

AmerisourceBergen Manufacturer Packaging and Logistics Requirements Guide

AmerisourceBergen

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Version Notes:

Version 1.1 – April 2019 – First revision.
Version 1.3 – January 2023 – links and contact updates.

I. INTRODUCTION

1.0 PURPOSE AND SCOPE

We are united in our responsibility to create healthier futures.

AmerisourceBergen is driving innovative partnerships with global manufacturers, providers and pharmacies to improve product access and efficiency throughout the healthcare supply chain. As part of the largest global generics purchasing organization, the leading specialty pharmaceutical services provider and the partner with more community and health system pharmacy relationships than any other—we're well positioned to help you capitalize on the dynamic changes in healthcare. From product commercialization and distribution to pharmacy, provider and manufacturer solutions, we're working with you every day to enhance patient care.

This document provides operational guidance and expectations to ensure the efficient delivery of pharmaceutical and consumer goods from you, our valued trading partners, to AmerisourceBergen's Distribution Services distribution centers and ultimately to our end customers and patients. This includes our National Distribution Center, Consumer Regional Distribution Centers, Full-line Forward Distribution Centers, Specialty Distribution Centers and American Health Repackaging.

This document and requirements contained within may be updated at any time and it is therefore important that manufacturers periodically review the current revision of this manual for updates.

2.0 UNDERSTANDING WHO TO CONTACT

To ensure timely response to both minor and critical requests, it's important to AmerisourceBergen to ensure our partners know who to contact.

Request Type	Contact Information
General Accounts Payable Inquiries	abcvendorservices@AmerisourceBergen.com
Drug Supply Chain Security Act (DSCSA) Questions	securesupplychain@AmerisourceBergen.com
General Packaging Question	Mfg-Ops@AmerisourceBergen.com
Product Recalls Notifications	recall@AmerisourceBergen.com
National Distribution Center Inbound Delivery	NDCInbound@AmerisourceBergen.com
Wholesale Acquisition Cost (WAC) Price Changes	scdm@AmerisourceBergen.com
Product Quantity and Dimension Changes	ProductDataChanges@AmerisourceBergen.com
General Vendor Setup Questions (ATP form, Vendor Packet, etc.)	Contact your Category Manager
EDI Accounts Payable	APGFSS-EDI@AmerisourceBergen.com
General EDI Technical Questions	EDI.Technologies@AmerisourceBergen.com
Contracts and chargebacks	ccbdi845844849@amerisourcebergen.com
EPCIS Onboarding	SSCDataServices@amerisourcebergen.com

II. DOING BUSINESS WITH AMERISOURCEBERGEN

3.0 BEING A BUSINESS PARTNER WITH AMERISOURCEBERGEN

3.1 New Manufacturer Setup

Prior to engaging in business with AmerisourceBergen distribution services businesses, the company requires that the manufacturer enter into a Distribution Services Agreement.

For more information about establishing a relationship with AmerisourceBergen, contact:

- NewSupplierRequests@amerisourcebergen.com

An AmerisourceBergen representative will work with you to provide access to ABSetUp, our online portal, in which you will complete and upload documents that we require to establish a trading relationship.

This packet includes the following documentation:

- Supplier Fact Sheet
- Indemnification Agreement
- Certificate of Insurance
- Credit Evaluation
- Returns Goods Form
- W9 Form
- Authorized Trading Partner Form (Rx Only)
- Licenses:
 - DEA (Rx only)
 - State Licenses

AmerisourceBergen requires the following tasks be completed prior to the first purchase orders being placed:

- Provide contact information to applicable AmerisourceBergen Buyer and Category Management resource
- Update Distribution Lists to include necessary AmerisourceBergen contacts
- Provide product lead times information to Buyer
- Established EDI 850, 855, 856, and 810 connections to AmerisourceBergen's EDI Specifications
- Place EDI Test Purchase Order (850)

3.2 New Item Setup Process

When launching a new product, or changing a product's National Drug Code (NDC), manufacturers must ensure that the following documents are submitted through ABSetup, our online portal, to have the item setup in our systems:

- Product Information via ABCSetup.com
- HDA new product form (Rx only) – ABSetup Portal– www.abcsetup.com
- Safety Data Sheet (SDS) – Every manufacturer is required to provide an SDS for each product they ship to AmerisourceBergen or its subsidiaries at the time a new item is setup, or a written statement that an SDS is not required.
- Readable copy of individual unit package (label or package flat)
 - Include all sides
 - Must include human readable and barcodes (where pre-printed)
- Readable copy of homogenous case package (label)
 - Must include human readable and sample barcodes
- Puerto Rico Department of Health Registration for all drugs OTC and Rx. (See Appendix □)

Because of both the FDA Unique Device Identifier (UDI) and Drug Security Supply Chain Act (DSCSA), we do require that both UDI and DSCSA identifiers be included when submitting the HDA new product form.

- Medical Devices – GS1 Global Trade Item Numbers (GTINs) or HIBCC Identifiers, Units of Measure, and Quantities for all packaging levels, *including* inner-packs.
- Prescription Drugs – GS1 Global Trade Item Numbers, Units of Measure, and Quantities for all packaging levels, *including* inner-packs and bundles.

3.3 Product Data Maintenance

1. **Packaging Configuration Changes.** Certain types of product packaging and/or configuration changes may require that the manufacturer notify AmerisourceBergen's master data team at least 30 days prior to those configuration changes physically entering the supply chain. This will ensure that any automated processes dependent on size parameters, or quantities, are updated and won't result in incorrect product receipts or product stoppages.

AmerisourceBergen supports GS1 standards to identify products. Its recommended manufactures consult GS1 Healthcare Global Trade Item Number (GTIN) Allocation rules when changing packaging and labeling (see section □).

When to notify AmerisourceBergen:

- Product Case Dimension Size Changes – Changes from 10"x12"x6" (W x H x D) to 24" x6"x 6" (this is also expected to result in a new GTIN).
- Product Case Quantity Changes – Changes of contained quantity from 144 saleable units to 120 (this is also expected to result in a new GTIN).
- Creation of a Serialized Inner pack (Rx only) – Use of a "bundle" to improve material handling of bottles (introduction of a new GTIN, Units of Measure, and saleable quantity).

- Addition of a GTIN on product packaging – Adding a GTIN to a product in addition to the UPC.
- Changes in country of origin – i.e. moving product manufacturing origin from USA to India.

Manufacturers should notify AmerisourceBergen of configuration changes by emailing: ProductDataChanges@amerisourcebergen.com.

