



MWI VENDOR PARTNERSHIP GUIDE

MWI Operations
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I. INTRODUCTION

1.0 Purpose and Scope

We are united in our responsibility to create healthier futures.

MWI Animal Health AmerisourceBergen (known as MWI for the purposes of this document) is driving innovative partnerships with global manufacturers, providers, and pharmacies to improve product access and efficiency throughout the animal healthcare supply chain. As the world's largest animal health organization, pharmaceutical and supplies distributor, and the global leader in animal health services--- we are here to help you capitalize on the dynamic changes in animal health.

This document provides operational guidance and expectations to ensure the efficient delivery of pharmaceutical and consumer goods from you, our valued animal health partners, to MWI distribution centers and ultimately to our end customers and patients.

This document, and the requirements contained within, may be updated at any time. 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 MWI 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 : purchasingdataintegrityspecialists@mwianimalhealth.com
Product Recalls Notifications	MWIcompliance@mwiah.com
National Distribution Center Inbound Delivery	MWIRedistRecv@mwianimalhealth.com
General Vendor Setup Questions (EDI, Vendor Packet, etc.)	tradevendormaint@mwianimalhealth.com
EDI Accounts Payable	APGFSS-EDI@amerisourcebergen.com
General EDI Technical Questions	EDIservices@mwiah.com
Product Dimensions and Case Quantity Changes	MWIOperations@mwianimalhealth.com

* Specialty Products & Distribution – For specialty products, distribution and price changes please contact your representative.

II. DOING BUSINESS WITH MWI ANIMAL HEALTH

1.0 Being a Business Partner with MWI Animal Health

The following section defines MWI expectations for beginning a relationship as a Business Partner with MWI.

2.0 New Manufacturer Setup

Prior to engaging in business with MWI, the company requires that the manufacturer enter into a distribution services agreement. For more information about establishing a relationship with MWI, contact categorymanagement@mwianimalhealth.com:

- MWI
- Securos
- Micro
- Specialty Groups

A representative of MWI will work to gather the appropriate documentation and answer any questions a manufacturer may have.

3.0 New Item Setup

3.1 New Item Setup Process

When launching a new product or changing a product's National Drug Code (NDC), in order to have the item set up in our systems manufacturers must ensure that all required documents are submitted to their assigned MWI category manager or through MWI Setup.

The required documents are:

- Product Information via link – need to make sure this has DIMS, and packaging types.
 - HDA new product form (Rx only)
 - MWI Setup
- Safety Data Sheet (SDS) – Every manufacturer is required to provide an SDS for each product they ship to MWI or its subsidiaries at the time a new item is set up, or a written statement that an SDS is not required.
- Individual unit package (label or package flat) – must be legible
 - Must include human readable and sample barcodes (where pre-printed)
- Homogenous case package (label) – must be legible

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 for Human RX.

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

Measuring Procedures for Selling Units, Inner-packs, Master Cases and Pallets:

- Always record dimensions in this order: depth, width, height, in inches;
- Depth is the front to back dimension of the product; width is the horizontal dimension, and height is the vertical dimension;

- Always enter the largest dimension of depth, width, and height; the deepest, widest, and tallest points, of how the product will be shipped, reflect true product displacement;
- Always give the precise weight for a selling unit in pounds

4.0 Product Data Maintenance

4.1 Packaging Configuration Changes

Product packaging or configuration changes require that the manufacturer notify MWI's master data team at a minimum of 30 days prior to changes physically entering the supply chain. This will ensure that processes dependent on size parameters or quantities are updated and will not result in incorrect product receipts or product stoppages.

MWI supports GS1 standards to identify products. It is recommended that manufacturers consult GS1 Healthcare Global Trade Item Number (GTIN) Allocation rules when changing packaging and labeling.

When to notify MWI:

- Product Case Dimension Size Changes – Changes from 10"x12"x6" (WxHxL) to 24"x6"x6" (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).
- Changes to the Inner Pack, Bundles, Packs or Loose products within a Product Case – the addition or removal of an Inner Pack, Bundle, or Pack that could affect saleable units.
- Addition of a GTIN on product packaging – Adding a GTIN to a product in addition to the UPC.
- Changes to the UPC – Changes to the UPC digit length or UPC version, or the addition of a UPC to a product.
- Changes in the country of origin – i.e., moving product manufacturing origin from USA to India.

