The Global Language of Business

GS1 US Best Practice Guidance for the Handling of Saleable Return Transactions

Release 1.0, September 15, 2026

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Document Summary

Document Item	Current Value
Document Title	GS1 US Best Practice Guidance for the Handling of Saleable Return Transactions
Date Last Modified	September 15, 2026
Document Description	This guideline outlines best practices for the effective handling of saleable returns focusing on the consistent application of GS1 Standards to support regulatory compliance and efficient data exchange. It details ownership, data sharing, and documentation requirements for Buyers and Sellers and provides recommendations for managing return scenarios using standardized electronic formats.

Log of Changes

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1 Introduction

This guideline serves as an industry resource for the consistent application of GS1 Standards to facilitate the reliable exchange of data between parties for saleable return transactions and to support regulatory and business requirements, including those of the U.S. Food and Drug Administration (U.S. FDA) Drug Supply Chain Security Act (referred to herein as "DSCSA").

This guideline was developed by the GS1 US Rx Secure Supply Chain Workgroup, a cross-industry group of manufacturers, wholesalers, dispensers, solution providers, and other stakeholders working collaboratively to support DSCSA implementation and promote interoperable supply chain practices.

The purpose of this guide is to support:

- Regulatory Compliance and Traceability – supporting traceability of DSCSA drugs and helping ensure a secure and compliant supply chain.
- Standardization of Processes – encouraging consistent approaches to verification, Electronic Product Code Information Services (EPCIS) event modeling, and exception handling among trading partners.
- Risk Reduction and Collaboration – reducing risks by aligning roles, responsibilities, and documentation expectations.
- Addressing Operational Gaps – helping resolve operational ambiguities related to the end-to-end handling of returns, including verification and exception management.

1.1 Terms for Clarity

This guide uses DSCSA and GS1-aligned terminology to promote shared understanding across trading partners. Terms referenced throughout this document include, but are not limited to:

- **Saleable Return:** A saleable return is a prescription drug product, as defined by DSCSA, in a unit package or homogeneous case that has been returned to a Seller by a Buyer and is intended to be reintroduced into commercial distribution, provided that the returned product identifier is successfully verified and associated to applicable transaction information and transaction statement prior to resale.
- **Verification:** Verification as per DSCSA, confirms that the product identifier affixed to the salable unit, package or homogeneous case corresponds to the product identifier assigned by the manufacturer or repackager.
- **Association:** Association is the process for connecting a returned product with the DSCSA transaction information and DSCSA transaction statement for the product.
- **Exception**: A condition in which product and/or data are not aligned, or verification cannot be completed as expected.

1.2 Role Definition

There are two primary roles we will refer to in the scenarios throughout this Guidance:

1. **The Seller** is the trading partner who sold the product to the Buyer and transferred ownership of the product. This party would be identified as the source-owning party, the Sold From. For saleable returns, the Seller receives product back from the Buyer.
2. **The Buyer** is the trading partner who purchased the product from the Seller. This party would be identified as the destination-owning party, the Sold-To. For saleable returns, the Buyer returns product to the Seller from whom the product was purchased.

2 Saleable Returns

- Under a saleable return scenario, a Buyer has ownership of a finished prescription drug product in scope for DSCSA requirements. While the product remains under the Buyer's ownership, the Buyer determines that the product should be returned to the Seller from whom the product was directly purchased.

  NOTE: Returns of **non-saleable product**, as well as returns initiated due to recalls, regulatory actions, suspect or illegitimate product investigations, or other compliance-driven reasons, are **out of scope** for this guide.