When manually communicating changes, the following must be included:

- The current Product Identifier (UPC, GTIN, etc.)
 - Description of the change including before and after values associated with change in quantity, dimensions, and location of manufacturing (country of origin).
 - New Product Identifiers and associated packaging levels (UPC, GTIN, etc.)
2. **Price Changes.** Manufacturers must notify AmerisourceBergen in the event of a wholesale acquisition cost (WAC) change by sending change information to:
- scdm@amerisourcebergen.com

3.4 Electronic Data Interchange (EDI)

With the advent of electronic file sharing, communicating information electronically greatly reduces the time and resources required to manage such interactions. ANSI (American National Standards Institute) is the governing organization that establishes EDI standards.

Within ANSI, HDA (Healthcare Distribution Alliance) establishes standards unique to the health care industry. However, HDA standards always fall within ANSI standards; they do not conflict with nor negate one another. Ideally, when trading partners use standardized communications in accordance with ANSI and HDA, communications are automated and efficient.

AmerisourceBergen supports a range of EDI document and transactions and complies with both the American National Standards Institute (ANSI) and the Healthcare Distribution Alliance (HDA) EDI guidelines.

List of EDI transactions received (inbound)

Document	Description
753	Request for Routing Instructions
810	Order Invoice
812	Credit/Debit Adjustment
824	Inbound Payment Confirmation
845	Bid award / Price authorization
849	Chargeback reconciliation
855	Purchase order acknowledgement
856	Advanced ship notice (includes DSCSA)
997	Data receipt

List of EDI transactions sent (outbound)

Document	Description
754	Routing Instructions
820	Payment order
844	Chargebacks
850	Purchase order
852	Product activity report
867	Product transfer and resale report

The following are EDI transactions that are required to facilitate DSCSA compliance and operational consistency of receiving product:

1. **Purchase Order Acknowledgement (855)**. Manufacturers are requested to provide an electronic Purchase Order acknowledgement via an EDI 855. Those delivering to the National Distribution Center are required to send an 855. This enables our replenishment operations to confirm the receipt of a purchase order (an EDI 850 transaction) from a buyer, eliminating the need to call or fax a confirmation. In addition, this provides pro-active visibility to potential back order scenarios.
2. **Advanced Ship Notice (856)**. Manufacturers are required to provide an electronic advanced ship notification for all deliveries to AmerisourceBergen distribution centers. This not only is our DSCSA regulatory document for applicable Rx products, but also aides in managing receiving and product quantity variances.

3.5 **Serialized Data Exchange (EPCIS)**

Starting in 2018, AmerisourceBergen will be accepting EPCIS files from manufacturers for the purposes of collecting product identifiers to meet the 2019 DSCSA saleable returns regulatory mandate.

For questions on serialized data requirements and to arrange testing and onboarding EPCIS exchange, please contact SSCDataServices@amerisourcebergen.com.

The latest serialized data exchange specification can be found on AmerisourceBergen's Manufacturer and Replenishment Operations website:

<https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment>

4.0 REPLENISHMENT OPERATIONS

This section applies to all purchases made to support our full-line and specialty drug distribution centers.

4.1 Purchasing Process

3. **Forecasts.** Forecasting periods are 4 weeks each (13 periods per year versus traditional monthly purchases). This ensures each forecast represents 28 days of usage.

Each AmerisourceBergen buyer maintains forecasts, as needed, based on many variables including, but not limited to: order day, product lead-time, order cycles, safety stock, seasonal variation, formulary changes, new business and sales trends.

Forecasts are maintained daily through various reports and sales usage data. Suppliers that are eligible to receive 852 inventory files will have visibility to this information provided through that process.

Generic manufacturers can access AmerisourceBergen's Certio platform for additional replenishment reporting and analytics. Manufacturers should reach out to their category manager to discuss getting access to Certio.

4. **Purchase Orders.** Purchase Orders are generated by replenishment operations. It is possible to group products onto separate POs based of specific manufacturer needs: multiple shipping locations, regional orders, specific temperature requirements, etc.

The following are the methods AmerisourceBergen supports for submitting purchase orders to manufacturers:

- Electronic Data Interchange (EDI 850) – Orders placed are electronically transmitted each business day based on the following frequency and schedule:
 - Transmitted every 15 minutes from 3:00am to 7:45am (ET)
 - Transmitted every 10 minutes from 8:00am to 9:30am (ET)
 - Transmitted every 20 minutes from 9:30am to 9:30pm (ET)
 - Controlled Substance Ordering System (CSOS) – DEA compliant method to electronically transmit narcotic orders via Axway CSOS system. DEA 222 forms are automatically generated then sent to the manufacturer and the DEA once per hour.
 - Fax – Manufacturers who are not set up to receive EDI will be sent orders via fax. This method is not preferable. Manufacturers not set up to receive narcotic orders via CSOS will be overnighted 222 forms the day orders are placed, per federal regulation.
5. **National Distribution Center Purchase Orders.** Demand, from the AmerisourceBergen forward distribution centers, is consolidated into a single master Purchase Order that is sent to the manufacturer via an EDI 850 document.
 6. **Consumer Regional Distribution Center Purchase Orders.** Demand, from the AmerisourceBergen forward distribution centers, will be provided on multiple purchases orders to manufacturers for delivery to their designated CRDC. Note that products should be packaged and palletized to the forward DC purchase orders to enable easier cross-docking.

4.2 Manufacturer Expectations

1. **Order placement and Lead Time.** Manufacturers are expected to provide accurate lead times for each Distribution Center. When purchase orders are placed, the replenishment system will generate delivery dates based on provided lead times.

All available products are expected to ship in full and delivered on or before the projected delivery dates. If an order is expected to be delivered past the due date, manufacturers must notify their assigned Replenishment Operations contact as soon as possible.

AmerisourceBergen communicates availability and delivery dates to the end customers; it is imperative to maintain accurate delivery information.

2. **Short Dating and Allocations.** Manufacturers must notify their assigned Replenishment Operations contact about any short-dated products. Manufacturers may not send short-dating without first receiving approval.

Manufacturers must notify their Replenishment Operations contact about any order cuts pertaining to allocated or backordered items.

3. **Back Orders.** Accurate backorder reporting is important to align product availability between AmerisourceBergen and its manufacturer partners. A unified message will provide realistic market expectations and drive superior service.

Manufacturers must notify their assigned Replenishment Operations contact all the products on backorder. The number and frequency of backorders will be reviewed on a quarterly basis and may have an overall impact on the operational replenishment metrics and scorecard.

