

October 2021

RE: Merck Update Regarding Meeting U.S. Drug Supply Chain Security Act Requirements

Dear Merck Customer:

As you know, the US Drug Supply Chain Security Act (DSCSA) was signed into law in November 2013 and is being phased in over a multi-year timeframe.

On an ongoing basis, we continually review any updated draft guidance documents from the FDA. We also collaborate with industry associations and partnerships on the 2023 implementation and remain committed to our customers on a successful path forward.

Because the relationships with our customers are vital to us, we are providing this update on our plans to meet the DSCSA requirements:

- Aggregation efforts on internal and external packaging lines continue to be on target, with completion of pallet-level aggregation targeted for Q2' 2023.
- Merck is aggressively working with our 3PL fulfillment partners to capture serialized data on outbound shipments, with transmission initiation of EPCIS event data targeted for early 2023. Based upon the aggregation efforts described above, Merck is aware that transmitted data may not be fully complete during the early implementation effort, but serialized events will still be sent.
- Merck will continue to provide electronic ASNs to direct wholesaler/distributors that have an existing connection through 856 EDI transactions.
- The onboarding of wholesaler/distributor customers that require EPCIS data exchange will be coordinated through our collaboration partner, SAP ICH.
- Drop ship EPCIS transactions, if applicable, are included as part of a later phase of the implementation, but still prior to the compliance date. We are participating in discussions with solution providers regarding how we can address this activity and provide a capability for end customers to access the information.
- Based upon customer feedback, Merck understands that an incomplete shipment event file will be acceptable until the compliance date of 27 November 2023.
- The full list of our Global Trade Item Number (GTIN) information, under the DSCSA Resources section of www.merckorders.com www.merckorders.com continues to be updated multiple times each year.
- The following is a list of serialization-exempt products; these products are packaged without the inclusion of a unique product identifier.

- a. STERILE DILUENT 0.7ML 10X1DOSE VIAL NDC 00006430900
- b. TICE RECON KIT/SOD CHLOR 50ML VIAL USA NDC 00052060101

c. BLACK WIDOW SPIDER ANTIVENIN

NDC 00006542402

As a reminder, Merck web portals will continue to allow both direct and indirect (drop ship) Merck customers electronic access to DSCSA-required TI/TH/TS. This data can be accessed under the DSCSA Resources section of www.merckorders.com, or within the Helpful Links section of www.merckvaccines.com

We appreciate your business and look forward to the opportunity to collaborate with you on this important initiative. If you have any serialization related questions or concerns, please contact us at usserialization@merck.com.

Thank you,

The Merck US Serialization Team