- The Buyer initiates the saleable return process by notifying the Seller of the Buyer's intent to return the product. Upon notification, the Seller communicates the applicable return conditions, instructions, and logistics to the Buyer, based on the commercial agreement between the parties. These instructions may include a Return Goods Authorization (RGA), Material Goods Authorization (MGA), Return Merchandise Authorization (RMA), or other mutually agreed upon return authorization. The Buyer then returns the product to the Seller in accordance with those instructions. Subsequently, the Buyer and Seller document the return in their internal system(s).
- Upon receipt of the returned product, the Seller performs association and verification of the product identifier, as required under DSCSA, to determine whether the product is eligible to be reintroduced into commercial distribution. Once these are successfully completed and the product is confirmed to be saleable, the Seller applies the appropriate disposition in accordance with its internal processes and regulatory obligations. (see FD&C Act § 582(c)(4)(D) & (E))
- Eligibility criteria for a saleable return, including timing, condition, and contractual requirements, are determined by agreement between the Buyer and the Seller and are outside the scope of DSCSA.
- In most scenarios, the Seller is a Wholesale Distributor; however, the Seller may also be another authorized trading partner, such as a Manufacturer or Repackager or a Dispenser in certain cases Products returned under this guidance may have been physically shipped by the Seller, a 3PL, or through a drop-shipment arrangement, depending on trading partner agreements. Drop-shipment scenarios related to returns are addressed in Section 2.3.1.

2.1 Saleable Return Process Overview

The saleable return process begins when the Buyer identifies product purchased from the Seller that may be eligible for return under the parties' commercial agreement. The Seller provides the applicable authorization, documentation requirements, and shipping instructions. After receipt, the Seller inspects the product, associates it to the original DSCSA Transaction Information and Transaction Statement, verifies the product identifier, and determines whether the product may be reintroduced into commercial distribution.

1. Buyer identifies product for return and captures relevant product identifier information, including Global Trade Item Number® (GTIN®) and serial number when available.
2. Buyer references the original supplier-provided TI/TS to identify the Seller from whom the product was purchased.
3. Buyer notifies the Seller of the intent to return product and provides information required by the Seller's return process.
4. Seller issues an RMA, RGA, MGA, or equivalent authorization and communicates return conditions, documentation requirements, and shipping instructions.
5. Buyer ships the product to the Seller and updates internal inventory and serialized item status to reflect the return.

6. Seller receives the returned product and places it into an appropriate holding status pending review.
7. Seller performs physical product inspection, association to original transaction records, and verification of the product identifier.
8. Seller determines the outcome: return to active inventory, continued quarantine, credit, replacement, return to Buyer, destruction, or another agreed upon disposition.
9. Seller communicates the outcome to the Buyer, and both parties close the return transaction in their internal systems.

2.2 Transaction Scenarios and Details

The following sections outline common return scenarios, including standard returns, products determined to be non-saleable, exception handling, and additional operational considerations. They are intended to help trading partners align on data sharing, reconciliation, and product disposition activities while supporting DSCSA requirements.

2.2.1 Data Sharing Between Trading Partners

For DSCSA purposes, a saleable return is a transfer of product from the Buyer returning the product to the Seller receiving it. Because the Buyer originally purchased the product from the Seller, a new electronic TI/TS exchange is not required between the original Buyer and Seller for the return (see FD&C Act § 581(24)). Supporting data for saleable returns may vary by trading partner agreement, operating model, and system capability. Some workflows may also involve third parties—such as logistics providers, reverse distributors acting in a transportation role, or solution providers—that support physical movement or data exchange without taking ownership of the product.

The following scenarios describe common industry approaches for saleable returns. They highlight operational considerations and options; they do not mandate a single implementation model.

Trading partners should maintain records that support return reconciliation, including the return authorization, product identifier information, original transaction reference, verification result, association result, disposition, and exception communications. These records may be maintained in internal systems.

Table 2.1: Overview of common return scenarios, outlining data-sharing requirements, operational considerations, and expected disposition outcomes.

Scenario	Data Sharing Approach	Operational Considerations	Expected Outcome
Standard saleable return	Buyer and Seller reference original TI/TS and return authorization; no new electronic TI/TS exchange is required between the original Buyer and Seller for the return.	Product is received as expected; association and verification are completed without exception.	Upon return of the product, Buyer updates internal inventory and serialized item status to reflect the return. Seller processes product as saleable and updates inventory status.
Product not saleable	Buyer and Seller exchange information needed to resolve disposition under the applicable agreement.	Product remains in quarantine or controlled status pending final disposition.	Seller applies remedy such as credit denial, return to Buyer, destruction, replacement, or other agreed action.
Exception	Parties communicate serialized identifier details and supporting documentation through agreed channels.	Association, verification, return authorization matching, or aggregation status requires investigation.	Buyer and Seller resolve the exception or apply the appropriate non-saleable disposition.