Communication Template. AmerisourceBergen has developed a standard backorder template to be used by manufacturers. The template consists of three tabs:

- Backorder Report – This section contains the actual data reported from the manufacturer
- Additional Data – Optional area to be populated at the manufacturer’s discretion
- AmerisourceBergen Report Guidelines –composition and formatting instructions

Manufacturers should send the completed backorder templates, as well as any questions, should be sent to their respective AmerisourceBergen Replenishment contact.

A blank excel template can be found on AmerisourceBergen’s Manufacturer and Replenishment Operations website. <https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment>

NDC#	Item Description	Current BO Reason (Select from Dropdown List)	Expected Availability Date (This Week)	Expected Availability Date (Previous Report)	Supplier Notes

4. **Manufacturer Interaction.** A strong partnership with AmerisourceBergen’s manufacturer trading partners is critical to achieving best in class service for the ultimate end customer. Working together to plan inventory levels, report market issues and prevent potential outages all contribute to this shared goal. Communication is vital and must be carefully developed so that problems can be identified and resolved quickly. AmerisourceBergen strives to be readily available to address concerns and we expect our partners to place as much value on rapid response times.

In order to meet customers’ needs the following metrics have been established with regard to service level, inventory availability and lead times. We focus on raw and adjusted service levels as important indicators of success.

Generics:	Raw Goal – 98%	Adjusted Goal – 99.8%
Branded:	Raw Goal – 98%	Adjusted Goal – 99.8%
Consumer:	Raw Goal – 94.5%	Adjusted Goal – 99.2%

Specific metrics are subject to manufacturer agreements and may vary. Please contact the AmerisourceBergen Strategic Global Sourcing and/or Replenishment Operations contact for clarification.

5. **Holiday and Year End Deliveries.** The holiday season presents a challenge with respect to closures, bad weather and erratic buying patterns. AmerisourceBergen will work with each manufacturer to execute a purchasing schedule that addresses closures, usage spikes and weather delays. This means setting an inventory plan that provides enough stock to carry our customers into the New Year while meeting strict delivery expectations so that product is in place before potential outages occur.
6. **System and Data Integrity.** Accurate data is a key aspect of ensuring accurate and timely purchases and deliveries of products. AmerisourceBergen requires accurate and timely updates on any key logistics product attributes: minimum order, buying multiple, case pack sizes/dimensions, layer and pallet quantities.

Changes to minimum order quantities, layer and pallet quantities should be communicated to the AmerisourceBergen Replenishment Operations contact.

Changes to product case quantity and dimension changes must go to AmerisourceBergen’s master data team:

ProductDataChanges@amerisourcebergen.com.

Notifications of long–term unavailability, NDC transitions and discontinuations should also be forwarded to the RO contact. Alignment between manufacturer and AmerisourceBergen systems will mitigate potential delays with respect to ordering, shipping and receiving.

4.3 Best in Class

Replenishment Operations monitor key metrics and generate quarterly scorecards to deliver best–in–class service to our customers and manufacturer partners.

AmerisourceBergen defines a manufacturer as being best–in–class for:

- Accepting EDI 850 Purchase Order placement for all purchase orders.
- Provide EDI 855 Purchase Order Acknowledgement for all purchase orders.

- Provide EDI 856 Advanced Ship Notifications for all purchase orders.
- Offer reasonable unit and order minimums.
- Proactively provide shipping schedules for holidays / closed dates.
- Ship on day of purchase order receipt.
- Accept controlled substances purchase orders via Controlled Substance Ordering System (CSOS).
- Provide ideal lead times:
 - Generic: 1–5 days.
 - Brand: 1–3 days.
 - OTC: 7–10 day.

5.0 PRODUCT DELIVERY

5.1 Product Identification and Packaging

1. **Unit Labeling.** AmerisourceBergen requires that each Prescription Drug lowest saleable unit is labeled according to the Healthcare Distribution Alliance “Guidelines for Bar Coding in the Pharmaceutical Supply Chain”.

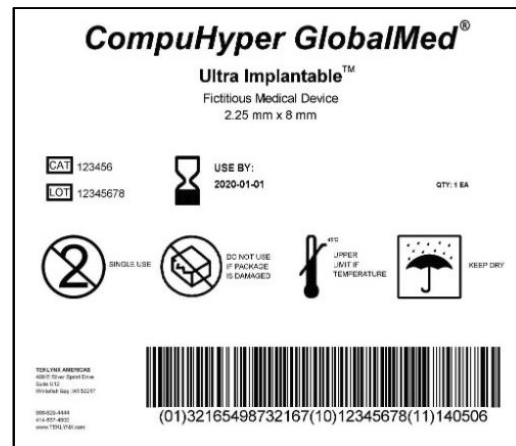
Applicable Rx products must also contain a 2D GS1 DataMatrix containing the DSCSA product identifier attributes (GTIN, Serial Number, Lot, Expiration).



DSCSA RX Serialized Unit Label



OTC Unit Label



Example Medical Device Label

Other products, such as medical devices, consumer health and medical foods must have their unique product identifier (UPC, GTIN, HIBCC, etc.) barcoded in accordance to the applicable standards (GS1 UPC–A, GS1–128, GS1 DataMatrix, etc.).

When prescribed in a point-of-sale environment (PoS), Prescription (Rx) and Over the Counter (OTC) units must also be labeled with a UPC–A linear barcode containing the product NDC. The use of other linear barcodes to encode the NDC, such as GS1 DataBar, is **not acceptable** as many point-of-sale and scanners cannot read those barcode formats.



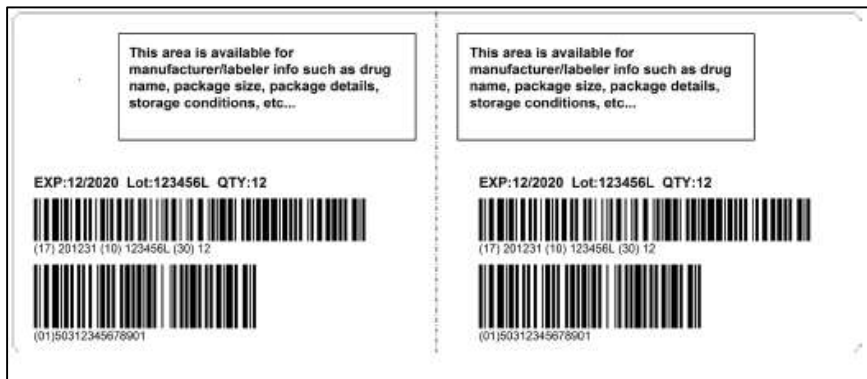
Example of the improper use of a GS1 DataBar

Case Labeling. AmerisourceBergen requires that each Prescription Drug homogenous case is labeled according to the Healthcare Distribution Alliance “Guidelines for Bar Coding in the Pharmaceutical Supply Chain”. See Appendix section □ for reference.

