Standard Pharmaceutical Product Information (Rx Product Only)

HDA

© August 2014

Introduction Type:	Post Launch Change		Final Version		Date:	4/11/2017

PRODUCT INFORMATION

Company Name:	Camber Pharmaceuticals
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205064
DUNS:	82-667-4775
Proprietary Name (If Applicable) and Established Name:	Aripiprazole Tablets 30MG 30CT
Selling Unit NDC:	31722-830-30
Individual Unit NDC:	31722-830-30
UPC:	331722830300
UDI:	NA
CVX Code:	
MVX Code:	NA
Description:	Light pink to pink round tablets imprinted with '99' on upper and 'I' on lower
Active Ingredient(s):	Aripiprazole
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 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	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	30
Strength:	30 mg
Dosage Form:	Oral Solid tablet
Product Shape:	Round
Product Color:	Light pink to pink
Product Imprint:	'99'/'I'

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?:	Abilify	

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		2D		Linear	Quantity	GTIN-14
Serialized?	Yes	x	Item		x	2D		Linear	1	00331722830300
If not, when?			Box/Carton/Bundle/Inner Pack			2D		Linear		
Items aggregated?	Yes	x	Case		x	2D		Linear	48	20331722830304
			Pallet			2D		Linear		

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? 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 48 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	48 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.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.01		3.25	1.5		
Box/Carton/Bundle/Inner Pack:						
Case:	5	13	4.25	10		48
Pallet:						96
UPC:	Case:					
	Carton:					

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$51.25
Federal Excise Tax Per Unit of Sale	
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

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:

HDA

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

- ☐ 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: N/A

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		DEA #:	No
by Supplier:		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

Purchase orders may be accepted by:

- a. EDI
- b. Autofax — Fax Number:
- c. Fax — Fax Number:
- d. Phone only — Phone No.:
- e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

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

Purchase order daily receipt cut off time by supplier

Cut off time: _____ Eastern

Shipping lead time of PO: _____ Hours _____ Days

Ships same day for next day receipt:

Ships for second day receipt:

Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight receipt available:

PO Receipt cut off time: _____ Eastern

Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Class of Trade Restriction:	

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method:
- Phone: _____ Phone #:
- Fax: _____ Fax #:
- EDI:

Overnight Fees apply:

Other fees apply:

Other Data Information Required to Process PO:	Return Instructions

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Contact # if product is received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

Miscellaneous Notes:	

	ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?