Date Issued: October 9, 2024

Subject: DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners

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 from certain requirements in section 582 of the FD&C Act[1] as described in this document.

In August 2023, FDA announced two compliance policy guidances[2] that explained, among other things, FDA's enforcement policy with respect to several Drug Supply Chain Security Act (DSCSA) requirements: (a) the enhanced drug distribution security requirements[3] in section 582(g)(1) of the FD&C Act; (b) verification requirements for wholesale distributors regarding saleable returned product[4] in section 582(c)(4)(D) of the FD&C Act and (c) verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act. Together, the compliance policy guidances established a stabilization until November 27, 2024, to accommodate additional time that trading partners in the pharmaceutical distribution supply chain may need to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) enhanced drug distribution security requirements.

FDA understands that many trading partners have made considerable progress with implementing enhanced drug distribution security requirements and initiating their systems and processes, particularly in establishing the data connections necessary to exchange electronic DSCSA transaction information and transaction statements with one another. Nevertheless, the Agency continues to receive comments and feedback from trading partners across the pharmaceutical distribution supply chain, who, despite having established or attempted to establish the necessary connections to facilitate secure, interoperable, electronic DSCSA data exchange with their trading partners, express concerns with readiness to properly meet the FD&C Act requirements noted above at the conclusion of the stabilization period on November 27, 2024. Specifically, such trading partners describe challenges resolving issues involving missing or erroneous data in electronic DSCSA transaction information and transaction statements without significantly delaying product distribution, including products that are in shortage. FDA recognizes that trading partners, who have initiated their systems and processes and have established electronic DSCSA data connections with their trading partners, may need additional time

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[1] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued guidance on waivers, exceptions, and exemptions from section 582 of the FD&C Act requirements, that 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 - if an exception or exemption applied to a broad segment of industry - a posting on its website). An exception or exemption that is established by FDA may be limited in duration or valid until further notice from FDA." Consistent with that guidance, we are posting these exemptions on our website.

[2] For more information, see the compliance policy guidances for industry, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies* (August 2023) and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies, Revision 1* (August 2023).

[3] *Enhanced drug distribution security requirements* refer to the requirements for interoperable, electronic, package-level product tracing, including systems and processes, in section 582(g)(1) of the FD&C Act.

[4] *Product* is defined in section 581(13) of the FD&C Act.

beyond November 27, 2024, when the stabilization period ends, to strengthen capabilities to mitigate data issues associated with electronic DSCSA transaction information and transaction statements and to ensure uninterrupted product distribution. Accordingly, FDA is issuing these exemptions to accommodate the additional time beyond November 27, 2024, that may be needed by trading partners who have initiated their systems and processes, including electronic DSCSA data connections, to strengthen capabilities to address challenges with data exchange, quality and reliability. FDA has determined that use of the authority to issue exemptions under section 582(a)(3) is appropriate at this time, in order to maintain public health and help ensure continued patient access to prescription drugs in the United States at a time of increased concern about potential shortages or supply chain disruption.

While FDA's compliance policies establishing the stabilization period ending November 27, 2024, explained that FDA did not intend to take action to enforce certain DSCSA requirements for trading partners generally, the current exemption applies only to those who have initiated systems and processes, as described above.

The exemptions apply to any product transacted by eligible trading partners who have initiated their systems and processes, as described in section 582(g)(1) of the FD&C Act, including electronic DSCSA data connections (which may include portals) with their immediate trading partners by November 27, 2024, and extend to trading partners throughout the pharmaceutical distribution supply chain who subsequently transact such product. For the purposes of these exemptions, eligible trading partners are those who have initiated their systems and processes by successfully completing data connections with their immediate trading partners and those who initiated processes including documentation of efforts to establish data connections but were not able to fully complete them with all immediate trading partners.

If trading partners do not need to rely on the exemptions in this document, the exemption for Small Business Dispensers issued by FDA on July 12, 2024[5], or any other previously established DSCSA exemption, we advise them to exchange electronic DSCSA transaction information and transaction statements and meet all other requirements of section 582(g)(1) of the FD&C Act beginning November 27, 2024. The exemptions described in this document do not apply to other requirements in section 582 of the FD&C Act. Trading partners who rely on the exemptions described in this document do not need to submit a notification or request for a waiver or exemption to FDA.

Manufacturers and Repackagers

FDA has determined that the following exemptions are appropriate for any products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025; the exemptions only apply to the trading partners, products, transactions, and section 582 requirements of the FD&C Act described in this document.

- The requirement under section 582(g)(1)(A) of the FD&C Act that the transaction information

[5] On June 12, 2024, FDA issued a letter with exemptions from the requirements of section 582(g)(1) of the FD&C Act to small dispensers (defined as the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians), 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). On July 12, 2024, FDA re-issued the letter with clarifying edits to the June 12, 2024, issuance.