Below are two examples, from the guidelines, that depict what a homogenous case label should look like:



Example of Rx Serialized Homogenous Case Label



Example of OTC Homogenous Case Label

Other products, such as medical devices, consumer health and medical foods must have their cases and inner-packaging labeled with the product name, quantity, and product identifier such as UPC, GTIN, or HIBCC code. In addition, the product identifier must be barcoded in accordance to the applicable standards (GS1 UPC-A, GS1-128, GS1 DataMatrix, etc.).

It is expected that each case is labeled using a corner wrap label, or identical labeling on two adjacent sides. This creates redundancy, and prevents handling delays in the event one side of a case is damaged in transportation.

It is never acceptable affix a case label to the top or bottom of the case.

5.2 Logistics Packaging

1. **Mixed/Repack/Partial Case Labeling.** AmerisourceBergen requires that each mixed, partial (less than full quantity), or repack is labeled according to the Healthcare Distribution Alliance “Guidelines for Bar Coding in the Pharmaceutical Supply Chain”. See Appendix section □ for reference.

Non–full cases are individually received and must be easily recognizable to ensure that accidental full case receipt is not performed. It is recommended to use a visual aid such as a bright yellow, or orange, placard to distinguish between a homogenous full case.

Below is an example, from the guidelines, that depict what a partial case label should look like:



Example Partial Case Labeled with SSCC

This is another example of a visually identified mixed case:



Examples of properly identifying “Repack” or “Mixed Pack”

It is *never* acceptable to reuse a homogenous case label to ship anything other than full case quantity. If a full case is reused, the full case label must be removed or blacked out to prevent receiving confusion.

2. **Shipping Labeling.** AmerisourceBergen requires that *each* individually shipped mixed case, or pallet contain a Serialized Shipping Container Code (SSCC) Label. This is often referred to as the ASN or shipping label.

This label must contain, at a minimum, Shipping From/To Information, AmerisourceBergen Purchase Order(s), and a GS1–128 Barcode containing an 18–digit SSCC code.

Below is an example of a properly formatted pallet shipping label:

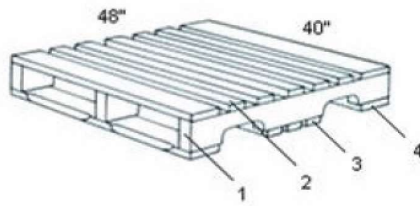
FROM: XYZ SUPPLIER 1060 W ADDISON ST CHICAGO, IL 60613	TO: CUSTOMER #1234 143 BEALE ST MEMPHIS, TN 38103
SHIP TO POSTAL CODE: (420) 38141 	CARRIER: RDWY ROUTE: 4768 B/L#: 0083273642
P.O.# (400) 8194696681 	
XYZ SUP	8194
SSCC: (00) 1 0003002 100000001 6 	

1. **Ship-From Information**
Enter the origin address
Rec'd Font Size 10-12pt; Area 1" x 1 1/4"
2. **Ship-To Information**
Enter the customer warehouse address
Rec'd Font Size 10-12pt; Area 1" x 2 1/4"
3. **Ship-To Postal Code**
Enter as shown, with bar code of zip code below
Rec'd Font Size 10-12pt; Area 1" x 2"
4. **Shipper Information**
Include four-digit SCAC code of carrier, route (opt), bill of lading or carrier/PRO number
Rec'd Font Size 10-12pt; Area 1" x 2"
5. **PO Number**
Enter the customer PO number with bar code of the number below
Rec'd Font Size 20-24pt; Area 1" x 4"
6. **Expanded Supplier Name**
Enter the first seven characters of the supplier's name
Rec'd Font Size 36-40pt; Area 1" x 2 1/4"
7. **Customer Warehouse ID**
Enter the four-digit customer warehouse number (first four digits from PO number)
Rec'd Font Size 36-40pt; Area 1" x 1 1/4"
8. **SSCC**
Enter the SSCC Identifier with large bar code below
Rec'd Font Size 18-22pt; Area 2" x 4"

3. **UPS / Fedex Labeling.** For FedEx shipments, the AmerisourceBergen Purchase order number must be provided in the PO field of the FedEx label.

For UPS shipments, the AmerisourceBergen Purchase Order number must be provided in one of the reference fields.

4. **Pallet Construction.** All pallets must be in good, stable condition and should be the standard pallet dimensions (48" x 40").



Description:

1. Stringers (3 min – 1½ x 3½ in.)
2. Top deck boards (max space of 3¼ in.)
3. Bottom deck boards
4. Bottom lead deck boards

All pallets must be heat treated and be free of chemicals and chemical treatments, including halogenated phenols (2,4,6–tribromophenol (TBP) or 2,4,6–trichlorophenol (TCP)).

5. **Pallet Stacking.** Product should not exceed pallet dimensions (i.e., falling off or hanging over the side) and shrink wrap should be intact.

In order to prevent loading damage, and reduce risks to associates unloading, Pallet height must not exceed 6'–0" (including pallet height).

Pallets should be shrink wrapped to ensure the product can move safely during transportation and reduce the opportunity for damage to occur during transportation.



Improperly stacked pallet over 6'



Damaged pallet construction



Pallet not properly packed

6. **Pallet Configuration.** All pallets should be Purchase Order (PO) specific and the PO number must be clearly identified on all four sides. It is acceptable to use the SSCC shipper label for this.

Like products must be grouped together as much as possible, separated by slip sheets, with heavier products on the bottom.



Example of using slip sheets to separate products or purchase orders

In the event multiple products from multiple purchase orders are stacked on an individual pallet, the use of slip sheets is required to separate the products on different purchase orders. In addition, each section of the pallet must be labeled with the PO#, or the pallet must have a container list attached that includes the PO numbers and corresponding items and quantities.

