[Company] Standard Operating Procedures	
Document Identifier	
Title:	Responding to Verification Requests of Distributed Product.
Version	
Effective Date	

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish and define the procedures for enhanced verification to meet the enhanced drug distribution security (EDDS) requirements effective November 27, 2023 under the U.S. Drug Supply Chain Security Act (DSCSA). Documentation of these activities in electronic form are the key steps for enabling the interoperable electronic verification of a product at the package level.

2. SCOPE

This SOP applies to functions responsible responding to product verification requests from Authorities and other Authorized Trading Partners (ATPs) for non-exempt prescription drug products within the United States as part of a secure and interoperable electronic system.

3. RESPONSIBILITIES

- **[Name/Department]:** Responds to product verification requests in compliance with the enhanced drug distribution security requirements.
- **[Name/Department]:** Confirms ATP status of product tracing and product verification requestors that are not Authorities.

4. DEFINITIONS

- **Authority.** The DSCSA requires prompt responses to certain types of requests for information from the Secretary "or other appropriate Federal or State official." The PDG Blueprint definition of Authority includes FDA, State Licensing Boards, and DEA.

- **Authorized Trading Partner (ATP):** The DSCSA restricts access to the distribution system for prescription drug products by requiring that trading partners of manufacturers, repackagers, wholesale distributors, third-party logistics providers (3PLs), and dispensers meet the applicable requirements for being ATPs. The DSCSA includes definitions for *authorized* and *trading partner* with respect to these categories. For example: "To be considered an authorized trading partner, a wholesale distributor must have a valid license under State law or section 583 of the FD&C Act, in accordance with section 582(a)(6) of the FD&C Act, comply with the licensure reporting requirements in section 503(e) of the FD&C Act, as amended by DSCSA, and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser."

- **Enhanced Drug Distribution Security (EDDS).** A set of requirements for enhanced drug distribution security at the package level under section 582 of the FD&C Act, as added by the DSCSA. These requirements, commonly known as the "enhanced system," are designed to improve the security of the drug supply chain and went into effect on November 27, 2023.

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- **OCI-Compliant Verifiable Credential:** A digital credential that conforms to the specifications outlined by the World Wide Web Consortium (W3C) and NIST Identity Assurance Level 2, and attests to the ATP status and identity of the credential holder in accordance with Partnership for DSCSA Governance (PDG) Blueprint credentialing requirements.

- **Product Identifier.** Under the DSCSA, non-exempt prescription drug packages must include "a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier [consisting of the NDC and a unique serial number], lot number, and expiration date of the product."

- **Partnership for DSCSA Governance (PDG).** A public-private partnership between industry and FDA established to define electronic interoperability requirements and guidelines, which are outlined in the Foundational Blueprint for 2023 Interoperability (the "PDG Blueprint").

- **PDG-Defined EDDS Network***:* Systems and processes to support the EDDS in compliance with the PDG Blueprint.

- **Verification.** Under the DSCSA, this refers to determining whether the product identifier affixed to, or imprinted upon, a package or homogenous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager. Under DSCSA 2023 requirements, trading partners must be able to verify a product identifier on a package or sealed homogenous case in a secure, electronic, interoperable manner.

- **Verification Router Service (VRS).** A network of trading partners and solution providers for the electronic interoperable exchange of verification requests and responses. The VRS automates some portions of the processes outlined in this SOP.

5. PROCEDURE

5.1. Product Verification of a Distributed Product

According to FDA guidance, "a manufacturer or repackager must respond to a request for verification from an authorized trading partner, even if that trading partner was not an immediate trading partner of the manufacturer or repackager." Package verification is conducted via request(s) and response(s).

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5.1.1. Responding to product verification request from Authorities

5.1.1.1. Search the [Company] system of record in order to verify product identifier on request corresponds to the standardized numerical identifier (SNI)15 or lot number and expiration date assigned to the product by the manufacturer or repackager.

5.1.1.2. Respond to the verification request no later than 1 business day from receipt of the request. For FDA, submit via the DSCSA portal in CDER NextGen. For other Authorities, send as directed in the request.

5.1.1.3. Maintain all verification messages for a minimum of 6 years.

5.1.2. Responding to verification request from another ATP

5.1.2.1. Confirm ATP status and identity. If ATP status cannot be confirmed via verifiable credential, other methods should be employed to confirm ATP status and identity prior to sending a response. If further information is required from the requestor in order to confirm ATP status and identity, request the required information within 1 business day of receiving the request.

5.1.2.2. Search the [Company] system of record in order to verify product identifier on request corresponds to the standardized numerical identifier (SNI)15 or lot number and expiration date assigned to the product by the manufacturer or repackager.

5.1.2.3. Respond to the verification request within 1 business day of confirming the requestor's ATP Status.

5.1.2.4. Maintain all verification messages for a minimum of 6 years.

6. REFERENCES

- Title II: Drug Quality and Security Act
- FDA, Identifying Trading Partners Under DSCSA, Draft Guidance July 2022
- FDA, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Guidance for Industry August 2023
- FDA, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs Guidance for Industry December 2023
- FDA, Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers
- PDG, Chapter 4: Product Identifier Verification Functional Design
- GS1, US DSCSA Implementation Suite
- OCI, DSCSA Interoperability Profile

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7. REVISION HISTORY

Version	Date	Description	Author
1.0	[Date]	Initial Release	[Author's Name]

8. APPROVED FOR RELEASE BY:

Name	Title	Signature	Date

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