Manufacturers should notify MWI of configuration changes by emailing:

purchasingdataintegrityspecialists@mwianimalhealth.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.)

Replenishment Operations needs to be immediately made aware of:

- Shipping issues. IE: Shortages, late shipments, delays
- Manufacture Backorders and ETAs
- Discontinued Items
- Item changes. IE: UOM, packaging, or label changes
- Pricing changes. Minimum 30 days notice.
- Upcoming customer and distributor promotions at purchasers@mwianimalhealth.com

4.2 Price Changes

Manufacturers must notify MWI in the event of a wholesale acquisition cost change. The methods below should be used to ensure changes are reflected in MWI's systems in a timely manner:

Price changes should be communicated to the following:

- CategoryManagement@mwianimalhealth.com
- Pricenotices@mwianimalhealth.com
- purchasers@mwianimalhealth.com

5.0 Electronic Data Interchange (EDI)

5.1 EDI Standards

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.

MWI 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.

EDI transactions received (inbound)

Document	Description
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
997	Data receipt

EDI transactions sent (outbound)

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

The following EDI transactions are required to facilitate the operational efficiency of receiving product as well as DSCSA compliance when applicable:

5.1.1 Purchase Order Acknowledgement (855)

Manufacturers are requested to provide an electronic Purchase Order acknowledgement via an EDI 855. Those delivering to K99 (MWI Redistribution Center) are required to send an 855. This enables the replenishment operations team to confirm the receipt of a purchase order (an EDI 850 transaction) from a buyer, eliminating the need to call or fax confirmation. In addition, this provides pro-active visibility to potential back-order scenarios.

5.1.2 Advanced Ship Notice (856)

Manufacturers are required to provide an electronic advanced ship notification for all deliveries to MWI distribution centers. This not only is our DSCSA regulatory document for applicable Rx products, but also helps in managing receiving and product quantity variances.

5.2 Serialized Data Exchange (EPCIS) Update

Starting in 2018, AmerisourceBergen will be accepting EPCIS files from manufacturers for the purpose of collecting product identifiers to meet the 2019 DSCSA saleable returns regulatory mandate. As we approach November 2023, all prescription human drugs purchased by MWI directly from the manufacturer will require serialized EPCIS data to be sent electronically by the vendor with every shipment.

For questions on serialized data requirements and to arrange testing and onboarding EPCIS exchange, please contact SecureSupplyChain@amerisourcebergen.com. The latest serialized data exchange specification can be found on MWI's Manufacturer and Replenishment Operations website.

6.0 Drug Supply Chain Security Act (DSCSA)

The safety and security of our nation's pharmaceutical supply is a top priority for MWI and a responsibility we take very seriously. A safe and reliable drug supply is central to our customers' business and critical to the health and well-being of patients. MWI is committed to complying with the DSCSA track and trace legislation in the most efficient manner possible where it applies to human prescription drugs.

Electronic TITHTS data is required for transactions in scope of DSCSA. TITHTS stands for:

- Transaction Information
 - Name
 - Strength
 - Dosage form
 - NDC
 - Container size
 - Number of containers
 - Lot number
 - Date of transaction (and shipment date if 24+ hours after transaction)
 - Business name and address of the person from whom ownership is being transferred
 - Business name and address of the person to which ownership is being transferred

- Transaction History
 - Transaction Information for each prior transaction going back to the manufacturer of the product. This will be sunset after November 2023.

- Transaction Statement – Indicating the Seller is:
 - Is authorized under the Act
 - Received the product from an authorized party
 - Received transaction information and a transaction statement from the previous seller, as required
 - Did not knowingly ship suspect or illegitimate product
 - Has systems and processes in place to comply with verification requirements
 - Did not knowingly provide false transactional information

- Did not knowingly alter transaction history
- Note: Cardinal Health supports the use of the abbreviated Transaction Statement recommended by HDA and PDSA. Seller has complied with each applicable subsection of FDCA Sec. 581(27) (A)–(G).
- All shipments of prescription drug product sent without required information will be placed directly in quarantine and if unresolved, will be returned to supplier based on established criteria.
- 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.
- For additional details regarding DSCSA requirements please reference sections: UDI, EDI, Serialized Data Exchange (EPCIS), and Bar Code requirements.