Pallet Container list		
PO #	NDC/Item #	Pallet Qty (Cases)
5552334455	1234-5650-10	5
5552334466	1234-5650-10	3
5552334477	1234-5650-10	7
5552334477	1234-5440-15	12
5552334477	1234-7650-20	6

Example of identifying multiple POs on a Pallet

- 7. **Transportation and Freight.** Pallets should not be pinwheeled in the truck and should not have any vertical obstructions preventing unloading of the product. All pallets must be readily retrievable on the tail of the trailer.

Pallets are not to be double or triple stacked to help ensure product is not damaged during transportation to AmerisourceBergen; this will result in damaged product.



Improperly stacked pallets

The use of “Do Not Double Stack” placards is highly recommended, as well as having the conversation with individual carriers about the importance of not double stacking. Most of the double stacking of pallets occurs at the carrier’s cross dock.



Example of “Do Not Double Stack”



Damaged “Double Stack” warning

- 8. **Controlled Products.** All controlled products must be separate pallets from ambient and refrigerated products.
- 9. **Refrigerated or Frozen Products.** All refrigerated products must be clearly labeled and separated from ambient and controlled products. Refrigerated product pallets must be clearly identified as such on all four sides of the pallet.

10. **Packing List and Bill of Lading.** A master packing list must accompany each shipment and be on the tail of the transportation truck. Each packaging slip must contain, organized by pallet and purchase order, a list of items and their respective quantities.

Each pallet, with either mixed products or purchase orders, must have a container list identifying the POs, items, and quantities on that pallet.

Item	Product Name / Strength / Dosage Form / Container Size	NDC	Lot Number	Qty Ordered	Qty Shipped
CHECK PRODUCT LABEL FOR STORAGE REQUIREMENTS					
0003	1210 Oxytocin Inj 100 usp Liquid PK = 25 EA PO: 008419188 Order: 3044576	6332301210	6013343	4 PK	4 PK
0004	1210 Oxytocin Inj 100 usp Liquid PK = 25 EA PO: 008421433 Order: 3070629	6332301210	6013343	8 PK	8 PK
0005	1210 Oxytocin Inj 100 usp Liquid PK = 25 EA PO: 008422272 Order: 3079496	6332301210	6013343	16 PK	16 PK
0025	1210 Oxytocin Inj 100 usp Liquid PK = 25 EA PO: 008422899 Order: 3086279	6332301210	6013343	8 PK	8 PK
0001	1311 Doxycycline for Inj USP 100 mg Lyophilized PK = 10 EA PO: 008424531 Order: 3104584	6332313011	6013312	40 PK	40 PK
0007	271301 Sumatriptan Succinate Inj 6 mg Liquid PK = 1 EA PO: 008424531 Order: 3104584	6332327301	6011707	100 PK	100 PK
0012	28204 Clindamycin Phosphate Inj	6332328204	6013342	8 PK	8 PK

Example packing list showing individual purchase orders, items, and quantities.

The bill of lading must be filled out for each load, all purchase orders must be listed, and the number of pallets/cases clearly marked.

Manufacturer email address for any logistics issues must be on the bill of lading.

11. **Parcel Pack (FedEx/UPS).** Using master tracking number for multiple boxes/cartons is prohibited; multiple parcels should be shipped separately with their own tracking numbers.

Distribution Centers receive against the tracking number and FedEx/UPS considers the chain of custody complete. Using a master tracking number often leads to incorrect receipts associated with split-shipments.

5.3 Transportation and Deliveries

1. **Forward Distribution Center Deliveries.** When delivering directly to a forward distribution center, and not the National Distribution Center, the following should be followed.
 - FedEx heavyweight control substance deliveries – drivers must remain at the distribution center, during the receipt of product, to ensure that AmerisourceBergen can get an accurate piece count
 - Delivery hours – AmerisourceBergen accepts deliveries in our distribution centers between 6:00 a.m. and 12:00 p.m. local times.
 - Scheduling Deliveries – Carriers should contact the distribution center to schedule deliveries. This is necessary due to the volume and number of carriers arriving at our locations. Below are the contacts to schedule an appointment

2. **Trucking Expectations.** Purchase orders are expected to be shipped in clean well-maintained trucks and in accordance with any product temperature requirements.
Generally speaking, full case orders of 20 or more cases should be shipped via less-than-truck-load (LTL) or full-truck-load (FTL) carrier and not UPS / FedEx.
3. **Signing for Delivery.** All deliveries are subject to a final detailed inspection and count. The initial signature on delivery documents is based off a brief scan and quick count.

Manufacturers with short claim windows should be aware that they may receive higher false claims because AmerisourceBergen has not had adequate time to research the item(s) before submitting the claim.

To quickly resolve issues, it is recommended that the manufacturer email be present on the Bill of Lading.

4. **Security of Transportation Loads.** The security of the supply chain is of the utmost important. It is recommended to use the following security features when shipping to AmerisourceBergen:
 - Always use black or dark colored shrink wrap to minimize visibility and identification of product being shipped.
 - Do not mix controls with non-controls in the same skid, over pack box/carton.
 - When shipping controls, pack multiple boxes in one over pack box or one pallet. Shipping multiple boxes via parcel carrier for the same product may lead to product loss and diversion.

Manufacturers need to respond back to AmerisourceBergen's regulatory personal, on missing controlled products, within 24 hours; there is no exception to this guideline. If AmerisourceBergen is not contacted within 24 hours, the manufacturer has the responsibility to file a DEA form 106.

5. **Accepting of Transportation Loads.** All deliveries are subject to a final detailed inspection and count. The initial signature on delivery documents is based off a brief scan and quick count.

Manufacturers with short claim windows should be aware that they may receive higher false claims because AmerisourceBergen has not had adequate time to research the item(s) before submitting the claim.

6. **Environmental Sustainability.** Manufacturers should strive to minimize or eliminate single-use containers when possible and consider reusable alternatives. Ideally, manufacturer will either ship on refrigerated trucks or only provide recyclable and/or compostable containers that are Styrofoam alternatives. In most locations across the United States there are no outlets for recycling Styrofoam.

Furthermore, manufacturers should provide dunnage and packaging materials that are easily recyclable or reusable.

7. AmerisourceBergen Locations. Below are all AmerisourceBergen Ship-to facilities. This includes the full-line and specialty distribution centers as well as American Health Packaging.

