



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  Pre-Approval Change  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  
 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?

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		
Box/Carton/Bundle/Inner Pack:	0.05		2.5	1.5		
Case:	1.1	6.75	3.375	4.875	0.064	12
Pallet:	5.15	10.5	6.75	7.375	0.302	48
UPC:	Case:					
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized? If not, when? Items aggregated?	Level	Item	Saleable Unit	Quantity		GTIN-14
				2D	Linear	
	Box/Carton/Bundle/Inner Pack					
	Case					
	Pallet					

**COST INFORMATION**

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

**WHOLESALE USE ONLY:**  
 Vendor #:   
 Whsl. Code #:   
 Fine Line 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? No  
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

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

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# \_\_\_\_\_

### ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) \_\_\_\_\_

Controlled Substance Code \_\_\_\_\_

Listed Chemical (List I or II) No

If yes, indicate which: \_\_\_\_\_

Is it a scheduled listed chemical product? No

### 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: \_\_\_\_\_

### 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: <span style="float: right;">_____</span>	
Is the product a NIOSH hazardous drug? <span style="float: right;">_____</span>	
If yes, indicate which: <span style="float: right;">_____</span>	

### Hazardous Waste Identification

EPA Hazardous Waste Code: NA

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? Yes

If Yes, is it managed with a pharmacy registry? No

Website URL: N/A

Comments / Details: (For example, iPledge program?)  
None

**REMS:** Yes

REMS Program Manager Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name: \_\_\_\_\_

Site Enrollment Number assigned by Supplier: \_\_\_\_\_

DEA #: No

PCPDP #: No

NPI #: No

Comments None

**Registry:** No

Registry Program Contact Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Comments \_\_\_\_\_

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 732-529-0430

Is product returnable for credit: Yes

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments? \_\_\_\_\_

\_\_\_\_\_

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

\_\_\_\_\_

**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: 60%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 30%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><u>No</u></td> <td>Fax Number: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax Number: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><u>No</u></td> <td>Phone No.: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><u>No</u></td> <td>Site Address: <input style="width: 100%;" 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: 30%;">Name:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 100%;" type="text"/></td> </tr> </table>	a. EDI	<u>Yes</u>		b. Autofax	<u>No</u>	Fax Number: <input style="width: 100%;" type="text"/>	c. Fax	<u>Yes</u>	Fax Number: <input style="width: 100%;" type="text"/>	d. Phone only	<u>No</u>	Phone No.: <input style="width: 100%;" type="text"/>	e. Supplier Web Site only	<u>No</u>	Site Address: <input style="width: 100%;" type="text"/>	Name:	<input style="width: 100%;" type="text"/>	Phone:	<input style="width: 100%;" type="text"/>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <u>2:30PM</u> Eastern</p> <p>Shipping lead time of PO: <u>24/48</u> Hours <input style="width: 50px;" 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 style="width: 100%;" type="text"/>																			
Phone:	<input style="width: 100%;" 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: 50px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <u>Yes</u></p> <p>PO Receipt cut off time: <u>2:30PM</u> 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><b>Priority Overnight receipt available:</b> <u>Yes</u></p> <p>PO Receipt Cut off time: <u>2:30PM EST</u></p> <p><b>Saturday Overnight receipt available:</b> <u>No</u></p> <p>PO Receipt Cut off time: <input style="width: 100%;" 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>No</u></td> <td style="width: 60%;">Phone #:</td> </tr> <tr> <td>Fax:</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax #:</td> </tr> <tr> <td>EDI:</td> <td style="text-align: center;"><u>Yes</u></td> <td><u>732-562-8788</u></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>No</u>	Phone #:	Fax:	<u>Yes</u>	Fax #:	EDI:	<u>Yes</u>	<u>732-562-8788</u>
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																			
<p>Patient Procedure Date: <input style="width: 100%;" type="text"/></p> <p>Physician Name: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 100%;" type="text"/></p> <p>Physician State License #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 100%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 100%;" 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:																				
<input style="width: 100%; height: 100px;" type="text"/>																				