7.0 Replenishment Operations

7.1 Purchasing Process

7.1.1 Forecasts

MWI uses historical sales and new customer demands to generate forecasts. Each forecast period is comprised of 4-weeks of data for a total of 13 periods per year. This ensures each forecast period represents 28 days of usage.

Each Buyer is responsible for maintaining forecasts for every item in every warehouse based on many variables, including, but not limited to: Order Day requirements, product lead times, order cycles, seasonal variations, promotions, new customer onboarding, and sales trends.

7.1.2 Purchase Orders

Purchase Orders are generated based on several factors, including, but not limited to: vendor order requirements (minimum orders), item specific forecasts, vendor lead times, safety stock, and current inventory levels. Orders are generated for each of MWI's warehouses individually. MWI supports purchase order submissions by the following methods:

- EDI – Preferred method
- Email by PDF format
- Controlled Substance Ordering System (CSOS) – DEA compliant method to electronically transmit narcotic orders via Axway CSOS system. DEA 222 forms are automatically generated and sent to the manufacturer, and the DEA, once per hour.

7.1.3 Drop Ship

MWI offers customers the opportunity to order products direct from the vendor on items not offered in MWI's stock inventory. All drop ship items are approved by Category Management and must have a new item form submitted to ensure proper set up within our systems. Drop Ship Purchase Orders are generated each time a customer places an order for an item and are sent to the vendor for processing.

Replenishment Operations needs to be immediately made aware of:

- Shipping issues. IE: Shortages, late shipments, delays
- Manufacture Backorders and ETAs
- Discontinued Items
- Item changes. IE: UOM, packaging, or label changes
- Pricing changes. Minimum 30-day notice
- Upcoming customer and distributor promotions

8.0 Palletization and Trailer Loading

8.1 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 ¾ 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)).

8.2 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 72' or 6'–0'' (including pallet height) for mixed product pallets or 4' 8'' or 56'' on same/full product pallets.

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'

OBJ



Damaged pallet construction



Pallet not properly packed

8.3 Pallet Configuration

All pallets should be Purchase Order (PO) specific, and the PO number must be clearly identified on all four (4) 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	1234-565010	5
5552334466	1234-565010	3
5552334477	1234-565010	7
5552334477	1234-544015	12
5552334477	1234-765020	6

Example of identifying multiple POs on a Pallet

8.4 Trailer Loading

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”
8.5 Controlled Products

Damaged “Double Stack” warning

All controlled products must be separate pallets from ambient and refrigerated products.

8.6 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.

9.0 Shipment Documentation

9.1 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.

9.2 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.

10.0 Logistics Packaging

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 where one side of a case is damaged in transportation.

10.1 Mixed/Repack/Partial Case Labeling.

MWI Animal Health requires that each mixed, partial (less than a full case quantity), or repack is labeled accordingly.

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:



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

accordance to the applicable standards (GS1 UPC-A, GS1-128, GS1DataMatrix, 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 (see example), is not acceptable, as many PoS scanners cannot read those barcode formats.



Each unique, lowest saleable unit must have a unique barcode. This includes variations on color, size, and package quantities. Inner-packs, and Master Cases of products must have their own unique barcode and cannot be the same as the lowest saleable unit. Promotional items must also contain their own unique barcode.

- You may be required to submit labels and/or marked products for test scanning. This is to ensure that both your company and MWI use barcodes of acceptable quality.
- Test your GS1 and/or UPC codes before shipping products. Barcodes that do not scan will be subject to return at the Vendor's cost and a Vendor charge back to compensate labor costs to correct the problem.

11.1.2 Case Labeling

MWI Animal Health requires that all cases be labeled with a product identifier in a human readable and a standard barcode format.

