



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Product Post Launch Change

Final Version

Date:

PRODUCT INFORMATION

Company Name: Application:

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):

DUNS:

Proprietary Name (if Applicable) and Established Name:

Selling Unit NDC: Individual Unit NDC: UPC:

UDI: CVX Code: MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:
 City: State: Zip:
 Key Contact: Email:
 Phone Number: Fax:

Product Therapeutic Classification:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):

Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:
 Name:
 Number:
 Group E-mail:

c. Special regulations for product in any states?
 Special returns requirements for this product?

d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?

e. Shelf life:
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device?
 reverse numbered?
 co-licensed?
 Is the Product...
 Direct-Ship Only
 Is the Product...
 Unit of Use

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose NDC, indicate NDC here:

Country of Origin

Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size:

Strength:

Dosage Form:

Product Shape:

Product Color:

Product Imprint:

ORDER INFORMATION

Unit of Sale
 Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Powder Multi
 Other: Write In

What is the NDC selling unit?

 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?
 Each
 Inner/Carton/Pack
 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? GLN:

Is product exempt from DSCSA?

If yes, select exemption:
 Other exemption - Write in:

Is product repackaged? If Yes, was original product purchased direct from mfr?

Is product sold by manufacturer's exclusive distributor? If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.15		3.625	1.5		
Box/Carton/Bundle/Inner Pack:	1.75	6.75	3.875	5	0.076	12
Case:	17.5	14.5	8.875	11.5	0.856	96
Pallet:						4800
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	Level	Item	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack		<input checked="" type="checkbox"/>	1	00331722721509
<input checked="" type="checkbox"/>	Case		<input checked="" type="checkbox"/>	12	10331722721506
<input checked="" type="checkbox"/>	Pallet		<input checked="" type="checkbox"/>	96	30331722721500

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 Federal Excise Tax Per Unit of Sale
 As of date:

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Finesse Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.
 *Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> No Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Yes Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> No Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> No Site Address: <input type="text"/> Minimum Order Quantity: <input type="text" value="case pack"/> Supplier's Customer Service Number: <input type="text" value="732-529-0430 x466 x465 x467 x470"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text" value="2:30PM"/> Eastern Shipping lead time of PO: <input type="text" value="24/48"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> No Drop Ship service fee billed with each order: <input type="checkbox"/> No Drop Ship miscellaneous fees billed: <input type="checkbox"/> No Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> Yes PO Receipt cut off time: <input type="text" value="2:30PM"/> Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text" value="2:30PM EST"/> Saturday Overnight receipt available: <input type="checkbox"/> No PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="checkbox"/> No Phone #: <input type="text"/> Fax: <input type="checkbox"/> Yes Fax #: <input type="text" value="732-562-8788"/> EDI: <input type="checkbox"/> Yes Overnight Fees apply: <input type="checkbox"/> Yes Other fees apply: <input type="checkbox"/> No
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No Restricted to retail pharmacy only: <input type="checkbox"/> Yes Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text" value="732-529-0430"/> Is product returnable for credit: <input type="checkbox"/> Yes URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> No Is product order for restocking purposes? <input type="checkbox"/> No