

© August 2014 Introduction Type: New Item Final Version Date: 4/19/2017

PRODUCT INFORMATION
Company Name: Camber Pharmaceuticals
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 207419
Application: ANDA
DUNS: 82-667-4775
Proprietary Name (if Applicable) and Established Name: Oxycodone and Acetaminophen Tablets 2.5MG/325MG 100CT
Selling Unit NDC: 31722-948-01 Individual Unit NDC: 31722-948-01 UPC: 331722948012
Description: White to Off white capsule shaped tablet debossed with 'T 191' on one side and plain on other
Active Ingredient(s): Oxycodone and Acetaminophen
URL for Additional Product Information: www.camberpharma.com
Address: 1031 Centennial Avenue, Piscataway
Key Contact: Customer Service
Phone Number: 732-529-0430
Product Therapeutic Classification:

SPECIAL HANDLING AND STORAGE REQUIREMENTS
a. Temperature - Indicate the USP temperature range for this product.
Temperature Range: Controlled Room - between 20 and 25 C (68° - 77° F)
Other Temperature Range Requirement (write in):
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No
b. Contact for temperature excursion questions:
Name: Soma Raju
Number: 732-529-0423
Group E-mail: somaraju@heterousa.com
c. Special regulations for product in any states?
Special returns requirements for this product? No
d. Store product (unit of sale) upright? No
Protect product (unit of sale) from light? No
e. Shelf life: 24 Months
Initial shelf life at launch (if different):

ADDITIONAL PRODUCT INFORMATION
Is the Product... a legend device? No
reverse numbered? No
co-licensed? No
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: United States
Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION
Size: 100
Strength: 2.5MG/325MG
Dosage Form: tablet
Product Shape: capsule
Product Color: White to off-White
Product Imprint: T 191

ORDER INFORMATION
Unit of Sale: Bottle, Box/Carton (checked), Ampule, Glass, Tube, Vial Liquid Sgl, Vial Liquid Multi, Vial Powder Sgl, Vial Powder Multi, Other: Write In
What is the NDC selling unit? 1 box of 24 bottles (Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type? 24 Inner/ Carton/ Pack Case

FOR GENERIC DRUG PRODUCTS
I. Orange Book Rating: AB
II. Generic Equivalent to What Brand?: Percocet
 Authorized Generic *If Authorized Generic, other section fields are not applicable

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? Yes
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No
If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor? No
Has FDA granted waiver/exception/exemption for product? No
If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION
Table with columns: Item, Weight Lbs., Dimensions (US msmts.) [Depth, Height, Width], Volume (Cube), # Pieces.
Row 1: Item: Box/ Carton/ Bundle/ Inner Pack, Weight: 3.11, Depth: 12.3, Height: 3.8, Width: 8.3, Volume: 0.225, Pieces: 24

GTIN PRODUCT INFORMATION
Serialized? Yes
If not, when?
Items aggregated? No
Table with columns: Level (Item, Case, Pallet), Saleable Unit, Quantity, GTIN-14.
Row 1: Level: Item, Saleable Unit: 1, Quantity: 1, GTIN-14: 00331722948012
Row 2: Level: Box/ Carton/ Bundle/ Inner Pack, Saleable Unit: 24, Quantity: 24, GTIN-14: 10331722948019

COST INFORMATION
Regular Cost
Invoice Cost (WAC) (\$) \$162.98
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) n/a

Controlled Substance Code CII-Oxycodone 9143

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: _____	
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: _____

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: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 10%;"></td> <td style="width: 60%;"></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><u>732-562-8788</u></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:	<u>732-562-8788</u>	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: <input type="text" value="No"/></p> <p>Ships for second day receipt: <input type="text" value="No"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text" value="Yes"/></p>
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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"/>																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																								
<p>Expedited freight fees billed with each order: <input type="text" value="No"/></p> <p>Drop Ship service fee billed with each order: <input type="text" value="No"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text" value="No"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input type="text" value="Yes"/></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: <input type="text" value="Yes"/></p> <p>PO Receipt Cut off time: <input type="text" value="2:30PM EST"/></p> <p>Saturday Overnight receipt available: <input type="text" value="No"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text" value="Yes"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text" value="Yes"/> Fax #: <input type="text" value="732-562-8788"/></p> <p>EDI: <input type="text" value="Yes"/></p> <p>Overnight Fees apply: <input type="text" value="Yes"/></p> <p>Other fees apply: <input type="text" value="No"/></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														
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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 <input type="text" value="Yes"/></p> <p>Restricted to retail pharmacy only: <input type="text" value="Yes"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text" value="No"/></p> <p>Restricted from US territories? (explain in comments) <input type="text" value="No"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text" value="732-529-0430"/></p> <p>Is product returnable for credit: <input type="text" value="Yes"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text" value="Yes"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p>																								
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? <input type="text" value="No"/></p> <p>Is product order for restocking purposes? <input type="text" value="No"/></p>																								
Miscellaneous Notes:																									
<input style="width: 100%; height: 80px;" type="text"/>																									