Location Name	Address	DEA License #	HIN
AmerisourceBergen Corporate	1 West First Avenue, Conshohocken, PA 19428	N/A	9KN5Q8J00
ABDC - Amityville	5500 New Horizons Blvd., N. Amityville, NY 11701	RB0363630	3HNADB500
ABDC - Atlanta	3930 MASON MILL RD, BUFORD, GA 30518	RA0515063	4GEP4JA00
ABDC - Bethlehem	5100 Jandl Blvd., Bethlehem, PA 18017	RA0336924	304J96500
ABDC - Boston	101 Norfolk Street, Mansfield, MA 02048	RA0290724	J81TK1600
ABDC - Brooks	345 International Blvd., suite #400A, Brooks, KY 40109	RA0219798	K56MWJW00
ABDC - Chicago	1001 West Taylor Road, Romeoville, IL 60446	RA0322824	CJKRME600
ABDC - Columbus	6305 LaSalle Drive, Lockbourne OH 43137	RA0314562	6B3243T00
ABDC - Columbus NDC	6301 LaSalle Drive, Lockbourne, OH 43137	RA0471108	637WX4D00
ABDC - Corona	1851 California Avenue, Corona, CA 92881	RA0289050	U1V4YH900
ABDC - Dallas	501 Patriot Parkway, Roanoke TX 76262	RA0316958	5LFRL6N00
ABDC - Denver	501 W. 44th Avenue, Denver, CO 80216	RA0290988	4DX2VT400
ABDC - Des Moines-Seattle	2141 S 211TH ST Suite A, Des Moines, WA 98198	RA0513437	A9L4W6A00
ABDC - Dothan	2811 Horace shepherd dr., Dothan, AL 36303	N/A	F2TWB5M00
ABDC - Honolulu	238 Sand Island Access Rd. #M1, Honolulu, HI 96819	RA0289048	LBCCJRU00
ABDC - Houston	12727 W. Airport Blvd., Sugar Land, TX 77478	RA0289276	JFLQXTZ00
ABDC - Indianapolis	4860 Indianapolis Road. Whitestown, IN 46075	RA0509490	DGR0L5A00
ABDC - Kansas City	11200 N. Congress Ave., Kansas City, MO 64153	RA0326276	LEK30YK00
ABDC - Louisville	6001 Global Distribution Way, Suite 102, Louisville, KY 40228	RA0556742	9DNNRPC00
ABDC - Montclair	5566 Arrow Highway, Montclair, CA 91763	RA0626183	HDQBCGN00
ABDC - Morrisville	120 Trans Air Drive, Morrisville, NC 27560	RA0363301	49FBQ3W00
ABDC - Newburg	108 Rt 17K Suite 1, Newburgh, NY 12550	RA0522056	C72YAWP00
ABDC - Olive Branch	12577 Stateline Road, Olive Branch, MS 38654	RA0504743	68PWHWC00
ABDC - Orlando Vista	10910 Lee Vista Blvd Suite 401, Orlando, FL 32829-8076	RA0464406	20X2CER00
ABDC - Phoenix	7775 W Buckeye Road Suite 150, Phoenix, AZ 85043	RA0512411	7CLYR3W00
ABDC - Puerto Rico	Calle Diana Lot 14&21, Amelia Industrial Park, Guaynabo, PR 00968	RJ0249563	FG42P3T00
ABDC - Reno	1195 Trademark Dr., suite 102, Reno, NV 89521	N/A	EK12LK600
ABDC - Richmond	9900 Jeb Stuart Pkwy., Glen Allen, VA 23059	RA0289000	TO0M7KU00
ABDC - Sacramento	1325 West Striker Avenue, Sacramento, California 95834	RA0310603	ELWQXFX00
ABDC - Salt Lake City	1765 Fremont Drive, Salt Lake City, UT 84104	RA0289098	7IMJGR100
ABDC - Shakopee	500 Innovation Drive, Shakopee, MN 55379	RA0501216	D3DT7JC00
ABDC - Williamston	One Industrial Park, Williamston, MI 48895	RA0290736	RMFF03A00
American Health Packaging - Columbus	2550-A John Glenn Ave, Columbus, OH 43217	RA0221325	9VM92WX00
ASD Healthcare - Anaheim	5100 E. Hunter Avenue Suite 101, anaheim, CA 92807	N/A	CALVF6N00
ASD Healthcare - Brooks	345 International Blvd., suite #400A, Brooks, KY 40109	RA0219798	E5CHWBJ00
ASD Healthcare - Carrollton	5025 Plano Pkwy, Ste 200, Carrollton, TX 75010	N/A	JAFRC9K00
ASD Healthcare - Columbus NDC	6301 LaSalle Drive, Lockbourne, OH 43137	See above	94MYA0700
ASD Healthcare - Dothan	2811 Horace shepherd dr., Dothan, AL 36303	See above	51MBRJD00
ASD Healthcare - Linthicum Heights	514 Progressive Dr., suite X, Linthicum Heights, MD 21090	N/A	
ASD Healthcare - Phoenix	7775 W Buckeye Road Suite 150, Phoenix, AZ 85043	See above	C42RJRJ00
ASD Healthcare - Reno	1195 Trademark Dr., suite 102, Reno, NV 89521	N/A	CBV7R5L00

ASD Healthcare - Montclair	5566 Arrow Highway, Montclair, CA 91763	RA0626183	C0M70Y300
ASD Healthcare - Boston (Mansfield)	101 Norfolk Street, Mansfield, MA 02048	See above	89YNFQ700
ASD Healthcare - Indianapolis	4860 Indianapolis Road. Whitestown, IN 46075	See above	7GR0VGP00
ASD Healthcare - Olive Branch	12577 Stateline Road, Olive Branch, MS 38654	See above	36M84V200
ASD Healthcare - Roanoke	501 Patriot Parkway, Roanoke TX 76262	See above	K76LW7L00
Besse Medical - Columbus NDC	6301 LaSalle Drive, Lockbourne, OH 43137	See above	HEKEBRV00
Besse Medical - Brooks	345 International Blvd., suite #400A, Brooks, KY 40109	See above	FJ097BP00
Besse Medical - Reno	1195 Trademark Dr., suite 102A , Reno, NV 89521	See above	83FA8CK00
Besse Medical - Dothan	2811 Horace shepherd dr., Dothan, AL 36303	See above	71WKW7R00
Besse Medical - Montclair	5566 Arrow Highway, Montclair, CA 91763	See above	JJ53EL900
Oncology Supply - Columbus NDC	6301 LaSalle Drive, Lockbourne, OH 43137	See above	6F039JG00
Oncology Supply - Brooks	345 International Blvd., suite #400A, Brooks, KY 40109	See above	6FMG5G800
Oncology Supply - Dothan	2811 Horace shepherd dr., Dothan, AL 36303	See above	23VLX7P00
Oncology Supply - Reno	1195 Trademark Dr., suite 102A , Reno, NV 89521	See above	6DT5RNV00
Oncology Supply - Montclair	5566 Arrow Highway, Montclair, CA 91763	See above	E568FT500

5.4 National Distribution Center Deliveries

The AmerisourceBergen National Distribution Center (NDC), located in Lockbourne Ohio, allows RX manufacturers to improve their supply chain by providing a single point of entry into the AmerisourceBergen Distribution Services supply chain. This solution streamlines the delivery and product management for those manufactures utilizing this service.

