Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies

Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

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Contains Nonbinding Recommendations

TABLE OF CONTENTS

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Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is for trading partners[2] — namely manufacturers, wholesale distributors, dispensers, and repackagers[3] — who are subject to requirements for enhanced drug distribution security under section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54). These requirements go into effect on November 27, 2023.[4] FDA is issuing this guidance to address industry readiness to comply with these requirements.

This guidance announces the Food and Drug Administration's (FDA or Agency) compliance policies regarding enforcement of the enhanced drug distribution security requirements[5] under section 582(g)(1) of the FD&C Act that will go into effect on November 27, 2023. FDA believes the compliance policies provided in this guidance will help supply chain stakeholders, particularly trading partners, by accommodating the additional time that may be needed to continue to develop and refine appropriate systems and processes to conduct interoperable, electronic tracing at the package level, to achieve robust supply chain security under the DSCSA while helping ensure continued patient access to prescription drugs.

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[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration.

[2] *Trading partner* is defined in section 581(23) of the Federal Food, Drug, and Cosmetic Act (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 same product tracing requirements of section 582 of the FD&C Act.

[3] *Manufacturer*, *wholesale distributor*, *dispenser*, and *repackager* are defined in section 581(10), (29), (3), and (16) of the FD&C Act, respectively.

[4] See section 582(g)(1) of the FD&C Act. ("On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:")

[5] For the purpose of this guidance, *enhanced drug distribution security requirements* refers to the requirements for interoperable, electronic, package-level product tracing, including specified systems and processes, in section 582(g)(1) of the FD&C Act.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. DSCSA

The DSCSA was signed into law on November 27, 2013. The DSCSA outlines critical steps for building an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added section 582 to the FD&C Act, which established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of product[6] through the pharmaceutical distribution supply chain. Section 582 of the FD&C Act also imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023.[7]

B. Enhanced Drug Distribution Security

The compliance policies described in this guidance address the requirement that beginning November 27, 2023, the use of electronic-based approaches generally will be required among all trading partners to meet the enhanced drug distribution security requirements outlined in section 582(g)(1) of the FD&C Act. As described in this provision (and generally summarized below), on that date, trading partners are required to:

(1) Use secure, interoperable, electronic approaches to exchange transaction information,[8] which must include package level product identifiers[9] for each package included in the transaction, and to exchange transaction statements;[10,11]

(2) Have systems and processes in place to verify products at the package level;[12]

[6] *Product* is defined in section 581(13) of the FD&C Act as a prescription drug for human use in a finished dosage form for administration to a patient without substantial further manufacturing. See section 581(13) of the FD&C Act for specific exclusions.
[7] See section 582(g)(1) of the FD&C Act.
[8] *Transaction information* is defined in section 581(26) of the FD&C Act.
[9] *Product identifier* is defined in section 581(14) of the FD&C Act.
[10] *Transaction statement* is defined in section 581(27) of the FD&C Act.
[11] See section 582(g)(1)(A) and (B) of the FD&C Act.
[12] See section 582(g)(1)(C) of the FD&C Act.

(3) Have systems and processes in place to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary,[13] or other appropriate Federal or State official, in the event of a recall or for investigations of suspect or illegitimate product;[14]

(4) Have systems and processes in place to facilitate the gathering of information needed to produce the transaction information for a product going back to the manufacturer, as applicable, in the event of a request by the Secretary, or other appropriate Federal or State official, on account of a recall or for suspect or illegitimate product investigations, or in the event of a request by an authorized trading partner (in a secure manner that protects confidential commercial information and trade secrets) for purposes of investigating a suspect product or assisting with such a governmental request;[15] and

(5) Have systems and processes in place to accept saleable returns under appropriate conditions, i.e., being able to associate the saleable return product with the transaction information and transaction statement associated with that product.[16]

Until November 27, 2023, wholesale distributors, dispensers, and repackagers can use *either* paper-based or electronic-based methods[17] to provide transaction history,[18] transaction information, and transaction statements to subsequent purchasing trading partners as long as the selected method allows the information to be exchanged in a manner that complies with the requirements of section 582(c)(1), (d)(1), and (e)(1) of the FD&C Act, respectively. However, under section 582(b)(1)(C) of the FD&C Act, manufacturers have been required since November 2017 to use electronic-based methods to provide transaction history, transaction information, and transaction statements to subsequent purchasing trading partners, except that the manufacturer may provide transaction history, transaction information, and transaction statements in a paper format if the subsequent purchaser is either a: (1) State licensed health care practitioner authorized to prescribe medication; or (2) licensed individual who dispenses product in the usual course of professional practice and is under the supervision or direction of a licensed prescribing health care practitioner.[19]

Since the enactment of DSCSA, FDA and trading partners have been preparing for the implementation of the enhanced drug distribution security requirements imposed by section

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[13] In practice, references in the FD&C Act to *the Secretary* generally mean FDA. The Secretary of Health and Human Services (the Secretary) has redelegated to the Commissioner of Food and Drugs (Commissioner), with authority to redelegate (except when specifically prohibited), authority including functions vested in the Secretary under the FD&C Act — see FDA Staff Manual Guide 1410.10 at https://www.fda.gov/media/81983/download.

