Product Identifier Requirements

- Section 581(14) of the Federal Food Drug and Cosmetic Act (FD&C Act, or the Act) defines the term "product identifier" as "a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product."
- Section 581(20) of the FD&C Act defines the term "standardized numerical identifier" as "a set of numbers or characters used to uniquely identify each package or homogenous case that is composed on the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters."

The updated SIP Proposal and SOPs in Attachment I continue to discuss the product identifier using varied, incomplete language as described below:

- Pages 44-45 of the updated SIP Proposal: The product identifier to be included on labels of imported drugs will "meet the specifications as specified in Section 581(14) of the DSCSA and contain the following:
    - Machine-readable bar code unique to that lot of imported prescription drugs;
    - Standardized Numerical Identifier (up to 20 characters and including the NDC);
    - Lot number; and
    - Expiration date."

  FDA Note: This description does not reference the human-readable format, as FDA previously noted in its August 14 RFI. The human- and machine-readable information must be specific not to each lot, but to each package or homogenous case, in accordance with the definition of "standardized numerical identifier," which is a part of the product identifier as specified in section 581(14) of the FD&C Act.

  Agency Response: See changes on pages 44-45 of the attached SIP Proposal.

- WI 600.03 in Attachment I
    - Page 1: Defines "Product Data (2D Barcode)" as "a set of information that includes a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product."
    - Step 7.5 [redacted]

  FDA Note: This description in step 7.5 does not completely reflect the definition of "Product Data (2D Barcode)" definition provided in the WI or the product identifier definition in section 581(14). The description should reference the human-readable component and (Standardized Numerical Identifier (SNI)). Additionally, the human- and machine-readable information must be specific to each package or homogenous case, not each lot.

  Agency Response: See revised WI 600.03 Prescription Drug DSCSA Track/Trace, steps 4.0 and 7.5. Definitions were added for product identifier and standardized numerical identifier, and the terminology in 7.5 was revised to reflect the newly added definitions. For ease of review, we have provided a red-lined version of this WI.

- WI 600.08 in Attachment I
    - Page 1: Defines "Product Identifier" as "a standardized graphic that includes a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier…,the standardized numerical identifier, lot number, and expiration date of the product."
    - Step 7.4 states [redacted]

- [redacted]

FDA Note: This description in step 7.4 does not completely reflect the definition of "Product Identifier" provided in the WI or the product identifier definition in section 581(14) in that it does not reference the human-readable component and does not include the SNI. The human- and machine-readable information must be specific to each package or homogenous case, not each lot.

Agency Response: See WI 600.09 Prescription Drug Relabeling Requirements and Process, created to replace WI 600.08. For ease of review, we have provided a red-lined version comparing the two WIs.

Illegitimate Product Notification Requirement

Section 582(c)(4)(B) of the FD&C Act requires that the wholesale distributor, upon determining a product in the possession or control of the wholesale distributor is an illegitimate product, **notify FDA and all immediate trading partners not later than 24 hours** of making such determination, as noted by FDA in the August 14 RFI. The following SOPs in Attachments H and I retain language that is inconsistent with illegitimate product notification requirements in section 582.

- Attachment I, SOP 2002
  - Defines "illegitimate product" as the term is defined in section 581(8) of the FD&C Act.
  - Step 7.2.3: [redacted]
- Attachment H, SOPs 2003 and 7003
  - SOP 2003, step 7.12.1: [redacted]
  - SOP 7003, step 7.12.: [redacted]

FDA Note: Where such products are determined to be illegitimate as defined in section 581(8) of the FD&C Act (e.g., those that are counterfeit, those that are unfit for distribution), FDA and immediate trading partners that LifeScience Logistics has reason to believe may have received such illegitimate product must be notified within 24 hours of such determination (see section 582(c)(4)(B)(ii) of the FD&C Act).

Agency Response: See revised SOP 2002, Handling, Storage, Packaging & Distribution, steps 7.2.3 and 7.2.4; and revised SOP 7003, Prescription Drug Returned Merchandise, step 7.18. [redacted] For ease of review, we have provided red-lined versions of these SOPs.

