

Waiver, Exception, or Exemption (WEE) and Small dispenser exemption

Waiver, Exception, & Exemption (WEE)

If trading partners, distributors, or dispensers are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act, or you have concerns about readiness or access disruption, you may request a waiver or exemption from those requirements. The obligation to comply with enhanced drug distribution security requirements will not be paused or extended upon submission of a request or while FDA's response is pending. The agency expects efforts be continued to meet the requirements until FDA has approved or denied the request.

- **Waiver:** Request if requirements result in undue economic hardship or for emergency medical reasons, including public health emergencies.
- **Exception:** Request if a product is packaged in a container too small to accommodate necessary labeling.
- **Exemption:** Request for other products or transactions to maintain public health or for other appropriate reasons.

To learn more about waivers, exceptions, and exemptions beyond the stabilization period [click here](#)

Steps to file Waivers, Exceptions, & Exemptions (WEE)

1. All WEE requests must be submitted through the FDA's CDER NextGen portal.
[click here](#)
2. Create a user ID and password for access to the NextGen portal.
3. The WEE submission form is available within the portal.

Small dispenser exemption until November 27, 2026

On June 12, 2024 the FDA announced 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.

To learn more about the small dispenser exemption [click here](#)

What this means for small dispensers

- Small dispensers have additional time to have SOPs and processes for DSCSA in place.
- The updated returns and claims process in effect still applies.