Human Health Prescription Drug homogenous case subjected to additional requirements in accordance with the Healthcare Distribution Alliance “Guidelines for Bar Coding in the Pharmaceutical Supply Chain.” See the following section for references and examples.

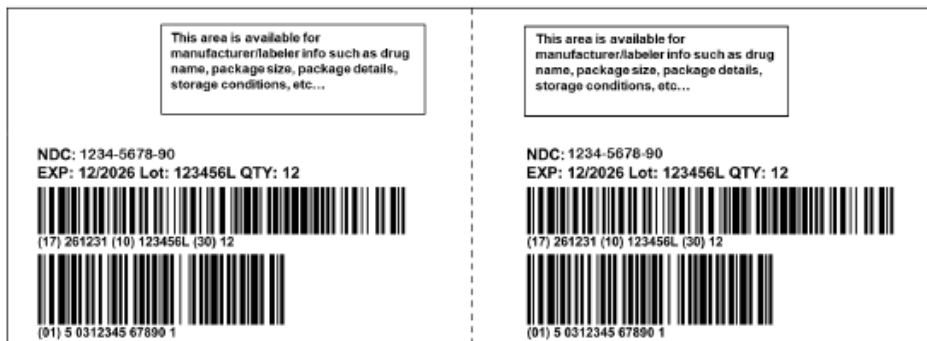
Example 1:

Depicts what a homogenous case label should look like for serialized prescription drugs:



Example 2:

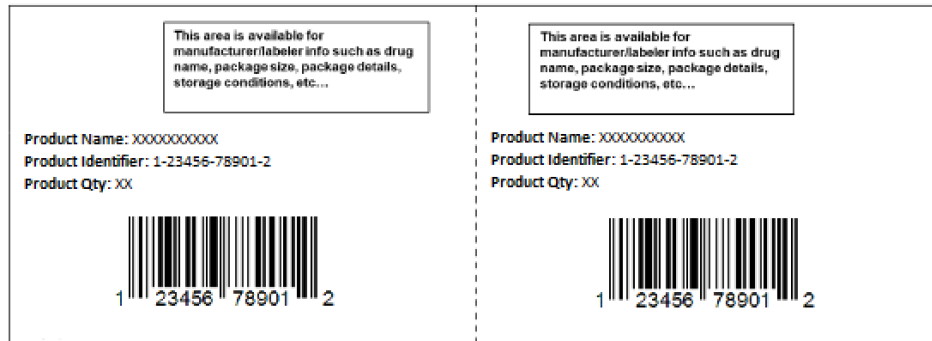
Depicts what a homogenous case label should look like for Non serialized drugs and medical devices:



11.1.3 Other products

Products such as consumer goods 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.).

Example 3:



11.2 Barcoding Density

In order to ensure effective and reliable scanning, use bar codes with the lowest possible density. Wider bars and spaces are easier to interpret and less likely to have voids and specks of dirt which can hinder a barcode's ability to scan.

11.3 Contrast

Because the GS1 and UPC symbols must be read by optical scanning equipment, it is especially important that it is printed properly. MWI requires that all barcodes be printed using black ink. Barcodes printed in other colors, especially red and purple, cannot be scanned by MWI's laser scanners.

12.0 Delivery Appointments

Delivery appointments are recommended for all deliveries to MWI Distribution and required for (K99) Redistribution Center, except for small parcel shipments. All purchase orders within a shipment must be noted at the time of appointment request.

- Prepaid Vendors – You or your prepaid carrier are required to request delivery appointments. It is your responsibility to maintain all your appointments.
- Collect Vendors – MWI partner carriers are required to request delivery appointments.

PO Dates - Purchase Orders are created with a *ship by date* for collect freight shipments, and a *delivery requested by date* for prepaid freight shipments

Appointment Timeline - Delivery appointments should be made as early as possible, and no later than two days prior to the PO delivery date.

Rescheduling Appointments - 24-hour advanced notice is required for re-scheduling appointments. Missed deliveries must also be rescheduled.

Unloading - All trailers will be unloaded within 2 hours, regardless of freight terms. If the carrier arrives early, MWI obligation to unload will start at the scheduled appointment time, not at the time of arrival.

