Date Issued: August 6, 2026

Subject: DSCSA Exemptions from Certain Requirements Under Section 582 of the FD&C Act for Small Business Dispensers Until November 27, 2027

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) to grant exemptions to small business dispensers[1] – and, where noted, small business dispensers' trading partners[2] –from certain requirements of sections 582(g)(1) and 582(d)(4) of the FD&C Act,[3] as outlined below, until November 27, 2027.

To maintain public health and help ensure continued patient access to certain prescription drugs in the United States, in July 2024, FDA granted exemptions[4] to small business dispensers – and where applicable, their trading partners – from certain requirements of sections 582(g)(1) and 582(d)(4) of the FD&C Act.[5] That exemption for small business dispensers remains applicable until November 27, 2026.[6]

The requirements under section 582(g)(1) of the FD&C Act, commonly referred to as the *enhanced drug distribution security requirements*, are intended to facilitate interoperable, electronic tracing at the package level of products in the U.S. pharmaceutical distribution supply chain.[7] The FD&C Act recognizes the potential unique technological and operational challenges related to compliance with these requirements for small business dispensers.[8]

To help address those challenges, section 582(g)(3) of the FD&C Act obligates the Agency to conduct the "Assessment of Small Dispensers."[9] Under that provision, FDA is required to contract with a private, independent consulting company to conduct a technology and software assessment that looks at the feasibility of small business dispensers conducting interoperable, electronic tracing of products at the package level.[10] Once the analysis is completed, FDA

[1] Section 582(g)(2)(B)(i) of the FD&C Act specifically refers to agency authority to create alternative timelines for compliance with section 582(g)(1) of the FD&C Act requirements for "small business dispensers with 25 or fewer full-time employees."

[2] *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the product tracing requirements of section 582 of the FD&C Act.

[3] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued *Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (August 2023). This guidance includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or posting on the Agency's website if an exception or exemption applies to a broad segment of industry). An exception or exemption that FDA establishes may be limited in duration or valid until further notice from the Agency." Consistent with that guidance, we are posting these exemptions on our website.

[4] See the 2024 Exemptions from certain requirements under section 582 of the FD&C Act for small dispensers at https://www.fda.gov/media/179256/download?attachment.

[5] See https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/waivers-and-exemptions-beyond-stabilization-period

[6] https://www.fda.gov/media/179256/download?attachment.

[7] See Final Guidance Entitled "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act" (August 2023).

[8] See sections 582(g)(3) and (4) of the FD&C Act.

[9] See https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-assessment-small-dispensers.

[10] See section 582(g)(3)(A) of the FD&C Act.

must also publish the final assessment for public comment[11] and hold a public meeting at which public stakeholders may present their views on the assessment.[12]

As of the date of this notification, there are still steps under section 582(g)(3) of the FD&C Act that are not yet completed as the current small business dispensers' compliance date of November 27, 2026 approaches. Accordingly, FDA is granting an exemption for small business dispensers for an additional one-year period. While significant progress has been made toward implementation of the enhanced drug distribution security requirements, FDA has determined that this extension is appropriate to maintain public health and help ensure continued patient access to certain prescription drugs in the United States. We note that the enhanced drug distribution security requirements remain in effect and are applicable for all other trading partners who do not meet the definition of a small business dispenser.

For the purpose of this exemption, FDA continues to define a dispenser[13] as a small business dispenser if the corporate entity that owns the dispenser has a total[14] of 25 or fewer full-time employees[15] licensed as pharmacists or qualified as pharmacy technicians.[16]

If a small business dispenser relies on the exemptions outlined below, we recommend communicating such reliance to its trading partners as needed to further facilitate distribution of product without difficulty or delay. The exemptions described below do not apply to other requirements in section 582 of the FD&C Act.

FDA has determined that the following FD&C Act exemptions for small business dispensers – and, where noted, their trading partners – continue to be appropriate from November 27, 2026, until November 27, 2027:

- The requirements under section 582(d)(4)(A)(ii)(II) and (B)(iii) of the FD&C Act for dispensers to verify the product identifier of the statutorily designated proportion of suspect or illegitimate product in the dispenser's possession or control. Small business dispensers are still obligated to meet all other verification requirements of section 582(d)(4) of the FD&C Act.
- The requirement under section 582(g)(1)(A) of the FD&C Act that the transaction information and the transaction statements be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of section 582(h) of the FD&C Act. Small business dispensers and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements[17] for transactions of product.
- The requirement under section 582(g)(1)(B) of the FD&C Act that the transaction information required to be exchanged include the product identifier at the package level for each package included in the transaction. Small

[11] See section 582(g)(3)(D)(ii) of the FD&C Act.
[12] See section 582(g)(3)(D)(iii) of the FD&C Act.
[13] See Section 581(3) of the FD&C Act for the definition of *dispenser*.
[14] The total number of employees as of November 27, 2026.
[15] For the purpose of these exemptions, we are adopting the Internal Revenue Service's (IRS) definition of "full-time employee." The IRS defines a *full-time employee* as "for a calendar month, an employee employed on average at least 30 hours of service per week, or 130 hours of service per month." For additional information on identifying full-time employees, see https://www.irs.gov/affordable-care-act/employers/identifying-full-time-employees.
[16] We recognize that section 582(g) of the FD&C Act refers to "dispensers with 25 or fewer full-time employees" without limiting such employees to those who are licensed pharmacists or authorized pharmacy technicians. However, the exemptions being granted here, pursuant to section 582(a)(3) of the FD&C Act, apply to a broader category of dispensers.
[17] Beginning on November 27, 2023, section 582(k)(1) of the FD&C Act effectively ended the requirement for trading partners to provide and receive transaction history.

business dispensers and their trading partners may continue to exchange transaction information that does not include the product identifier at the package level for each package included in the transaction.

- The requirement under section 582(g)(1)(C) of the FD&C Act that systems and processes for verification of product at the package level, including the standardized numerical identifier, be in accordance with the standards established under the guidance issued pursuant to section 582(a)(2) of the FD&C Act and the guidances issued pursuant to paragraphs (2), (3), and (4) of section 582(h) of the FD&C Act. Small business dispensers and their trading partners may continue to rely on current methods for verification activities.
- The requirement under section 582(g)(1)(D) of the FD&C Act for systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary, or other appropriate Federal or State official, in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product. Small business dispensers and their trading partners may continue to rely on current methods to respond to requests for such information.
- The requirement under section 582(g)(1)(E) of the FD&C Act for systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable (i) in the event of a request by the Secretary, or other appropriate Federal or State official, on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary, or other appropriate Federal or State official, with a request described in clause (i). If small business dispensers directly transacted the product(s) subject to the request, they may use current methods to respond to such requests with their relevant transaction information.
- The requirement under section 582(g)(1)(F) of the FD&C Act that each person accepting a saleable return have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement for the product. Small business dispensers' trading partners may use current methods to accept saleable returns.

The exemptions described in this notification are not intended to provide, and should not be viewed as providing, a justification for delaying efforts by small business dispensers to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges small business dispensers to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements to strengthen supply chain integrity and further protect public health. Small business dispensers and their trading partners who utilize these exemptions do not need to submit any additional information to FDA.

Sincerely,

MICHAEL M. LEVY -S

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