



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

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: Address 2:
 Phone Number: Email:
 Product Therapeutic Classification: Fax:

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 a legend device?
 reverse numbered?
 co-licensed?
 Is the Product...
 Is the Product...
 Is the Product...

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:

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?:

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?

GTIN PRODUCT INFORMATION

	Serialized?	If not, when?	Items aggregated?	Level		Saleable Unit		Quantity	GTIN-14
				Item	Box/Case/Pallet	Unit	Unit		
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	2D	<input type="text"/>	<input checked="" type="checkbox"/>	2D	00331722926010
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	2D	<input type="text"/>	<input type="checkbox"/>	2D	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="checkbox"/>	2D	<input type="text"/>	<input checked="" type="checkbox"/>	2D	10331722926017
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	2D	<input type="text"/>	<input type="checkbox"/>	2D	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	2D	<input type="text"/>	<input type="checkbox"/>	2D	
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	2D	<input type="text"/>	<input type="checkbox"/>	2D	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	2D	<input type="text"/>	<input type="checkbox"/>	2D	

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

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

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.077	10.8	3.2	7	0.14	24
Case:						
Pallet:						220
UPC:						
Case:						
Carton:						

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? 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? Yes

Controlled by State(s)? Yes

ARCOS Reportable? Yes

Schedule No. (inc. N for non-narcotic) _____

Controlled Substance Code CII-Methylphenidate 1724

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: _____

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: No

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> <hr/> <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>
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"/>																		
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: Phone: <u>No</u> Phone #: <input style="width: 100%;" type="text"/></p> <p>Fax: <u>Yes</u> Fax #: <u>732-562-8788</u></p> <p>EDI: <u>Yes</u></p> <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							
<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																	
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"/>																		