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FDA finalizes two guidances clarifying DSCSA enforcement exemptions and issues product identifier Q&A

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Yesterday, the U.S. Food and Drug Administration (FDA) finalized two important Drug Supply Chain Security Act (DSCSA)-related guidances that aim to help pharmaceutical trading partners understand their compliance obligations for packages and homogenous cases of product that are not labeled with a product identifier and that are in the distribution supply chain at the time of the effective date of the requirements of the DSCSA. The FDA issued these guidances due to the FDA's decision to delay by one year – until November 27, 2018 – the FDA's enforcement of the requirement for manufacturers to affix or imprint product identifiers, known as "serialization."

The first guidance, "Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy," confirms the extended serialization deadline. It finalizes the July 2017 draft guidance conveying that the FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of product before November 27, 2018, representing a one-year delay in enforcement of this DSCSA requirement.

The second guidance, "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier" ("grandfathering guidance") finalizes its November 2017 draft guidance, which clarifies that a package or homogenous case of product that is not labeled with a product identifier is eligible for an FDA enforcement exemption under the DSCSA only if the product was packaged by the manufacturer or repackaged by the repackager before November 27, 2018. The exemption allowing repackagers to sell product without a product identifier that they repackaged before November 27, 2018 represents a change from the draft guidance based on comments indicating that repackagers will need time beyond November 27, 2018 to sell such already-packaged products.

Significantly, the grandfathering guidance provides helpful examples of the types of documentation on which a trading partner may rely to establish that a package or homogenous case was packaged or repackaged before November 27, 2018. In one example, the FDA says that if transaction information or transaction history shows a sale before November 27, 2018, a trading partner can reasonably conclude that the product was packaged or repackaged before November 27, 2018. In another example, the FDA indicates that a trading partner may rely on a manufacturer's or repackager's transaction statement – which must include a representation that the owner did not knowingly ship suspect or illegitimate product – as "one indication" that the

product was packaged before November 27, 2018, absent other indications that the product may be suspect or illegitimate. The FDA did state that if a trading partner who owns the product requests a manufacturer or repackager to provide the packaging date, the manufacturer or repackager should supply it; however, the FDA did not recommend that trading partners request such packaging date information.

The grandfathering guidance also sets out related exemptions from DSCSA requirements for grandfathered packages and homogenous cases of product (i.e., those packaged or repackaged before November 27, 2018) based on the specific types of trading partners.

- **Manufacturers** are exempted, for grandfathered products, from their DSCSA-imposed duty to verify products at the package level using the product identifier when they determine that such products in their possession or control are suspect, or when they receive a verification request from the FDA or from an authorized trading partner in possession of such product.
- **Wholesale distributors** are exempted, for grandfathered products, from the DSCSA requirement they engage in transactions involving only product encoded with a product identifier beginning November 27, 2019, and from the requirement that they undertake certain activities to determine whether a product is illegitimate.
- **Dispensers** are exempted, for grandfathered products, from the DSCSA requirement that they engage in transactions involving only product encoded with a product identifier beginning November 27, 2020, and that they verify the product identifier of a portion of packages beginning November 27, 2020, as part of an investigation conducted to determine whether a product is illegitimate.
- **Repackagers** are exempted, for grandfathered products, from the DSCSA requirement to only engage in transactions of product encoded with a product identifier beginning November 27, 2018, and to verify products at the package level using the product identifier beginning November 27, 2018.

Last, the grandfathering guidance exempts trading partners at every level in the supply chain from DSCSA requirements to verify the product identifiers of saleable returned packages or sealed homogenous cases of grandfathered products that are intended for further distribution, if those packages or cases were in the pharmaceutical distribution supply chain before November 27, 2018.

The grandfathering guidance makes clear that all the above exemptions are only from the requirements specifically involving product identifiers. Trading partners must fulfill all other DSCSA obligations involving grandfathered products that do not depend on the product identifier, such as the obligation to validate applicable transaction history and transaction information.

Also worth noting is that because the DSCSA authorizes the FDA to exempt grandfathered product from the product identifier requirement through guidance rather than through regulation, the grandfathering guidance has legally binding effect. Such legally binding status for guidance documents is an exception to the usual rule that guidance documents provide only recommendations and do not have a binding effect.

Expanding on this direction is a third document published yesterday, "Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers" (Q&A), which includes 19 answers addressing topics such as linear barcode requirements, FDA contacts, serial number appearance requirements, GS1 Global Trade Identification Numbers, Quick Response codes, 2D data matrix barcodes, waiver requests, and other labeling requirements. The Q&A also provides a table that

matches different unit sizes to their DSCSA barcode identification requirements, and lists prescription drugs that are excluded from the DSCSA, including blood components intended for transfusion, imaging drugs, and homeopathic drugs. While the Q&A does not change the requirements, the Q&A is intended to assist manufacturers and repackagers in standardizing the format of information in the product identified. The Q&A makes clear that current good manufacturing practice requirements (CGMP) apply to affixing or imprinting the product identifier, and therefore manufacturers, repackagers, and other trading partners should be sure that adequate quality controls are in place.

If you have any questions about the impact of the DSCSA guidance documents discussed above, please contact any of the authors or the Hogan Lovells attorney with whom you commonly work.

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