[14] See section 582(g)(1)(D) of the FD&C Act.

[15] See section 582(g)(1)(E) of the FD&C Act.

[16] See section 582(g)(1)(F) of the FD&C Act.

[17] See section 582(a)(2)(A) of the FD&C Act; see also sections 581(25) and 581(27) of the FD&C Act.

[18] Beginning Nov 27, 2023, section 582(k)(1) of the FD&C Act effectively ends the requirements for trading partners to provide and receive transaction history. However, under section 582(g)(1)(E) of the FD&C Act — as described in section II.B — trading partners must by that date have systems and processes necessary to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, in the event of a recall or for certain investigations.

[19] See section 582(b)(1)(C)(i)–(ii) of the FD&C Act.

582(g)(1) of the FD&C Act.[20] Trading partners are continuing to put in place the necessary systems and processes in order to electronically exchange product tracing information[21] with each transaction[22] of product in anticipation of the November 27, 2023, effective date for these requirements. While trading partners have the obligation to comply with the requirements in section 582 of the FD&C Act, there are other stakeholders involved and affected, including but not limited to: solution providers, standards organizations, trade and professional organizations, state authorities, and federal authorities.

FDA understands that collaboration and alignment among trading partners and other stakeholders throughout the supply chain are critical for achieving interoperability under the DSCSA. FDA has heard from stakeholders, including a broad representation of trading partners, about concerns regarding trading partner readiness and the need for clarity and flexibility to ensure trading partners can continue to move product through the supply chain when the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act take effect.[23] While FDA generally expects trading partners to have the systems and processes in place to meet these requirements as of November 27, 2023, we recognize that some technical and operational issues, including issues involving trading partners and other affected stakeholders, may not be fully resolved by that time.[24] The Agency also understands that additional time beyond November 27, 2023 may be needed for systems to stabilize and be fully interoperable for accurate, secure, and timely electronic data exchange. This guidance is intended to provide clarity and flexibility to trading partners to help ensure continued patient access to prescription drugs as the supply chain transitions to the interoperable, electronic product tracing at the package level under the DSCSA. The compliance policies in this guidance can help trading partners throughout the supply chain implement the requirements under section 582(g)(1) of the FD&C Act by accommodating the additional time that may be needed to implement, troubleshoot, and mature their systems and processes while supporting the continued availability of products to patients.

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[20] For example, FDA has issued a number of guidances and has held several public meetings to support the efficient and effective implementation of DSCSA requirements. Additionally, FDA's DSCSA Pilot Project Program offered stakeholders the opportunity to explore and evaluate methods for the enhanced drug distribution security requirements to go into effect on Nov 27, 2023. See FDA's DSCSA web page, available at https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

[21] Product tracing information to be exchanged under the enhanced drug distribution requirements of section 582(g)(1) of the FD&C Act refers to the transaction information, including product identifiers at the package level pursuant to section 582(g)(1)(B), and the transaction statement.

[22] *Transaction* is defined in section 581(24) of the FD&C Act as the transfer of product between persons in which a change of ownership occurs. For specific exemptions, see section 581(24)(B) of the FD& Act.

[23] On Dec 7–8, 2022, FDA held a virtual public meeting on DSCSA Implementation and Readiness Efforts for 2023, available at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa-implementation-and-readiness-efforts-2023-12072022. The purpose of this public meeting was to provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to share their perspectives on DSCSA implementation.

[24] For example, FDA has issued a proposed rule to amend FDA regulations governing the format of the NDC. The regulation, if finalized, would establish a uniform, 12-digit format for the NDC. See FDA's proposed rule, "Revising the National Drug Code Format and Drug Label Barcode Requirements" (87 FR 44038), available at https://www.federalregister.gov/documents/2022/07/25/2022-15414/revising-the-national-drug-code-format-and-drug-label-barcode-requirements. Trading partners may need to consider how to best plan for potential NDC format changes and incorporate them into their systems and processes if or when such changes become effective.