2.2.2 Standard Saleable Return — Product Deemed NOT Saleable

If the Seller determines that the returned product cannot be reintroduced into commercial distribution, the product should remain in quarantine or another controlled status while the Seller and Buyer resolve the return. Reasons may include product condition, storage concerns, damaged labeling, inability to complete association or verification, or other criteria established by agreement.

The process for returns in this scenario is identical to the process in Section 2.1 Steps 1 through 7. If the product is found to not be saleable, the Seller takes appropriate action based on that finding:

1. Buyer identifies product for return and captures relevant product identifier information, including GTIN and serial number when available.
2. Buyer references the original supplier-provided TI/TS to identify the Seller from whom the product was purchased.
3. Buyer notifies the Seller of the intent to return product and provides information required by the Seller's return process.
4. Seller issues an RMA, RGA, MGA, or equivalent authorization and communicates return conditions, documentation requirements, and shipping instructions.
5. Buyer ships the product to the Seller and updates internal inventory status to reflect the return.
6. Seller receives the returned product and places it into an appropriate holding status pending review.
7. Seller performs physical product inspection, association to original transaction records, and verification of the product identifier.

If product is deemed not saleable the following steps apply:

1. Seller concludes the product is not saleable and determines the outcome: return to Buyer, continued quarantine, investigate as suspect, credit, replacement, destruction, or another mutually agreed disposition.
2. Seller communicates the outcome to the Buyer, and both parties close the return transaction in their internal systems.

2.2.3 Exception Handling for Saleable Returns

Exception handling may be required when product and data do not align, association cannot be completed, verification fails, or the product does not match the expected return authorization. The best practice steps for saleable returns in Section 2.1 should be followed; however, exceptions may occur. Trading partners should communicate exceptions through agreed channels and include sufficient serialized identifier information to support investigation and resolution. The list below, while not inclusive of all exception scenarios that may occur, are possible common scenarios that could be encountered during the returns process. (this is not an exhaustive list language) Internal exception handling processes should be followed to determine appropriate steps for resolving exceptions:

- Returned product cannot be associated to the original DSCSA transaction information and DSCSA transaction statement, including instances where product may have been returned to the wrong Seller or the original transaction record cannot be located.
- Returned product identifier cannot be verified against the product identifier assigned by the manufacturer or repackager. If the initial verification attempt is unsuccessful, trading partners may use other agreed verification methods before determining whether the product should be handled as suspect product.
- Returned product does not match the expected RMA, RGA, MGA, or equivalent return authorization, including discrepancies in product identifier, quantity, packaging level, or return reference.

- Serialized product identifier data is incomplete, delayed, inaccurate, or unavailable, creating a product-with-no-data reconciliation issue that must be resolved before final disposition.
- Aggregation or disaggregation status differs from the original shipment and requires additional reconciliation, such as confirming parent-child relationships, packaging level, or serialized unit details, before final disposition.

2.3 Additional Considerations

The Rx Secure Supply Chain Workgroup identified several areas that may require additional trading partner alignment when applying this guidance in operational settings. These considerations do not change the core saleable return process but may affect how parties document, reconcile, and close the return.

2.3.1 Drop Shipments

In a drop-shipment arrangement, the physical shipper may differ from the commercial Seller. Trading partners should align on which party authorizes the return, receives the returned product, associates the return to the original sale, and provides any documentation needed for reconciliation. The process should maintain clarity between the commercial transaction and the physical movement of product.

2.3.2 Replacement Products

A replacement product is a new physical shipment initiated after the replacement product supplier, most often the Manufacturer, determines that replacement is the appropriate remedy. Trading partners should align on how the replacement order is initiated, which reference number supports reconciliation, what location identifiers are required, and how any drop-shipment model will be handled. Since a replacement product scenario is not itself a return, it is out of scope for this best practice guide and should follow applicable DSCSA transaction requirements.

