NOVARTIS

Drug Supply Chain Security Act Information

The Drug Supply Chain Security Act (DSCSA) is federal legislation passed in 2013 that creates national requirements for tracing pharmaceutical products throughout the entire supply chain. This new legislation includes provisions for product identification, tracing, enhanced verification, detection and response, suspect and illegitimate notification, wholesaler and third-party logistics provider licensing.

Full implementation of DSCSA has result in standardized, unit-level traceability throughout the entire drug supply chain — from the manufacturer to the pharmacy (or provider).

Enhanced Verification

Enhanced Verification refers to the compliant process by which Novartis receives requests from its Authorized Trading Partner or Regulator, determines whether the product identifier provided corresponds to the product identifier imprinted by Novartis, and reports its finding to the Authorized Trading Partner or Government official.

Enhanced verification manual process

An Enhanced Verification request may be initiated by an Authorized Trading Partner (ATP) that has the product in their physical possession or by a Regulator. Novartis uses the VRS (Verification Response System) for automatic responses and can be used by ATPs that are in the network. Verification request provides a “True” or “False” response if the four (4) attributes LOT, EXP, GTIN, SN in the 2D barcode and Human Readable text corresponds with the information in the Novartis database and the serial number is designated as “Active”.

Please follow these steps to initiate a manual verification request to Novartis:

1. Download and complete this form (PDF 0.1 MB). All fields denoted with an asterisk (*) are required.
2. If possible, take photos of the product label, including name, strength, NDC, LOT, EXP, GTIN, SN and the 2D Matrix Code.
3. Attach the completed form and photo(s) to an email and send to verification.novartis@verification.com

Novartis will acknowledge receipt of your Verification request. Novartis will confirm the Requester is an Authorized Trading Partner or Regulator prior to any request. If further information, Novartis will be contact you. Please ensure to provide a name, phone number and email in your Verification request.

If the response is “FALSE”, Novartis will consider this a Suspect product. Novartis will initiate a Suspect Product investigation. Novartis expects the requestor to cooperate in any suspect product investigation.

Product Trace

A Product Trace is executed to support suspect, illegitimate, or recalled product investigations or Regulator compliance audits. A Trace is gathering information about products, supply chain partners, and exchange of

ownership. The Trace response will include the Product Information, SN and the “sold to” and “ship to” information from Novartis to a customer.

Product Trace Request

A manual Product Trace request may be initiated by an Authorized Trading Partner (ATP) or Regulator for a suspect and / or illegitimate product investigation, recalled product investigation or audit.

Please follow these steps to initiate a Product Trace request to Novartis:

1. Please send an email for a product trace to the following email dscsa.trace_request@novartis.com.
2. Please add to the email subject line: Product Trace-Enter “Company or Regulator Name”
3. Provide at minimum the following information:

- Person or Department Name
- Contact Information: Phone Number or Email
- Requester GLN
- Return email address
- Response Requested: All known or last owners with TI information
- Investigation reason: Suspect or Illegitimate Product. Recall or Compliance audit
- 3911 Incident Number if Applicable
- Name of Product/ Strength to be traced with the NDC, GTIN, SN, LOT and Expiration date

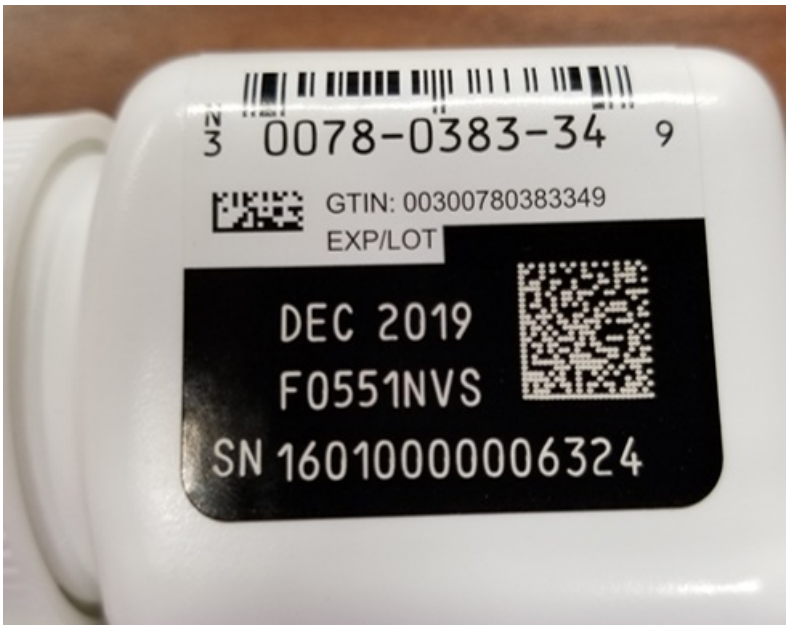
Novartis will acknowledge receipt of your trace request. Prior to any response Novartis will confirm the requester is an Authorized Trading Partner or Regulator. If Novartis requires further information, you will be contacted, so please ensure you provide a name, phone number and email in your request.

Who may enter an Enhanced Verification or Trace Request?

An Enhanced Verification or Trace request may be initiated by an Authorized Trading Partner who has physical possession of the product or a Regulator doing an audit or investigation. Trading Partners must have a valid state license to be considered an authorized trading partner. If Novartis determines your not an Authorized Trading partner or regulator, an additional investigation will be required before we will respond with the response. Additional information might be required, so please ensure you provide a name, phone number and email in your request.

If you are a Patient, not an Authorized Trading Partner

- If you or the patient you are acting on behalf of are currently experiencing side effects, please contact your doctor or other medical health professional.
- If you or the patient you are acting on behalf of have questions about the product, packaging, or labeling, please contact your doctor or pharmacist.
- If you or the patient you are acting on behalf of wish to report side effects, you may report side effects to Novartis Pharmaceuticals at 1 888 NOW NOVA (669 6682). You may also report side effects to FDA at 1 800 FDA 1088.
- Patient you are acting on behalf of have any other questions regarding product verification, please contact your pharmacist.



Key Terms

GTIN: (Global Trade Item Number) is a globally unique 14-digit number used to identify products in the supply chain. The GTIN, as well as other key product attributes, are automatically identified when a 2-D bar code is scanned.

LOT: (Lot Number) is combination of letters, numbers, or symbols from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

EXP: is the product expiration date.

SN: (Serial Number) is a unique serial number that is placed on the sellable unit to identify that unit which can be verified by Novartis.

Authorized Trading Partner: Pharmaceutical trading partner that has a valid state license to dispense prescription drugs in the US.

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