Given the efficient nature of the NDC Model, logistics and product performance is critical to minimize supply chain disruption, delivery delays, and time spent waiting to move product.

In addition to the prior product and logistics requirements, the following are required for those manufacturers utilizing the NDC – enabling the most efficient supply chain.

1. **NDC Delivery Schedule.** Companies must deliver to the National Distribution Center up to 60 mins prior of their scheduled arrival time. Early arrival to the NDC does not guarantee receipt of the shipment at that time. Should the company not meet their scheduled arrival time, AmerisourceBergen must notify the company. At that time, the company will have 30–days to correct the delivery time.
2. **Delivery Schedule Deviations.** AmerisourceBergen reserves the right to charge the company \$1500/occurrence for any delay after the 30–day correction period. This charge will not apply to delays resulting from force majeure or traffic accidents. The charge for delayed shipments to the National Distribution Center will reset each calendar year on January 1.
3. **Purchase Orders.** Manufacturers must ship completed purchase orders on a single truck. If the contents of the PO are greater than the capacity of a truckload, the content of the entire PO and the number of associated truckloads shall be on–site at the National Distribution Center within 30 minutes of each other.
4. **Bills of Lading.** The Bill of Lading must be emailed to the National Distribution Center prior to delivery – NDCInbound@AmerisourceBergen.com.
5. **Signing for Delivery.** All deliveries are subject to a final detailed inspection and count. The initial signature on delivery documents is based on a brief scan and quick count.

Manufacturers with short claim windows should be aware that they may receive higher false claims because AmerisourceBergen has not had adequate time to thorough research the item(s) before submitting the claim.
6. **Case Sizes.** Manufacturers delivering to the NDC are requested to meet the homogenous case physical requirements:
 - Homogenous Case Dimensions (length x width x height):
 - The smallest a case may be is 6”x9”x4”;
 - The largest a case may be is 24”x24”x12”
 - Homogenous Case Weight:
 - The lightest a case can weigh is 1lbs.
 - The heaviest a case can weigh is 30 lbs.

Failure to meet these requirements may result in additional handling, management, and potential damages during delivery.

6.2 Product Recalls

1. **Notification.** In the event of a product recall or withdrawal, notifications must be sent to recall@amerisourcebergen.com and include the NDC affected, applicable lot or batches, and what applicable action to take:
 - Wholesale Level Recall – Quarantine and prevent further distribution of effected product found within AmerisourceBergen’s current distribution network inventory.
 - Customer Notification Recall – in addition to the wholesale level actions, customers will only be notified by AmerisourceBergen when AmerisourceBergen is handling the customer notification process for retail or consumer level events. Some manufacturers may choose to handle this activity directly or have their designated third party handle it instead.

2. **Timing.** Recall and/or product withdrawal notifications will be distributed to the AmerisourceBergen Distribution Centers any time during normal business hours. They are not distributed on weekends and holidays.

Product inventory locations will be promptly inspected and necessary quarantine procedures will be executed to ensure the product is prevented from further distribution.

3. **Recall Returns.** It is always desirable for AmerisourceBergen to return any effected product, we have in our physical possession, promptly in order to obtain credit for this product quickly.

Please caution that the replenishment operations team has usually repurchased new product within just a few days after a recall event has occurred.

If AmerisourceBergen is handling the customer return activity on behalf of a manufacturer, multiple returns of the affected product may be made based on the timing of customer returns.

6.3 Product Returns

AmerisourceBergen utilizes Inmar Supply Chain and PharmaLink as our preferred reverse logistics and destruction vendors.

1. **Timing.** Products are only shipped to Inmar once per month, from each applicable AmerisourceBergen facility.

These products will then be processed and reviewed by Inmar to assess eligibility for credit to AmerisourceBergen. If eligible, Inmar will create a single debit for all products, across all facilities.

These debits will be created on the 15th of each month. These debits will have a prefix that starts with '053' in the manufacturers EDI 812 document.

2. **Product Exclusions.** AmerisourceBergen does not send the following product categories to our reverse logistics vendor:

- Liquid Nutritionals
- Durable Medical Equipment / Home Healthcare Equipment (wheelchairs, canes, etc.)

3. **Return Disposition.** If the returned product is eligible for credit, the manufacturer will be contacted by Inmar directly to obtain a Return Authorization (RA). It is the expectation of AmerisourceBergen that the requested RAs will be provided in a timely manner by the manufacturer to Inmar.

Inmar will take one of the following actions based on the manufacturer's guidance:

- Ship product directly back to them;
- Ship product directly back to their third party returns vendor;
- Destroy product at the manufacturers request; or
- If the product is not eligible for any credit, Inmar will destroy the product.

4. **Direct Return Shipments.** Inmar also handles returns directly on behalf of many manufacturers. In the event that AmerisourceBergen is making a direct shipment to Inmar, as the designated agent of a specific manufacturer (product returned as part damages claim, direct return of controlled drugs, etc.), this product will not be co-mingled with any other regular returns processing shipments.

7.0 ACCOUNTS PAYABLE

Global Financial Shared Services Accounts Payable supports all AmerisourceBergen Corporate and Distribution Services.

The preferred method for receipt of invoices and credit memos is via EDI810 and EDI812. Please contact the Accounts Payable EDI team for assistance with electronic exchange of invoices and credits at APGFSS-EDI@AmerisourceBergen.com.

Please submit full monthly account statements electronically in excel format by the 5th business day of each month for reconciliation. Statements should be sent to venrec@amerisourcebergen.com.

For questions, concerns, or discrepancies concerning deductions, manufacturers should contact Accounts Payable at abcvendorservices@AmerisourceBergen.com.

