



November 22, 2019

LSPedia Inc.

RE: DSCSA Compliance Manufacturer Supplier Letter

Dear Valued Trading Partner,

The Drug Supply Chain Security Act (DSCSA), enacted on November 27, 2013 aims to help combat the threat of pharmaceutical diversion by enhancing the traceability of prescription pharmaceutical products in the U.S. This letter communicates wholesale Distributor's DSCSA implementation plan using LSPedia as their DSCSA solution provider in the area of ASN, EPCIS, VRS, and Interoperability.

1 [2015 Lot Tracing Requirement](#)

All suppliers shall continue send ASN for Transaction History, Transaction Information, and Transaction statement using ASN 856 formatted to the [HDA 856 Specification](#). If you are not currently sending ASN, please click this link to [establish ASN connection](#) process with us.

2 [EPCIS use for DSCSA 2018 Serialization Requirement](#)

Suppliers who are ready to provide outbound EPCIS data, please click [establish EPCIS connection](#) to begin the EPCIS data exchange process. Your wholesale distributor customers will use the internal EPCIS data repository to verify serialized packages before sending a verification request (VRS API call). For EPCIS, please complete the attached GTIN Datasheet to allow sufficient information needed for integration.

3 [DSCSA Verification Requirements \(VRS\)](#)

The [FDA enforcement discretion for wholesalers](#) did not give manufacturers and repackagers the same latitude on responding to verification requests. Please note that there is no enforcement discretion for manufacturers.

3.1 [Verification Router Service \(VRS\)](#)

If you prefer VRS or want to use both EPCIS and VRS, you can establish a VRS connection with LSPedia taking the following two action items.

3.1.1 [Supplier VRS/EPCIS Onboarding](#)

Please click and complete the [VRS Supplier Form](#) to start the VRS onboarding process. Be sure to attach your completed GTIN Datasheet. If you cannot complete all the questions on the form, please indicate with "not complete" for what you cannot supply and return the form any way, we will follow-up later. We need a Point of Contact (PoC), so please designate a group email address to receive VRS notifications for negative responses (e.g. [groupname@company.com](#)); you can then add or delete individual emails as needed.

3.1.2 [GTIN Datasheet](#)

The GTIN datasheet contains sections for NDC (11), package level GTIN, inner pack GTIN, case level GTIN, and PoC corresponding to each GTIN. The PoC will receive alert notifications described in 3.2 and 3.3. Please complete the attached GTIN Datasheet and upload it along with the VRS Supplier form in 3.1.1.



We believe offering the flexibility of two methods, EPCIS and/or VRS, will allow suppliers to meet the interoperability verification requirement. To be clear, we will only verify through the EPCIS and/or VRS network. We will not support manual verification requests, one-off solutions, or one-off API integration. Training for the negative verification and investigation process we are implementing will be presented soon; aiding suppliers' ability to coordinate responses to the investigations.

3.2 [Verification of Suspect/Illegitimate Product Starting November 2019](#)

We will continue current best practices for suspect and illegitimate products in accordance to DSCSA section 582 (c)(4)(A) – (C). For record keeping purposes, if your product is involved in a suspect/illegitimate product investigation, your wholesaler customers will use LSPedia's response system (onescan.lspedia.com). The system will generate an email alert with a notification link for you to respond to. If you are not registered on OneScan, the notification link will take you to the registration page. Registration is required to ensure permission to authorized trading partners (ADR) only.

3.3 [Verification of Saleable Returns November 2019 to November 2020](#)

Test verifications: Test verifications are performed for both EPCIS and VRS in a controlled test environment via the LSPedia test system (onescantest.lspedia.com). We can setup the process to scan some of your products in live warehouse environment or you can Submit Test Data (see below) for testing verification requests. Testing in the test system (not production) are test in nature. They are not subject to 582 (c)(4)(D) requirement, instead as noted in 3.2, the email alert will be turned off. For products that receive a false negative verification during this testing phase, they are considered "test of process" and not a "request for verification".

Submit Test Data: To provide test data, you can either use the [test data form](#) or attach a spreadsheet in the form. To enter the test data in the form, please enter 1 test data (GTIN, Serial#, Lot#, and Expiration Date) per test protocol. If you are attaching a spreadsheet, please use the [test data template](#). The PoC will be notified immediately when your data has been tested.

Production verifications: Upon successful testing, you can request the move to production environment. At that point, when encountering a negative product notification, you will receive an email alert with a notification link to begin the coordinated investigation process. Registration to OneScan is required for you to respond. To ensure smooth transition to production, we recommend you register and complete OneScan training before February 28, 2020.

4 [2023 Interoperability](#)

Inbound EPCIS data is required for all shipments for 2023 Interoperability (more info to come).

5 [Your Action Items](#)

Your action items are:

- 1) (optional for EPCIS enablement) Complete the Establish Connection Form in section 2
- 2) Complete the VRS Supplier Form for either/both EPCIS and VRS in section 3.1.1
- 3) Complete the GTIN datasheet, which works for both EPCIS and VRS
- 4) Submit test data for VRS testing in section 3.3



We appreciate your efforts in collaborating with us to safeguard the supply chain. Please complete your action items by 12/31/2019. If you have questions or concerns, please contact support@lspedia.com or call 248.458.4367.

Thanks in advance from the LSPedia DSCSA Implementation Team.