FDA Issues Long-Awaited Grandfathering Guidance

On November 27, the FDA posted guidance around grandfathering product under DSCSA. While it is draft guidance that is subject to change based on public comments prior to being finalized, there are directional insights to be gained from an initial review.

Background

DSCSA specifies that the FDA shall create and finalize guidance relating to the grandfathering of product under the product identifier (serialization) requirements. This newly issued guidance is the FDA's draft response to this DSCSA requirement. It specifies circumstances where packages and homogeneous cases of product that are "in the pharmaceutical distribution supply chain at the time of the effective date of the requirements" of DSCSA, shall be exempted from certain provisions of DSCSA product identifier requirements. The FDA states that this draft guidance must be read in conjunction with the FDA's previously issued draft guidance on product identifier requirements published this summer to determine the full effect for pharmaceutical manufacturers and other members of the pharmaceutical supply chain.

Key Summary Implications

While the language in the guidance is somewhat convoluted, the common interpretation is that a package or homogeneous case not labeled with a product

identifier will be exempt from the manufacturer serialization requirements if there is documentation that it was packaged by the manufacturer prior to November 27, 2018.

The guidance specifies that a product or homogeneous case of product is “in the pharmaceutical distribution supply chain” if such product was packaged by the product’s manufacturer before Nov. 27, 2018. Thus, a package or homogeneous case of product that is not labeled with a serialized product identifier is eligible for an exemption only if the product’s manufacturer packaged the product before Nov. 27, 2018. Such product, to be eligible, must be accompanied by documentation that it was packaged by the manufacturer before Nov. 2018. This could be the sale of a drug product into the supply chain prior to that date, or other documentation relatively attesting to packaging which occurred prior to the date such as batch records or the transaction statement made about such product during a sale.

We believe that this is the intended interpretation of the manufacturer’s serialized product packaging requirements. We must point out though that there is some ambiguity due to the language used in the guidance, in particular because the statement of product eligibility for grandfathering by the manufacturer is in the scope section and it is not explicitly stated in the list of two manufacturer requirements clearly denoted as being exempt highlighted later on in the guidance. It also does open up the question as to if the full intent of the FDA’s guidance is to allow drug product that was packaged prior to Nov. 27, 2018, but not yet sold, to be sold by the manufacturer into the supply chain until expiry date.

The other major implications are for the rest of the supply chain and basically allow wholesale distributors, dispensers, etc., an exemption from following related buy/sell and verification requirements for product that is covered under grandfathering. For example, distributors can continue to buy/sell drug product without a product identifier past Nov. 27, 2019, up until expiration date, as long as the product was packaged prior to Nov. 27, 2018.

Guidance Details

For product where there is documentation that the product involved in a transaction was in the pharmaceutical supply chain before Nov. 27, 2018, the following exemptions and modifications apply:

Manufacturers:

- Manufacturers investigating suspect product in their possession/control, w/o a product identifier, to determine if it is illegitimate, do not have to verify the product at the package level.
- Manufacturers do not have to respond to a request for verification of a drug product at the package level by an authorized trading partner.

Wholesale Distributors:

- Distributors may still engage in buy/sell transactions beginning Nov. 27, 2019 with product that does not have a product identifier as long as such product was packaged before Nov. 27, 2018.
- Distributors are not required to verify product at the package level using the product identifier beginning Nov. 27, 2019 for such exempted product as part of a suspect/illegitimate product investigation.

Dispensers:

- Dispensers may still engage in buy transactions beginning Nov. 27, 2020 with product that does not have a product identifier as long as such product was packaged before Nov. 27, 2018.
- Dispensers are not required to verify product at the package level using the product identifier beginning Nov. 27, 2020 for such exempted product as part of a suspect/illegitimate product investigation.

Repackagers:

- Repackagers may still accept ownership of product that does not have a product identifier after Nov. 27, 2018 if it was packaged by the original manufacturer before Nov. 27, 2018.
- Repackagers wishing to transfer ownership of product without a product identifier on/after Nov. 27, 2018 must add a product identifier to the product prior to sale.v Repackagers are not required to verify product at the package level using the product identifier beginning Nov. 27, 2018 for such exempted product as part of a suspect/illegitimate product investigation.
- If a repackager initially repackaged and sold product without a product identifier before Nov. 27, 2018, they are exempt from the requirement to verify the product identifier when receiving a request to do so from an authorized trading partner for such product.

