browser?url=https%3A%2F%2Fwww.fda.gov%2Fdrugs%2Fdrug-supply-chain-security-act-dscsa%2Fdrug-supply-chain-security-act-dscsa-waivers-exceptions-and-exemptions&traceToken=1728502377;rivhs_hosted;https:/www.fda.gov/drugs/drug-su&clickId=C04BB373-0A24-431A-BFCF-E9980ACE33C7) page for more information.