

By Electronic Mail

Customer Name
Address

September 08, 2017

Regarding: Title II of the Drug Quality and Security Act – Sandoz Inc. Updates

Dear Valued Partner,

The Drug Quality and Security Act (DQSA) was signed into law on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, identifies the requirements for building an electronic, interoperable system to identify and trace prescription drugs distributed in the United States.¹ On June 30, 2017, the FDA issued a draft one year non-enforcement guidance to the November 27, 2017, requirements. For preparation of the next manufacturing DQSA milestones and taking in consideration the non-enforcement draft and multiple solutions to comply with the regulation, Sandoz is providing an update on our ongoing efforts of Lot Level Tractability and Product Serialization.

As of November 27, 2017:

- Sandoz intends to have all products packaged by March 01, 2018 imprinted with a 2-D Data Matrix on each sellable unit and homogeneous shipper that includes the GTIN, a 14 digit numerical Serial Number, Lot and Expiry and human readable print of the same according to GS1 standards.
- Full cases will have an HDA (Healthcare Distribution Alliance)-compliant case label. Partial Cases will be serialized with an SSCC (Serial Shipping Container Code) label.
- Sandoz inventory of non-serialized product after November 26, 2017 will continue to be sold until such stock is depleted unless prohibited by FDA grandfathering guidance
- Transaction Information, history and statement will be sent electronically using an ASN (Advance Shipping Notice) through Sandoz's third party supplier, TraceLink. If you are not connected to Tracelink, a copy of the DSCSA compliant Packaging list will be obtainable through Sandoz's web portal "Customer Connect".
- In 2017, Sandoz will gradually introduce serialized product by SKU, after exhausting non-serialized inventory.
- Sandoz will not provide serial number verification services prior to November 27, 2017.
- Sandoz will communicate by November 2017, our processes for receiving enhanced verification request
- Sandoz is evaluating options on how best to communicate with to our customer's information on Sandoz product master data –GTIN (Global Trade Information Number) information. Sandoz is investigating Orgin or another third party provider
- Currently, Sandoz has no plans to implement aggregation for 2017. Sandoz will continue to keep you informed on our progress in complying with the DQSA requirements

As of November 27, 2019

- To support authorized trading partner's need to verify sellable returns prior to re-distribution, Sandoz is working to provide a customer-friendly technical solution. Sandoz is participating in the HDA Verification Router Service work group to support the development of such solution.

As a Valued Customer, Sandoz would like your feedback as to your intentions to participate in the HDA verification process, and your plans for verification of serial numbers (with manufacturers).

Overly Sandoz will continue to keep you informed on our progress in complying with the DSCSA requirements

Please send any questions or requests for additional information to Kirko.kirkov@sandoz.com and dave.mason@novartis.com

Thank you,

Scott Smith
Vice-President Commercial Operations US
US Generics Operating Unit.

¹ U.S. Food and Drug Administration, *Drug Supply Chain Integrity*, Drug Supply Chain Security Act (DSCSA), available at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>

Customer Questionnaire

Company Name: _____

Preferred contact information (email or Phone #):

Will your company be using Orgin to obtain GTIN Information from a manufacturer?

Yes or No

Please place an X

If yes, will your company require a manufacturer to join Orgin or can they use another third party?

Yes or No

Please place an X

For the 2019 sellable returns requirement for wholesalers, will your company participate in the HDA sponsored router service for serial number verification? (Dispensers excluded from question)

Yes or No

Please place an X

If No, what is your requirement to verify serial numbers for manufacturers for sellable returns?

(Please explain)

When does your company expect to initiate serial number exchange with a manufacturer?

_____ (MM/YEAR)

Please return by email to: dave.mason@novartis.com by September 20, 2017

This questionnaire will help Sandoz provide the expected customer service for DSCSA



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