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.[6] Eligible manufacturers, repackagers, and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements[7] for products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025.

- 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 (e.g., the National Drug Code, serial number, lot number, and expiration date) at the package level for each package included in the transaction. For products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025, eligible manufacturers, repackagers, and their trading partners may continue to exchange transaction information for product that does not incorporate – at the package level for each package in the transaction – the product identifier.
- 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. Eligible manufacturers, repackagers, and their trading partners may continue to rely on current methods for verification of product at the package level for products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025.
- 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. Eligible manufacturers, repackagers, and their trading partners may continue to rely on current methods to respond to such requests for such information for products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025.
- 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). Eligible manufacturers, repackagers, and their trading partners may use current methods to respond to such requests, for products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025, with

[6] For more information, see the FDA guidance for industry, "*DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs*."

[7] 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.

the relevant transaction information if they directly transacted the product(s) subject to the request.

- 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. Eligible manufacturers, repackagers, and their trading partners may use current methods to accept saleable returns for products introduced in a transaction into commerce by eligible manufacturers or repackagers from November 27, 2024, until May 27, 2025.

Wholesale Distributors

FDA has determined that the following exemptions are appropriate for any products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025; the exemptions only apply to the trading partners, products, transactions, and section 582 requirements of the FD&C Act described in this document.

- The requirement under section 582(c)(4)(D) of the FD&C Act to verify the product identifier, including the standardized numerical identifier, upon receipt of saleable returned product prior to further distribution. Eligible wholesale distributors are still obligated to meet all other verification requirements of section 582(c)(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. Eligible wholesale distributors and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements[8] for products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025.
- 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 (e.g., the National Drug Code, serial number, lot number, and expiration date) at the package level for each package included in the transaction. For products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025, eligible wholesale distributors and their trading partners may continue to exchange transaction information for product that does not incorporate – at the package level for each package in the transaction – the product identifier.
- 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. Eligible wholesale distributors and their trading partners may continue to rely on current methods for verification of product at the package level for products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025.
- 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,

[8] 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.

in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product. Eligible wholesale distributors and their trading partners may continue to rely on current methods to respond to such requests for such information for products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025.

- 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). Eligible wholesale distributors and their trading partners may use current methods to respond to such requests, for products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025, with the relevant transaction information if they directly transacted the product(s) subject to the request.
- 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. Eligible wholesale distributors and their trading partners may use current methods to accept saleable returns for products transacted by eligible wholesale distributors from November 27, 2024, until August 27, 2025.

Dispensers with 26 or more Full Time Employees[9]

FDA has determined that the following exemptions are appropriate for any products transacted by eligible dispensers from November 27, 2024, until November 27, 2025; the exemptions only apply to the trading partners, products, transactions, and section 582 requirements of the FD&C Act described in this document.

- The requirements under sections 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. Eligible 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. Eligible dispensers and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements[10] for products transacted by eligible dispensers from

[9] Eligible dispensers include, among other considerations described in this document, trading partners who do not qualify for the Small Business Dispenser exemptions issued by FDA on July 12, 2024.

[10] 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.

November 27, 2024, until November 27, 2025.

- 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 (e.g., the National Drug Code, serial number, lot number, and expiration date) at the package level for each package included in the transaction. For products transacted by eligible dispensers from November 27, 2024, until November 27, 2025, eligible dispensers and their trading partners may continue to exchange transaction information for product that does not incorporate – at the package level for each package in the transaction – the product identifier.
- 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. Eligible dispensers and their trading partners may continue to rely on current methods for verification of product at the package level for products transacted by eligible dispensers from November 27, 2024, until November 27, 2025.
- 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. Eligible dispensers and their trading partners may continue to rely on current methods to respond to such requests for such information for products transacted by eligible dispensers from November 27, 2024, until November 27, 2025.
- 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). Eligible dispensers and their trading partners may use current methods to respond to such requests, for products transacted by eligible dispensers from November 27, 2024, until November 27, 2025, with the relevant transaction information if they directly transacted the product(s) subject to the request.
- 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. Eligible dispensers' trading partners may use current methods to accept saleable returns for products transacted by eligible dispensers from November 27, 2024, until November 27, 2025.

As a condition of the exemptions from certain DSCSA requirements described in this document, the FDA expects eligible trading partners to communicate their reliance on the exemptions to their trading partners and that such exemptions, where applicable, also extend to transactions of product with trading partners. Such notification should occur through a readily accessible resource or communication

and should also provide a mechanism by which trading partners can confirm the applicability of the exemptions.

The exemptions described in this document are not intended to provide, and should not be viewed as providing, a justification for delaying efforts to implement the enhanced drug distribution security requirements in section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Sincerely,

Michael M. Levy -S

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