2.3.3 Aggregation and Disaggregation

Returns may occur at a different packaging level than the original shipment. For example, a sealed homogeneous case may be opened before return, or individual saleable units may be returned from a previously aggregated shipment. Trading partners should determine whether aggregation data is available and whether additional reconciliation is needed before final disposition. (See FD&C Act §§ 581(14), 581(20), and 582(g)(1)(F).)

2.3.4 340B Association Considerations

For 340B replenishment or other specialized commercial arrangements, the commercial relationship, original transaction record, and physical movement of product may require additional alignment. Trading partners should align on which party is requesting the return, which party authorizes the return, receives the returned product, associates the return to the correct original transaction records, and provides any documentation needed for reconciliation. The process should maintain clarity between the commercial arrangement, the DSCSA transaction records, and the physical movement of product before final disposition.

3 Appendix

3.1 Glossary of Terms

The following glossary consolidates key DSCSA, GS1 Standards, and saleable returns terminology used throughout this guide.

Term	Acronym	Definition
Government Definitions:		
Drug Supply Chain Security Act	DSCSA	The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. [Source: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa]
Transaction Information	TI	Information required by the DSCSA that describes the owning parties, the covered products, and dates that the activity took or is taking place. In an EPCIS document this information is spread throughout the file. Table 10-1 in Section 10 of the GS1 US DSCSA Implementation Guideline R1.3 maps DSCSA Data Attribute to relevant EPCIS segments. Sec. 581 ``(26) Transaction information.--The term `transaction information' means-- ``(A) the proprietary or established name or names of the product; ``(B) the strength and dosage form of the product; ``(C) the National Drug Code number of the product; ``(D) the container size; ``(E) the number of containers; ``(F) the lot number of the product; ``(G) the date of the transaction; ``(H) the date of the shipment, if more than 24 hours after the date of the transaction; ``(I) the business name and address of the person from whom ownership is being transferred; and ``(J) the business name and address of the person to whom ownership is being transferred. Source: (FDA.gov DSCSA text web document)

Term	Acronym	Definition
Transaction Statement	TS	An attestation by the seller of a covered product stating that they followed the directives set forth by the DSCSA. Table 10-1 in Section 10 of the GS1 US DSCSA Implementation Guideline R1.3 maps DSCSA Data Attribute to relevant EPCIS segments. Transaction Statement is also covered in Section 10.1. Sec. 581: ``(27) Transaction statement --The `transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction-- ``(A) is authorized as required under the Drug Supply Chain Security Act; ``(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act; ``(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582; ``(D) did not knowingly ship a suspect or illegitimate product; ``(E) had systems and processes in place to comply with verification requirements under section 582; ``(F) did not knowingly provide false transaction information; and ``(G) did not knowingly alter the transaction history. Source: (FDA.gov DSCSA text web document)
Trading Partner Definitions:		
Manufacturer		A manufacturer is defined in section 581(10) of the FD&C Act to mean: [W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).
Repackager		DSCSA defines repackager in section 581(16) of the FD&C Act as "a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction."
Wholesaler		DSCSA defines wholesale distributor in section 581(29) of the FD&C Act to mean "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA])."

Term	Acronym	Definition
Third Party Logistics	3PL	DSCSA defines a 3PL in section 581(22) of the FD&C Act to mean: [A]n entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.
Dispenser		The term dispenser, as defined in section 581(3) of the FD&C Act: (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).
GS1 Standards:		
GS1 Company Prefix	GCP	A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 Member Organization.
Global Trade Item Number®	GTIN®	The Global Trade Item Number (GTIN) is the globally unique GS1 identification number used to identify "trade items" (i.e., products and services that may be priced, ordered, or invoiced at any point in the supply chain).
Serialized GTIN	SGTIN	An SGTIN is the combination of a GTIN and a unique serial number of up to 20 alphanumeric characters.
Global Location Number	GLN	The Global Location Number (GLN) is the globally unique GS1 Identification Number used to identify parties and locations.
Serialized Global Location Number	SGLN	The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension.
Serial Shipping Container Code	SSCC	The Serial Shipping Container Code (SSCC) is the globally unique GS1 identification number used to identify individual logistic units. A "logistic unit" is defined as an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain.
Electronic Product Code	EPC®	The Electronic Product Code™ (EPC) is syntax for unique identifiers assigned to physical objects, unit loads, locations, or other identifiable entity playing a role in business operations.
Electronic Product Code Information Services	EPCIS	The EPC Information Services (EPCIS) standard defines a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.
EPCIS Event		A structured record used in EPCIS to capture what object was involved, when the event occurred, where it occurred, and why the event occurred in a business process.
Business Step	bizStep	An EPCIS data element that describes the business process step taking place when an event is captured, such as shipping, receiving, commissioning, or another defined step.