III. APPENDIX

8.0 REFERENCES

8.1 Regulatory Information

- FDA UDI Webpage”
<https://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/>
- FDA DSCSA Webpage:
<https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/>

8.2 Electronic Data Exchange Documents

- AmerisourceBergen EDI Specifications can be found in the Data Exchange section of the Manufacturer and Replenishment Operations webpage:
<https://www.amerisourcebergen.com/abcnew/manufacturer-operations-and-replenishment>
- AmerisourceBergen Serialized Data Exchange Specifications can be found in the Data Exchange section of the Manufacturer and Replenishment Operations webpage:
<https://www.amerisourcebergen.com/abcnew/manufacturer-operations-and-replenishment>
- AmerisourceBergen EDI Location Identifier List:
<http://publish.smartsheet.com/9a40c601a94c4600a6b64b1536a297c3>
- AmerisourceBergen locations address, GLN and SGLN list:
<http://publish.smartsheet.com/bea3b5e2e4d348328730ea21b552a24e>

8.3 Packaging and Labeling

- HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain can be found in the Labeling and Packaging section of the Manufacturer and Replenishment Operations page:
<https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment>

8.4 Product Setup

- GS1 Global Trade Item Number (GTIN) Allocation Rules
https://www.gs1.org/docs/gsmf/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
- HDA Standard Product Information Form (Rx Only)
[https://hda.org/publications/standard-pharmaceutical-product-and-medical-device-information-\(rx-product-only\)/](https://hda.org/publications/standard-pharmaceutical-product-and-medical-device-information-(rx-product-only)/)
- AmerisourceBergen Item Setup
<https://www.abcsetup.com>

8.5 Forms

- Backorder Report can be found in the Replenishment Operations section of the Manufacturer and Replenishment Operations webpage:
<https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment>

- HDA Standard Product Information Form (Rx Only):
[https://hda.org/publications/standard-pharmaceutical-product-and-medical-device-information-\(rx-product-only\)/](https://hda.org/publications/standard-pharmaceutical-product-and-medical-device-information-(rx-product-only)/)

9.0 PUERTO RICO REGISTRATION

Products that Require a Registration at the PR DOH (“División de Medicamentos y Farmacias, Departamento de Salud”) as per “Reglamento 156” are:

- Any substance considered a "drug" [Drug Definition: Any drug in dosage form suitable for use in human beings or other animals with at least one active ingredient and has been designed for use in the diagnosis, cure, mitigation, treatment or prevention of diseases and / or affect the structure or any function of the body] as defined in this Regulation, including, but not limited to, the following: Prescription (Rx) and Non Prescription Drugs (OTC) approved by the FDA.

Examples may include products such as: Homeopathic drugs; Veterinary drugs (Rx and OTC); Prefilled syringes/devices that contains a medication; Medicated gauze with at least one active ingredient; creams & ointments; drugs for internal and external use....

Products that Do NOT Require a Registration at the PR DOH

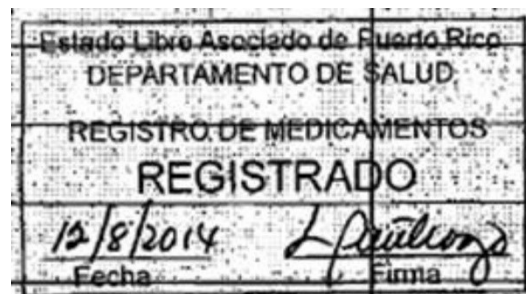
- Preparations (compounding) at the pharmacy level as per a legitimate prescription of a medical practitioner including extemporary preparations listed in the USP/NF prepared for use in a pharmacy on site.
- Medical Devices (at this time they are not enforcing registration of any medical device) such as crutches, wheelchairs, band aids, gauzes, intra uterine devices without medications, intraocular devices without medication, etc.
- Insecticides /Pesticides are not considered medications/drugs

REQUIRED DOCUMENT – EVIDENCE

The required documentation from the manufacturer will include the name of the form listed as “Lista Registro de Medicamentos” (Drug Registration List) or “Registro de Medicamentos” (Medication Record) from the Departamento de Salud, División de Medicamentos y Farmacias” (Health Department, Division of Drugs and Pharmacies).

Please be advised that the logo on the form may vary according to time frame because the agency logo tends to change frequently. Form (how it looks) may vary too, in general the appearance shall be the same; variances respond to the fact that the agency allows a Registrant (Representative Agent) to design the form electronically when submitting the manufacturers products using the basic model.

In order for the form to be accepted by AmerisourceBergen, as evidence of the registration of a product, the presence of the official seal with the Inspector’s signature and date is required (refer to the following example):



10.0 GLOSSARY OF TERMS

TERM	DEFINITION
CRDC	Consumer Regional Distribution Center
DSCSA	Drug Supply Chain Security Act - US Federal Law passed in 2013 mandating the identification of Human Prescription drugs with a product identifier consisting of NDC (GTIN), Lot, Expiration, and serial number. Each unit of sale a homogenous case is to be serialized and that product identifier affixed with a GS1 2D DataMatrix barcode
EDI	Electronic Data Exchange - used to enable electronic orders, invoicing, and shipping information throughout the supply chain.
EPCIS	Electronic Product Code Information Service - xml based format used to exchange serialized information and events.
FDC	Forward Distribution Center
GS1	GS1 is a not-for-profit organization that develops and maintains global standards for business communication. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically.
GS1 128	GS1 Linear Barcode used to store GTIN-14, Lot, Expiration, Serial Number, and if applicable date of manufacturer. Used to meet DSCSA and UDI regulations.
GS1 2D DataMatrix	GS1 2D Barcode used to store GTIN-14, Lot, Expiration, Serial Number, and if applicable date of manufacturer. Used to meet DSCSA and UDI regulations.
GTIN	Global Trade Identification Number - GS1 Assigned trade identifier. Based off the NDC Code for Prescription Drugs and OTC products. A GTIN-12 (UPC) can be used to identify the product and a GTIN-14 is used to identify the product AND packaging level. GTIN-14 is used for the purposes of DSCSA and UDI.
HDA	Healthcare Distribution Alliance
HIBCC	Health Industry Business Communications Council - standards body that assigns HIBCC codes that can be used as device identifiers for UDI. This can be used as an alternative to GS1
NDC	National Distribution Center or National Drug Code – Depending on Context
OTC	Over the Counter
SGS	Strategic Global Sourcing
SSCC	Serialized Shipping Container Code - a unique 18-digit number assigned to logistics units such as pallets, totes and mixed cases.
UDI	Unique Device Identification - FDA established regulation to implement a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form.
UPC	Universal Product Code - 12-digit GTIN used to identify OTC, consumer, and other products used at point of sale.
UPC-A	GS1 Linear Barcode used to store a UPC.