All:

- For companies receiving saleable returns without product identifiers after Nov. 27, 2018 that they intend to resell, such organizations (manufacturers, wholesale distributors, repackagers) are exempt from the requirement to verify the product identifier of such product prior to resale.

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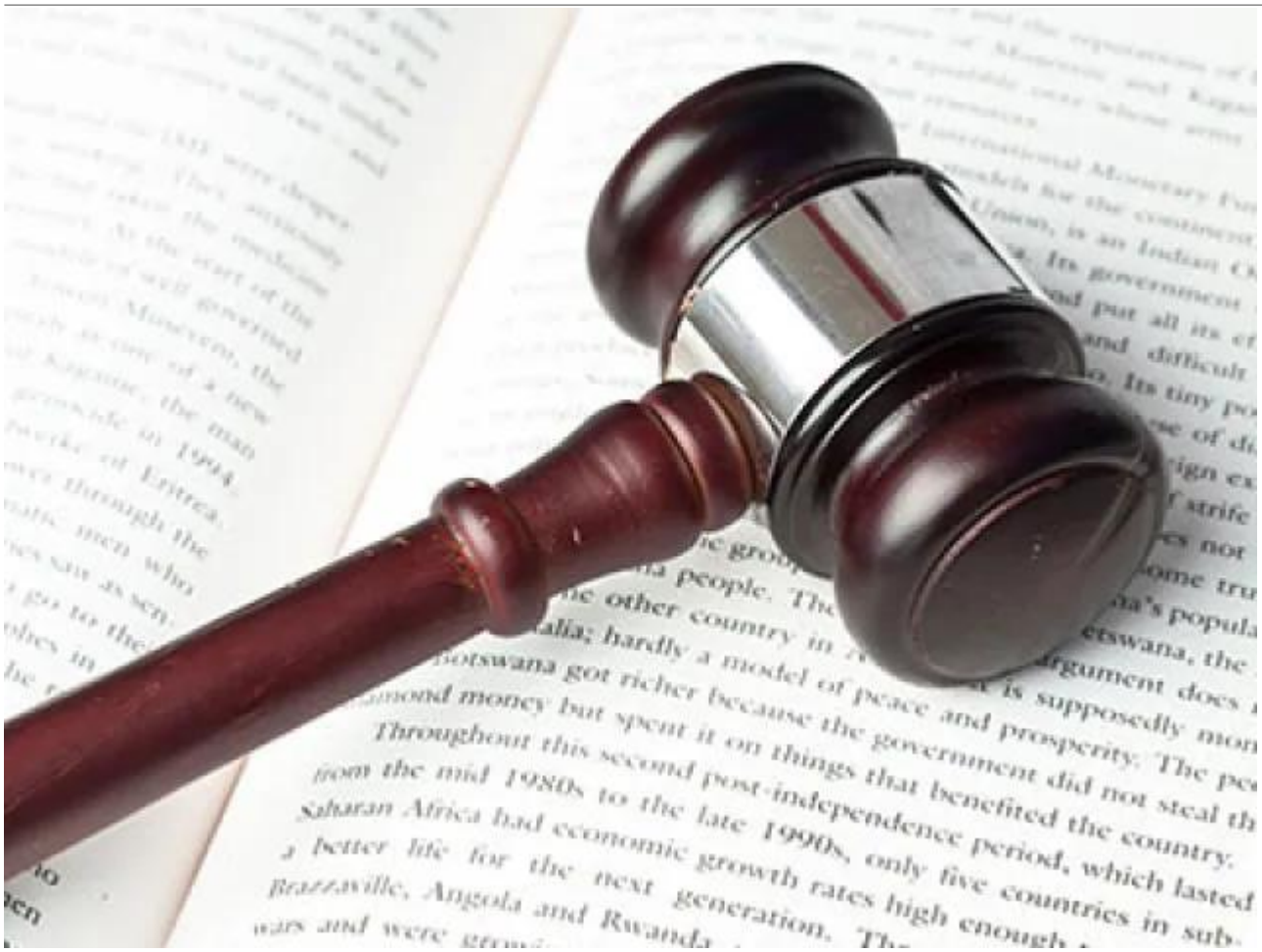

