



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

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?

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?

Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.15		3.75	1.875		
Case:	1.65	8	3.875	5.875	0.105	12
Pallet:	8.1	12.5	9	8.5	0.553	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 #:

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# _____

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

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level: _____

Is the product a NIOSH hazardous drug? _____
 If yes, indicate which: _____

Hazardous Waste Identification

EPA Hazardous Waste Code: NA

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No
 If Yes, is it managed with a pharmacy registry? _____
 Website URL: _____

Comments / Details: (For example, iPledge program?)

REMS: _____

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 _____

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: 50%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 40%;"></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: 50%;">Name: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Phone: <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>Purchase order daily receipt cut off time by supplier</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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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>Overnight receipt available: <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 style="width: 20px; text-align: center;"><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td style="text-align: center;"><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td style="text-align: center;"><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: <u>2:30PM EST</u></p> <p>Saturday Overnight receipt available: <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: 50%;">Phone: <u>No</u></td> <td style="width: 50%;">Phone #: <input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Fax: <u>Yes</u></td> <td>Fax #: <u>732-562-8788</u></td> </tr> <tr> <td>EDI: <u>Yes</u></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>No</u>	Phone #: <input style="width: 100%;" type="text"/>	Fax: <u>Yes</u>	Fax #: <u>732-562-8788</u>	EDI: <u>Yes</u>		
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Class of Trade Restriction:	Return Instructions																	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <u>No</u></p> <p>Restricted to retail pharmacy only: <u>Yes</u></p> <p>Restricted to hospital, clinics, and physician offices only: <u>No</u></p> <p>Restricted from US territories? (explain in comments) <u>No</u></p> <p>Comments: <input style="width: 100%; height: 50px;" type="text"/></p>	<p>Contact # if product is received damaged: <u>732-529-0430</u></p> <p>Is product returnable for credit: <u>Yes</u></p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <u>Yes</u></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 50px;" type="text"/></p>																	
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"/>																		