HDA

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:	New Item		Final Version	Date:	2/13/2020

PRODUCT INFORMATION

Company Name:	Camber Pharmaceuticals	**Application:**	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	207421
DUNS:	82-667-4775
Proprietary Name (If Applicable) and Established Name:	Dronabinol Capsules USP 10MG 60CT
Selling Unit NDC:	31722-962-60	Individual Unit NDC:		UPC:	331722962605
UDI:		CVX Code:		MVX Code:	
Description:	Pink round capsules containing clear to light yellow liquid, printed with 'A' in black ink.
Active Ingredient(s):	Dronabinol
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Avenue	Address 2:	
City:	Piscataway	State: NJ	Zip: 08854
Key Contact:	Customer Service	Email:	customerservice@camberpharma.com
Phone Number:	732-529-0430	Fax:	732-562-8788
Product Therapeutic Classification:	

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 Dose
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION

Size:	60
Strength:	10MG
Dosage Form:	Soft gelatin capsule
Product Shape:	Round
Product Color:	Pink
Product Imprint:	A

FOR GENERIC DRUG PRODUCTS

Authorized Generic	*If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Marinol

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	
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.

GTIN PRODUCT INFORMATION

		Level	Saleable Unit				Quantity	GTIN-14
Serialized?	Yes	x	Item		x	2D	Linear	1	00331722962605
If not, when?			Box/Carton/Bundle/Inner Pack			2D	Linear		
Items aggregated?	No	x	Case	x	x	2D	Linear	24	10331722962602
			Pallet			2D	Linear		
						2D	Linear		
						2D	Linear		
						2D	Linear		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range	Cold – between 2 and 8 C (36° – 46° 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?	No
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):	Months

ORDER INFORMATION

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

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.05		2.46	1.5		
Box/Carton/Bundle/Inner Pack:						
Case:	2.1	9	8	4	0.166	24
Pallet:						
UPC:	Case:					
	Carton:					

COST INFORMATION | WHOLESALER USE ONLY:

Regular Cost		Vendor #:	
Invoice Cost (WAC) ($)	$300.46	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

Please provide any additional information on page 2. | See new p. 3 for Designated Drop Ship Only. | Signature: |

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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#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ 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

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 — CIII - 7369
- Listed Chemical (List I or II) — No
  - If yes, indicate which:
- Is it a scheduled listed chemical product?: — No

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?

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax	No	Fax Number:	
c. Fax	Yes	Fax Number:	732-562-8788
d. Phone only	No	Phone No.:	
e. Supplier Web Site only	No	Site Address:	

Minimum Order Quantity: case pack

Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470

Contracted 3PL company / contact #:   Name:
     Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time: 2:30PM   Eastern

Shipping lead time of PO: 24/48   Hours   Days

Ships same day for next day receipt: No

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: Yes

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order: No

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: 2:30PM   Eastern

Days of week overnight is available:

x	Monday
x	Tuesday
x	Wednesday
x	Thursday
x	Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 2:30PM EST

Saturday Overnight receipt available: No

PO Receipt Cut off time:

Order receipt method:	Phone:	Yes	Phone #:	
	Fax:	Yes	Fax #:	732-562-8788
	EDI:	Yes		

Overnight Fees apply: Yes

Other fees apply: 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:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:	732-529-0430
Is product returnable for credit:	Yes
URL/Link to returns policy:	
Special regulations or returns requirements for this product in certain states?	Yes

If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?	No
Is product order for restocking purposes?	No