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FDA Gives More Time To Comply With Certain DSCSA Requirements

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This November, the Drug Supply Chain Security Act's (DSCSA) enhanced drug distribution security requirements will go into place. Under section 582 of the Food, Drug, and Cosmetic Act (FDC Act), all trading partners in the pharmaceutical supply chain are to use secure, interoperable electronic approaches to exchange transaction information and transaction statements and have product identifiers and verification systems for product at the package level.

In a new guidance document issued in August of this year, the FDA gave wholesalers and dispensers one more year to set up systems for some of the drug verification requirements of DSCSA.[1] This guidance, the *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect of Illegitimate Product—Compliance Policies,* is FDA's third extension of the agency's policy not to enforce those obligations. The delay will surely be welcomed by wholesalers and other trading partners who have been concerned that the immature systems for these verification requirements, if enforced, could disrupt the pharmaceutical distribution supply chain as a whole.

At the same time, FDA reminded industry that the guidance is not intended to provide justification for delaying the implementation of the enhanced drug distribution security requirements under section 582(g)(1) of the FDC Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Background On The FDA's Decision To Delay Enforcement

In November 2013, Congress passed the DSCSA, codified under new section 582 of the FDC Act, to ensure the safety and security of the U.S. pharmaceutical supply chain for certain prescription drug products. The law established several supply chain security requirements for all trading partners (manufacturers, repackagers, wholesalers, and dispensers) such as licensure, registration, reporting, product tracking and tracing, product identifiers, product verification, and handling suspect or illegitimate products. The various requirements went into effect gradually over the past 10 years.

The 2023 compliance policies set forth only a few of these DSCSA requirements for which FDA will continue to exercise enforcement discretion. These requirements are:

1. Under FDC Act § 582(c)(4)(D), starting on Nov. 27, 2019, wholesalers cannot further distribute a returned product without first verifying the product identifier (including the standardized numerical identifier) on each sealed homogeneous case of such product or, if not in a sealed homogeneous case, on each package. Unless it completes this verification step, the wholesaler is required to hold that saleable returned product as a suspect product.[2] Furthermore, FDC Act § 582(c)(1) requires the wholesaler to certify in transactions that its systems and process complied with drug product verification requirements.

2. Under FDC Act § 582(d)(4)(A)(ii), effective Nov. 27, 2020, dispensers must verify that the product identifier of at least three packages (or 10 percent of such suspect product, whichever is greater, or all packages if there are fewer than three packages) corresponds with the product identifier for a product in the dispenser's possession or control.

3. Finally, under FDC Act § 582(d)(4)(B)(iii), and after Nov. 27, 2020, dispensers must verify, using product identifiers, that they have not received a notification from FDA or a trading partner that the product in their possession or control is an illegitimate product.

The 2019 And 2020 Compliance Policies

On Sept. 24, 2019, FDA issued the *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy* guidance, an enforcement policy that announced a one-year delay in enforcement of the wholesaler requirement to verify saleable returned products. Subsequently, on Oct. 23, 2020, FDA issued the *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy* guidance, in which it extended the 2019 Compliance Policy by three more years, and issued a new policy that it did not intend to enforce the requirement for

dispensers to verify the product identifier to determine whether the product was suspect or illegitimate for three years. Therefore, FDA determined to not enforce any of the three requirements listed above until Nov. 27, 2020.

As the expiration of the 2020 compliance policies approached, FDA convened an industry meeting in December 2022 to discuss the implementation readiness efforts for the November 2023 expiration of its enforcement discretion policy. FDA received comments and feedback from attendees that the industry was not yet ready to implement the verification requirements:

- Wholesalers shared that the technology to build an interoperable electronic system to timely and efficiently verify the very large volume of saleable returned products was still immature, and the systems had not yet been tested and refined during actual production using real-time volume of saleable returned products.
- Similarly, dispensers described challenges with implementing their verification requirements because of the need to develop technologies and processes to support a robust verification system, especially because of the time needed to verify the product identifiers of a statutorily designated proportion of suspect and illegitimate products.

FDA recognized that enforcing these requirements when the required systems are not in place can potentially cause a disruption to the pharmaceutical distribution supply chain for certain prescription drugs. Recognizing that additional time is needed to develop these systems, FDA again extended the enforcement discretion policy for a full year.

The 2023 Compliance Policy

Just like the previous compliance policies, the 2023 compliance policy guidance addresses the readiness of wholesale distributors to comply with the FDC Act's section 584(c)(4)(D) requirements. FDA states that the agency does not intend to take action before Nov. 27, 2024, against wholesale distributors who do not verify the product identifier prior to resale or other further distribution of a returned package or sealed homogenous case of product. This extends the 2020 compliance policies by one year, from Nov. 27, 2023, to Nov. 27, 2024, with respect to enforcement of the requirement under section 582(c)(4)(D) of the FDC Act. In addition, FDA does not intend to take action against wholesalers who transact with other parties without having systems and processes in place to comply with the saleable return verification requirements, which conforms with FDA's intention not to enforce the saleable returned verification requirement.

Similarly, FDA does not intend to take action before Nov. 27, 2024, against dispensers who do not verify the product identifiers of suspect product as required by section 582(d)(4)(A)(ii)(II) of the FDC Act or against dispensers who do not verify the product identifiers of illegitimate product that are the subject of a notification from FDA or a trading partner as required by section 582(d)(4)(B)(iii) of the FDC Act. This represents a one-year extension of the 2020 compliance policies, from Nov. 27, 2023, to Nov. 27,

2024, with respect to enforcement of these requirements for dispensers to verify the product identifier when investigating suspect or illegitimate product.

Note that FDA's enforcement discretion policy does not apply to any of the other verification requirements set forth in section 582(d)(4) of the FDC Act, including the wholesaler requirement to verify whether a returned product is a suspect product. FDA has issued other guidance documents regarding its current thinking on the various other requirements. See, e.g., Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act –Compliance Policies (August 2023), at 5 (For example, "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 Nov. 27, 2024, does not incorporate—at the package level for each package in the transaction—the product identifier.").

Conclusion

FDA recognizes extending the enforcement discretion for another year "will allow wholesale distributors to focus resources and efforts on implementing the enhanced drug distribution security requirements."[3] FDA is optimistic that the extra time will permit wholesale distributors to timely, securely, and efficiently incorporate the verification of saleable returns with their development of the enhanced verification systems required by the DSCSA. The additional time will also allow wholesalers to test their ability to verify saleable returns using real-time volume, involving all trading partners.

References:

1. FDC Act § 581(3), (29)
2. FDC Act § 581(7), (11)
3. FDA, Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product— Compliance Policies, Guidance for Industry (Aug. 2023)

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