Please disregard SOP 2003, Commercial Returned Merchandise. SOP 7003 should be used for this program. SOP 2003 applies to the vendor's other lines of business.

Authorized Trading Partner Requirement

Section 582(c)(3) of the FD&C Act requires that the trading partners of a wholesale distributor may only be authorized trading partners. Under the importation rule, while importers are exempt from that requirement for transactions of eligible drugs with the foreign seller based in Canada (see 21 CFR part 251.14(d)(7)(iii)), importers are not otherwise exempt from that requirement. Specifically, as noted by FDA in the August 14 RFI, the importer's subsequent transactions with trading partners, such as dispensers (pharmacies), must be with authorized trading

partners.

- The SIP Proposal at page 42 states "LifeScience Logistics will be responsible for verifying the qualifications of all trading partners in the supply chain (e.g., foreign seller, laboratories, etc.) in compliance with Attachment I, SOP 1031, Vendor Qualification."
    - SOP 1031, [redacted]

  FDA Note: While this SOP discusses entities providing products to LifeScience Logistics, it does not appear to cover entities that LifeScience Logistics will be providing product to under the SIP. These entities, namely dispensers (pharmacies), must be authorized trading partners.

  Agency Response: Regarding all trading partners, including dispensers (such as pharmacies), see SOP 7005, Prescription Drug DSCSA Track and Trace Regulatory Requirements. This is the first submission of SOP 7005—
    - [redacted]

  In addition, WI 600.04, Prescription Drug Customer Setup, defines LifeScience Logistics' procedures to set up customers in its system. For purposes of WI 600.04, "customers" means "entities to whom LSL ships products to on behalf of the client, including wholesalers, distributors, 3PLs, dispensers, or end users." Step 7.6 [redacted]

- WI 600.05, [redacted]

  FDA Note: It is unclear whether "customers" includes dispensers, including pharmacies, to whom LifeScience Logistics distributes the product.

  Agency Response: The quoted language comes from WI 600.04, step 7.8, which reads, [redacted]

  WI 600.05, [redacted]

Requirement for Non-saleable Returns: Dispositioning in the U.S. and Preventing Exportation

Under 21 CFR part 251.14(a), the SIP Sponsor must ensure returned eligible prescription drugs are properly dispositioned in, and not exported from, the United States, as noted by FDA in the August 14 RFI. The updated SIP Proposal dated October 20, 2023 at page 37 includes the statement "For all returned prescription drugs deemed as non-saleable, the Importer will immediately place them in quarantine and arrange for their disposition at an authorized location in the U.S. All non-saleable returned prescription drugs are ineligible for export to Canada or other country."

However, we note the following language remains in the SOPs:

- Attachment H

- SOP 2003 Commercial Returned Merchandise, step 7.17: [redacted]
- SOP 7003 Prescription Drug Returned Merchandise, step 7.18: [redacted]

FDA Note: These statements introduce uncertainty about whether all eligible non-saleable returned products will in fact be dispositioned in the United States. These statements should be updated to ensure that there is clarity that the non-saleable is dispositioned appropriately.

Agency Response: See revised SOP 7003, Prescription Drug Returned Merchandise, step 7.18. [redacted]

Please disregard SOP 2003, Commercial Returned Merchandise. SOP 7003 should be used for this program. SOP 2003 applies to the vendor's other lines of business.

- Attachment H, WI 600.27 Prescription Drug Vendor Returns and Quarantine Shipping
  - Step 7.1: [redacted]
    7.1.5 [redacted]
  - [redacted] Step 7.10.4: [redacted]
    - [redacted]
  - [redacted]

FDA Note: To the extent this WI applies to non-saleable returned product that has been distributed in the U.S., this needs to be addressed so that non-saleable returned product is properly dispositioned in the U.S. and not exported.

Agency Response: See revised WI 600.27, Prescription Drug Vendor Returns and Quarantine Shipping, [redacted] For ease of review, we have provided red-lined versions of these SOPs.