FDA will continue to monitor trading partner readiness to meet the requirements under section 582(g)(1) during and after the period of the compliance policy in this guidance and is committed to supporting the efforts of trading partners to achieve enhanced drug distribution security. We note FDA has the authority under section 582(a)(3) of the FD&C Act to grant exemptions from certain requirements in section 582 of the FD&C Act – including after the compliance policy period in this guidance – when the Agency determines that an exemption is appropriate to maintain public health or is otherwise appropriate.[25]

This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under 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.

III. COMPLIANCE POLICIES REGARDING SECTION 582(G)(1)(B) OF THE FD&C ACT

Section 582(g)(1)(B) of the FD&C Act requires that, as of November 27, 2023, the transaction information required to be exchanged under section 582 include the product identifier (i.e., the standardized numerical identifier consisting of the NDC and serial number, lot number, and expiration date) at the package level for each package included in the transaction. FDA does not intend to take action to enforce this requirement until November 27, 2024. FDA is issuing this compliance policy to accommodate the additional time (beyond November 27, 2023) that may be needed by trading partners to achieve compliance and to help ensure continued access to prescription drugs as trading partners continue to refine processes for the inclusion of the product identifier at the package level for each package in a transaction into the transaction information in accordance with section 582(g)(1)(B).

In addition, FDA does not intend to take action to enforce the requirement under section 582(g)(1)(B) of the FD&C Act with respect to product that is introduced in a transaction into commerce by the product's manufacturer or repackager before November 27, 2024, and for subsequent transactions of such product through the product's expiry. This means that FDA does not intend to take action if the transaction information for product introduced in a transaction into commerce by the product's manufacturer or repackager before November 27, 2024, does not incorporate—at the package level for each package in the transaction—the product identifier. This policy will facilitate the use and exhaustion of product supply already in the supply chain prior to November 27, 2024.

[25] See https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-waivers-exceptions-and-exemptions and the guidance for industry *Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act* (August 2023) referenced therein. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

This section 582(g)(1)(B) compliance policy will not apply to product that is introduced in a transaction into commerce by the product's manufacturer or repackager on or after November 27, 2024.

IV. COMPLIANCE POLICIES FOR OTHER ENHANCED DRUG DISTRIBUTION SECURITY REQUIREMENTS UNDER SECTION 582(G)(1) OF THE FD&C ACT

FDA is issuing the following compliance policies with respect to the other requirements under section 582(g)(1) of the FD&C Act for the interoperable, electronic product tracing at the package level that go into effect on November 27, 2023.

Until November 27, 2024, FDA does not intend to take action to enforce:

- 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); and

- 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) and the guidances issued pursuant to paragraphs (2), (3), and (4) of section 582(h).

FDA believes these compliance policies will facilitate the continued use of methods currently used for providing, capturing, and maintaining data for the data exchange between trading partners for product tracing and verification while accommodating the additional time that may be needed for trading partners to continue to develop and refine systems and processes for electronic data exchange (e.g., modify IT capabilities, make business operations more routine, and modify business relationships as needed).

In addition, until November 27, 2024, FDA does not intend to take action to enforce:

- 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; and

- 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). Under this compliance policy, we recommend that trading partners respond to such requests with its relevant transaction information— if it directly transacted the product(s) that are subject to the request.

FDA believes these compliance policies will facilitate the continued use of methods currently being used by trading partners to respond to the type of requests for information described above while accommodating the additional time that may be needed for trading partners to mature the new systems and processes required for such activities under section 582(g)(1)(D) and (E) of the FD&C Act.

Lastly, until November 27, 2024, FDA does not intend to take action to enforce 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. FDA believes that this compliance policy will facilitate the continued use of methods currently being used by wholesale distributors[26] for associating a saleable return product with its applicable transaction information and transaction statement while accommodating the additional time that may be needed for all trading partners to mature the new systems and processes required for acceptance of saleable returns under section 582(g)(1)(F).

The compliance policies described above balance the development of robust interoperable, electronic tracing of product at the package level through the pharmaceutical distribution supply chain with the technical and operational complexities associated with the implementation of the enhanced drug distribution security requirements established by the DSCSA. FDA believes these compliance policies will support the development and utilization of accurate, efficient, and secure systems and processes to help protect patients from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful and to ensure adequate distribution of finished prescription drugs throughout the supply chain.

The compliance policies described in this guidance do not apply to other requirements in section 582 of the FD&C Act.

[26] Section 582(c)(1)(B)(i)(II) of the FD&C Act provides that, as of Nov 27, 2019, wholesale distributors may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. Under section 582(k)(2) of the FD&C Act, section 582(c)(1)(B)(i) sunsets on Nov 27, 2023.