Term	Acronym	Definition
Event Action	ADD / OBSERVE / DELETE	An EPCIS value that indicates whether an event adds objects to a context, observes objects in a context, or removes objects from a context.
Read Point		The location at which an EPCIS event is captured, such as a receiving dock, packing station, or other operational point.
Business Location	bizLocation	The location where objects are considered to be after an EPCIS event occurs, often represented using a GLN or SGLN.
Saleable Returns and Operational Terms:		
Saleable Return		A prescription drug product returned by the Buyer to the Seller and intended to be reintroduced into commercial distribution after verification and association to applicable transaction information and transaction statement occurs.
Association		The process of connecting a returned product to the original Transaction Information and Transaction Statement for that product to support saleable return processing.
Verification		The confirmation that the product identifier affixed to the saleable unit, package or homogeneous case corresponds to the product identifier assigned by the manufacturer or repackager.
Product Identifier		A standardized graphic that includes, in both human-readable form and on a data carrier, the standardized numerical identifier, lot number, expiration date, and serial number of the product.
Return Merchandise Authorization	RMA	A return authorization or reference issued by the Seller or its agent to identify and manage a return transaction.
Return Goods Authorization	RGA	A return authorization used to approve, track, and reconcile returned goods under the parties' return process.
Material Goods Authorization	MGA	A return authorization or reference used by some trading partners to approve, track, and reconcile returned material or goods under their return process.
Exception		A condition in which product, data, authorization, or system records do not align as expected and additional review or trading partner communication is needed.
Quarantine		A controlled inventory status used to segregate product pending review, investigation, verification, disposition, or other required action.
Disposition		The final status or handling outcome assigned to returned product, such as return to active inventory, continued quarantine, credit, return to Buyer, replacement, destruction, or another agreed remedy.
Drop Shipment		A fulfillment model in which the commercial Seller and the physical shipper may be different parties. For returns, trading partners should align on authorization, receipt, association, and reconciliation responsibilities.
Replacement Product		Product shipped as a new transaction or remedy after the returned product is processed and replacement is determined to be the appropriate outcome.
Aggregation		The relationship between one or more child trade items and a parent packaging or logistic unit, such as saleable units packed into a case or case packed onto a pallet.
Disaggregation		The process of breaking or changing an existing aggregation relationship, such as opening a case or separating units from a parent container.

Term	Acronym	Definition
Product-with-No-Data		An exception condition in which physical product is present but the expected electronic data or system record is missing, incomplete, delayed, or cannot be located.
Data-with-No-Product		An exception condition in which electronic data or system records exist, but the corresponding physical product is not present or cannot be matched.
Authorized Trading Partner	ATP	A trading partner that meets applicable DSCSA authorization requirements for its role, such as manufacturer, repackager, wholesale distributor, dispenser, or third-party logistics provider.
Buyer		The trading partner that purchased the product and initiates the return to the Seller.
Seller		The trading partner that sold the product to the Buyer and receives the product back during the saleable return process.
Data Carriers and Barcode Related:		
GS1 DataMatrix		GS1 DataMatrix is a two-dimensional (2D) barcode which may be printed as a square or rectangular symbol made up of individual squares.
Universal Product Code	U.P.C.	A U.P.C. is a type of barcode. Specifically, a UPC-A is a barcode that can hold a GTIN-12 and is familiar from its use on consumer products in North America.
Human Readable Interpretation	HRI	Human Readable Interpretation (HRI) is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode).
Human Readable Form		Human-readable refers to product identifiers on their packaging that can be read absent of requiring a machine.

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