Late Arrivals - Any carrier that arrives more than 30 minutes late for a scheduled appointment is deemed late for the appointment. MWI reserves the right to refuse, or simply not unload. If MWI decides to unload a late arrival, the unload window will start at the time the trailer is backed into the dock, not the start of the original delivery appointment.

13.0 Manufacturer Expectations

13.1 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 be 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.

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

13.2 Short Dating and Allocations

Manufacturers must notify their assigned Replenishment Operations contact about any short-dated products. Manufacturers may not send short-dated product without first receiving approval.

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

13.3 Cancel Dates

MWI reserves the right to refuse cancelled shipments. Any orders received after confirmed cancellation will be subject to be returned to vendor at vendor's expense.

13.4 Mis-ships

Variances to the PO in product model, number, SKU number, unit of measure, or quantity are considered mis-ships, and may be returned at the Vendor's expense.

Likewise, products and quantities should be shipped to the location noted on the PO. Product shipped to an incorrect location will be returned or forwarded at the Vendor's expense.

13.5 Back orders

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

Manufacturers must notify their assigned Replenishment Operations contact of any products that will be backordered. 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.

If a backorder must occur, the preference is to have the backorder combined with the next MWI order to the same location.

13.6 Manufacturer Interaction

A strong partnership with MWI'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. MWI 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.

Animal Health	Raw Goal – 98%	Adjusted Goal – 99.8%
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Specific metrics are subject to manufacturer agreements and may vary. Please contact the MWI Strategic Global Sourcing and/or Replenishment Operations contact for clarification.

13.7 Holiday and Year End Deliveries

The holiday season presents a challenge with respect to closures, bad weather and erratic buying patterns. MWI 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 the product is in place before potential outages occur. Manufacturers are also expected to contact their Replenishment Operations contact and the Distribution Center if unexpected delays are experienced, to maintain effective communication on product delivery lead times.

13.8 System and Data Integrity

Accurate data is a key aspect of ensuring accurate and timely purchases and deliveries of products. MWI 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 MWI Replenishment Operations contact.

Changes to product case quantity and dimension changes must go to MWI master data team:

purchasingdataintegrityspecialists@mwianimalhealth.com

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

13.9 Best In Class

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

MWI 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.
- Provide EDI 810 Invoice for all purchase orders
- Offer reasonable units and order minimums.
- Proactively provide shipping schedules for holidays/closures.
- Ship within 72 hours of receiving purchase order.
- Accept controlled substances purchase orders via Controlled Substance Ordering System (CSOS).

III. POST DELIVERY PROCESSES

1.0 Receiving Discrepancies

Product damage, shortage, incorrect shipment issues and other non-conformance issues related to shipping, and that are apparent must be reported to Supplier within 5 business days of delivery or credit will not be allowed. MWI should notify Supplier of such apparent issues within 5 business days or in the case of concealed damage or latent defect, within (30) days of discovery with the following information:

- Shipment issue
- Supplier invoice number
- MWI purchase order number
- All relevant product information associated with the issue including manufacturer's item number(s), lot number(s) and quantities
- Photos of damages if any in MWI's possession

If further information/documentation needed by Supplier to process a carrier claim or perform an investigation for resolution and such documentation is in the actual possession of MWI it must be provided by MWI within ten (10) days of receipt of request by Supplier.

If MWI discovers damage or an incorrect shipment issue upon delivery, freight will be rejected. MWI will use commercially reasonable efforts to ensure that any exception to delivery is notated on:

- The carrier's Bill of Lading and that the same is signed by MWI.

2.0 Merchandise Returns

If MWI wishes to return Products for any reason, MWI will notify Supplier of its intent to return Product, in order to obtain a Return Material Authorization ("RMA") from Supplier. MWI will provide written notice identifying the original purchase order number, lot numbers, quantities, and Product code numbers along with a specific reason for return.

- Supplier will pay for all return shipping costs and will waive any restocking fees related to the return of Non-conforming Products. "Non-conforming Products" mean any Product that (i) is delivered to MWI in a defective or damaged condition; (ii) does not conform to the Limited Warranties or any specific requirement of the Agreement; (iii) has been recalled by Supplier or any governing agency; (iv) was shipped to MWI in error, including incorrect quantities, incorrect location, and pricing errors; (v) is Short Dated Product that was not preapproved by MWI.