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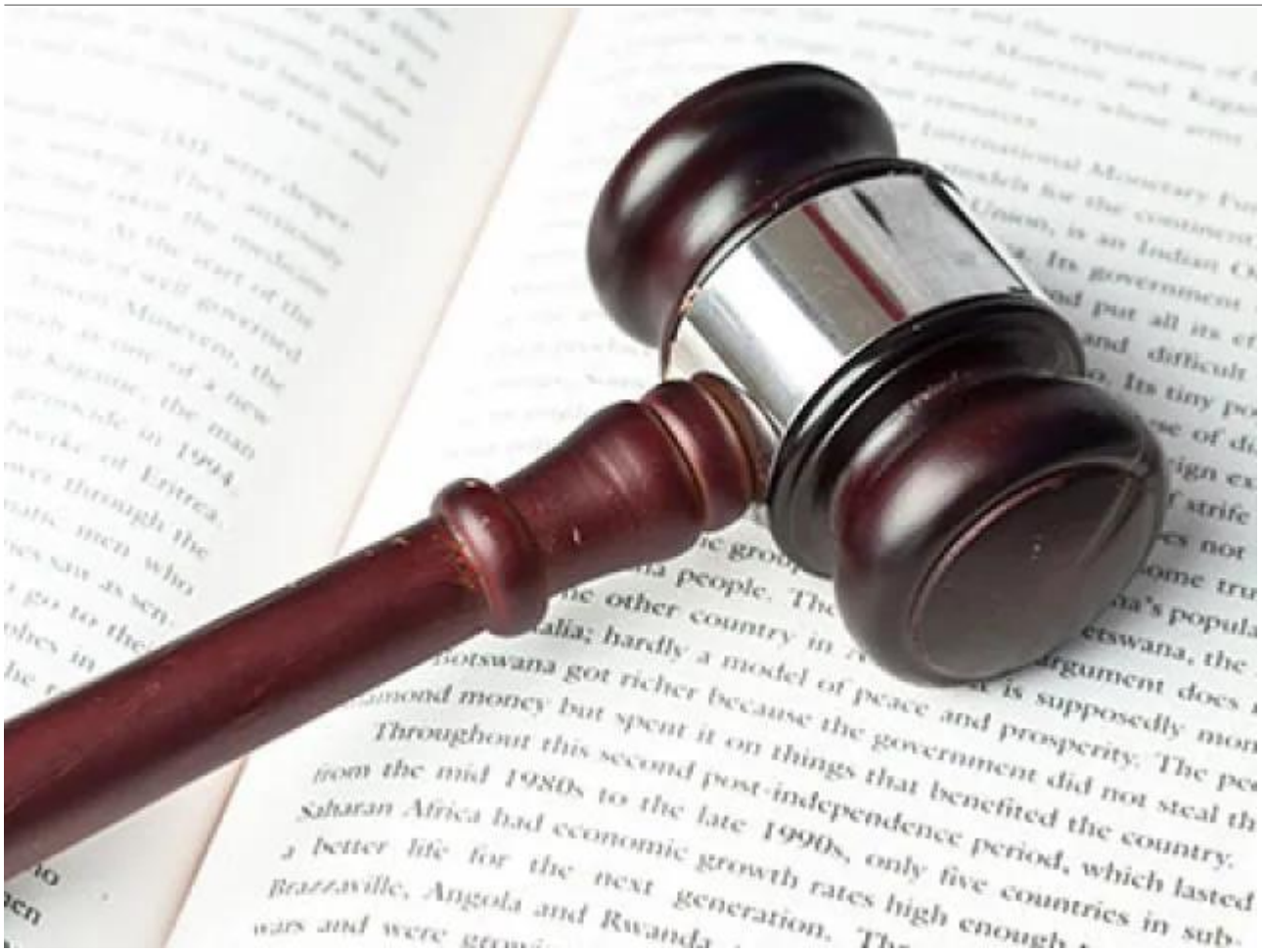

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