



## **The FDA has recently released a few guidance pieces for pharmacies regarding DSCSA.**

First, the FDA released the [\*“Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act”\*](#) seen [here](#).

In this guidance, FDA emphasized that pharmacies (known as “dispensers” in the DSCSA) and other trading partners’ product tracing information should be true, accurate, and complete. The FDA recognizes that there may be situations where there is a clerical error or discrepancy in the product tracing information that may not be indicative of a suspect product. As a result, the FDA stipulated that if a dispenser or other trading partner purchases a product and identifies a potential clerical error or other discrepancy in the product tracing information received, it should resolve the error or discrepancy within 10 business days. (Dispensers must respond within 2 business days to a request from the Secretary of HHS or other appropriate Federal or State official in the event of a recall or for the purpose of investigating a suspect product or illegitimate product.)

The second guidance is titled [\*Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies\*](#) seen [here](#).

In this guidance, the FDA confirms that it won’t take action against pharmacies before November 27, 2024, who aren’t compliant with the DSCSA.

Specifically, you have additional time to:

1) verify the product identifier of the statutorily designated proportion of suspect product as required by the DSCSA

and

2) verify the product identifier of the statutorily designated proportion of product that is the subject of an illegitimate product notification by FDA or a trading partner.

Lastly, the [\*DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry\*](#) seen [here](#), clarifies that pharmacies need a GLN to initiate trace requests and be an authorized trading partner of any distributor.