- When Supplier issues an RMA based upon MWI's receipt of damaged Product or Product shipped in error, a prepaid carrier "call tag" will be issued to MWI to return the RMA authorized Product to a Supplier facility. A replacement order will be shipped, if requested.

2.1 Product Recalls

2.1.1 Notifications

In the event of a product recall or withdrawal, notifications must be sent to Insert Email 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

2.1.2 Timing

Recall and/or product withdrawal notifications will be distributed to the MWI 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.

2.1.3 Recall Returns

It is always desirable for MWI 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 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.

1.0 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

IV. CONTINUING BUSINESS PROCESSES AND EXPECTATIONS

1.0 Vendor Compliance Violations and Fines

The Vendor Partnership Guide is an integral part of our Vendor Program Agreement. Failure to comply with the guidelines outlined in these pages will result in fines to Suppliers. Failure to follow our instructions outlined herein shall be considered as your agreement to pay any additional transportation, administrative, handling, or other costs incurred. Fines will be deducted from merchandise invoices.

The below table is the schedule of fines and associated code number. For convenience, this table has been separated by applicable Vendor Partnership Guide areas. Some codes may be used for multiple areas and application is determined solely by MWI.

The schedule is as follows:

CODE	COMPLIANCE VIOLATION	FEE
	100 - Palletization and Trailer Loading	
101	Mis-ship: SKU not on PO	\$250 per PO
102	Cartons on pallets not secured with shrink wrap or metal bands used	\$250 per P.O.
103	Load toppled	\$250 per P.O.
104	Shipped on Non-Standard, Non-GMA pallet	\$50 per pallet
105	Damaged pallets	\$50 per pallet
106	Same SKU pallet exceeds height requirement	\$50 per pallet
107	Same SKU within a PO on more than 1 mixed SKU pallet	\$250 per P.O.
	200 - Case/Pallet Labels and Configurations	
201	Mixed SKU pallet – carton label missing MWI PO, SKU, or Both	\$600 per PO
	500 - Shipment Documentation	
501	Missing BOL/Pro/ Packing List or missing/ references Incorrect PO on document	\$600 per P.O.

2.0 Vendor Compliance and Fine Dispute Process

All disputes must be communicated by Vendor to MWI within sixty (60) days from notification by MWI of the violation. A valid dispute must contain backup documentation to support the dispute. Dispute communications received after sixty (60) days from the notification will be denied as Vendor will be deemed to have agreed with the notification from MWI. When disputing a charge, the following steps should be taken:

- Notification will be sent via email from MWI to Vendor.
- To dispute, email MWIVendorDisputes@mwiah.com with “Dispute” and Vendor name in Subject line of email.
 - Attach any supporting documentation with an explanation as to why the violation is under dispute.
- A response to the dispute will be communicated by MWI within seven (7) business days of the original dispute.
 - MWI will request additional information if needed.
 - Denied requests will include specifics for reason of denial.
 - Dispute reversals will be sent to Accounts Payable for processing.

V. APPENDIX

Document References

1. Regulatory Information

- ✦ FDA UDI Webpage”

<https://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/>

- ✦ FDA DSCSA Webpage:

<https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

2. Electronic Data Exchange (EDI) Implementation Guides

- ✦ AmerisourceBergen EDI Specifications can be found in the Data Exchange section of the Manufacturer and Replenishment Operations webpage:

<https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment#anchor5>

- ✦ AmerisourceBergen Serialized Data Exchange Specifications can be found in the Data Exchange section of the Manufacturer and Replenishment Operations webpage:

<https://www.amerisourcebergen.com/manufacturer-solutions/manufacturer-operations-and-replenishment#anchor5>

- ✦ AmerisourceBergen EDI Location Identifier List:

<http://publish.smartsheet.com/9a40c601a94c4600a6b64b1536a297c3>

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>

PUERTO RICO REGISTRATION FOR HUMAN PHARMACEUTICAL ONLY

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 the 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):



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.