

DSCSA – 2020 Saleable Returns FDA Enforcement Discretion

AmerisourceBergen Position – December 2020

Dear Manufacturer Trading Partner,

On October 22, 2020, the FDA announced enforcement discretion for wholesale distributor verification of saleable returns until November 27, 2023. Based on this new guidance, and after discussions, both internally and with other industry partners, there is a strong desire as an industry to proceed forward in a more limited and controlled fashion.

What You Need to Know:

At AmerisourceBergen, we still see value in submitting verification requests, albeit limited to a few distribution centers, to be able to operationally capture and correct barcode issues, work through data integrity and organizational concerns, and stabilize exception-handling processes. We have always viewed EPCIS/VRS and other solutions we were putting in place in 2020 as foundational for 2023, and we want to ensure that foundation is reliably built and integrated into the pharmaceutical supply chain ahead of the final deadline.

What You Need to Do:

Accordingly, we ask that our manufacturer partners continue in a level of earnest so that we can work through issues now and not wait until the 2023 deadline. We are planning multiple pilots in 2021 to fully understand the 2023 end-to-end traceability process and exceptions-handling solutions required to avoid disruption in the supply chain.

Furthermore, we anticipate that we will need at least one year of data to help to prevent any gaps of information once the November 2023 regulation goes into effect. Based on this, we ask that if you're not currently sending EPCIS data, that you plan to achieve that by January 1, 2023 at the latest.

If you are not currently live with EPCIS or VRS, we ask that you provide your company's timeline and contact information to our team: SecureSupplyChain@amerisourcebergen.com.

Please let us know if you have any questions.
Thank you,

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