



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

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: Address 2:

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: Months 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 Power Multi, Other: Write In

What is the NDC selling unit? (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?

1	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? Rx billing unit to pharmacy: Each, Gram, Milliliter

(Write-in, e.g. 1 Vial)

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		
Box/Carton/Bundle/Inner Pack:	2.4		2.344	1.5		1
Case:	10.3	16.7	11.4	7.87		108
Pallet:						
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION

Serialized?	Yes	Item	Level		Quantity	GTIN-14
			Unit	Saleable		
If not, when?	<input type="text"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1	00331722639019
Items aggregated?	Yes	Case	<input checked="" type="checkbox"/>	<input type="checkbox"/>	108	30331722639010
		Pallet	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		

COST INFORMATION

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

WHOLESALE USE ONLY:

Vendor #: Whsl. Code #: FineLine Code:

For Designated Drop Ship Only Products, Please Use Page 3
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 Is the product a CA Prop 65 carcinogen? No
 Is the product a CA Prop 65 reproductive toxicant?
 Does the product label bear a CA Prop 65 warning?

c. Contact Hazard? No

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions.) No

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA?
 (if yes, answer a-e below and provide SDS) No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:
 Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity? No
 RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 No (if yes, identify method below)

Limited Quantity
 Consumer Commodity, ORM-D
 Small Quantity (49 CFR 173.4)
 Special Permit; DOT-SP
 Special Provision (listed in Column 7 of 49 CFR 172.101);
 SP#

SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
REMS: <input type="text"/>	
REMS Program Manager Name: <input type="text"/>	Phone: <input type="text"/>
Supplier Manages REMS registry exclusively: No	
Wholesale distributor support: No	
Provider Name: <input type="text"/>	
Site Enrollment Number assigned by Supplier: <input type="text"/>	DEA #: No
	PCPDP #: No
	NPI #: No

ADD'L STORAGE INFORMATION	
Is the Product... Controlled Substance? Yes	
Controlled by State(s)? No	
ARCOS Reportable? No	
Schedule No. (inc. N for non-narcotic) <input type="text" value="CIV"/>	
Controlled Substance Code <input type="text" value="2751"/>	
Listed Chemical (List I or II) No	
If yes, indicate which: <input type="text"/>	
Is it a scheduled listed chemical product?: No	

Comments

Registry: No
 Registry Program Contact Name: Phone:

Comments

CLASS OF TRADE RESTRICTION:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	
Restricted to retail pharmacy only: Yes	
Restricted to hospital, clinics, and physician offices only: No	
Restricted from US territories? (explain in comments) No	
Comments: <input type="text"/>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text" value="732-529-0430"/>	
Is product returnable for credit: Yes	
URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/>	
Special regulations or returns requirements for this product in certain states? No	
If so, which states? Other requirements? Comments? <input type="text"/>	

MISCELLANEOUS NOTES and/or Image of Product Barcode:	
<input type="text"/>	

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																								
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 10%;"></td> <td style="width: 50%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><u>No</u></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax Number:</td> <td>732-562-8788</td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><u>No</u></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><u>No</u></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <u>case pack</u></p> <p>Supplier's Customer Service Number: <u>732-529-0430 x466 x465 x467 x470</u></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table>	a. EDI	<u>Yes</u>			b. Autofax	<u>No</u>	Fax Number:	<input type="text"/>	c. Fax	<u>Yes</u>	Fax Number:	732-562-8788	d. Phone only	<u>No</u>	Phone No.:	<input type="text"/>	e. Supplier Web Site only	<u>No</u>	Site Address:	<input type="text"/>	Name:	<input type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text" value="2:30PM"/> Eastern</p> <p>Shipping lead time of PO: <input type="text" value="24/48"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <u>No</u></p> <p>Ships for second day receipt: <u>No</u></p> <p>Ships regular ground for 3-10 days receipt: <u>Yes</u></p>
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Name:	<input type="text"/>																								
Phone:	<input type="text"/>																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																								
<p>Expedited freight fees billed with each order: <u>No</u></p> <p>Drop Ship service fee billed with each order: <u>No</u></p> <p>Drop Ship miscellaneous fees billed: <u>No</u></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <u>Yes</u></p> <p>PO Receipt cut off time: <input type="text" value="2:30PM"/> Eastern</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <u>Yes</u></p> <p>PO Receipt Cut off time: <input type="text" value="2:30PM EST"/></p> <p>Saturday Overnight receipt available: <u>No</u></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Phone:</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 60%;">Phone #:</td> <td><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax #:</td> <td>732-562-8788</td> </tr> <tr> <td>EDI:</td> <td style="text-align: center;"><u>Yes</u></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <u>Yes</u></p> <p>Other fees apply: <u>No</u></p>	<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	Phone:	<u>Yes</u>	Phone #:	<input type="text"/>	Fax:	<u>Yes</u>	Fax #:	732-562-8788	EDI:	<u>Yes</u>				
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																								
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone # <input type="text"/></p> <p>Physician State License # <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <u>No</u></p> <p>Is product order for restocking purposes? <u>No</u></p>																								
Miscellaneous Notes:																									
<div style="border: 1px solid black; height: 80px; width: 100%;"></div>																									