

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014 Introduction Type: New Item								Final Version Date:								
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name:	Camber Pharmaceuticals Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for ND	DA/ANDA/BLA (drug); PMA/510(k)(med device):			202682	02682								Controlled Room – between 20 and 25 C (68° – 77° I			
DUNS:	826774775								Other Temperature Range Requirement			-				
	able) and Established Name: Atomoxetine Hydrochloride Capsules, 10mg 30ct									ite in)					1	
Selling Unit NDC:	31722-714-30 Individual Unit NDC:				UPC: 331722714303				1	,					•	
UDI CVX Code:				MVX Code:			Is this product to be shipped to customers on ice? No				•					
Description: Capsule; Cap: White opaque; Body: White opaque; I' on cap and '105' on body									Is this product to be shipped to customers on dry ice?							
Active Ingredient(s):  Atomoxetine								b. Contact for temperature excursion questions:								
UBL Co. A Life and Double Life and Co.								Name:			Soma Raju					
URL for Additional Product Information: www.camberpharm Address: 1031 Centennial Avenue			m		Address 2:			Number: Group E-mail:			732-529-0423 somaraju@heterousa.com					
City:	1031 Centennial Avenue Piscataway			State	NJ   Zip:   08854			Group E	-maii:		somaraju@i	ieterousa.co	Ш			
Key Contact:	Piscataway  Customer Service				Email: customerservice@camberpharma.com Fax: 732-562-8788			c Special regulations	for product in any st	tatos?			No			
Phone Number:	732-529-0430							c. Special regulations for product in any states?  Special returns requirements for this product?  No				•				
Product Therapeutic Classifi					102 002 0100			The special retains requirements for this product:					•			
d. Store product (unit of sale) upright?																
ADDITIONA	AL PRODUCT INFORM	IATION	<b>a</b>		PRODUC <sup>*</sup>	T DESCRIPT	TION INFORM	MATION	Protect product (unit of sale) from light?							
Is the Product			7						· · · · · · · · · · · · · · · · · · ·					Months		
a legend device?										elf life at launch (if	different):			24	Months	
reverse numbered?		No			Size: 30				minute shell the defluction (if differency.							
co-licensed?		No			Other with a second sec				ORDER INFORMATION							
Is the Product		Direct-Ship Only		Strength:		10mg										
Is the Product		Neither		Dosage F	orm:	Oral Solid			Unit of S			What is the		unit?		
				Dosage	O1111.	Oral Colla			x	Bottle		1 Bottle of 3				
If Unit Dose, is item bar coded to unit dose for hospital scanning?										Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
		No No	1	Product S	Product Shape: Capsule					Ampule						
If Unit Dose NDC, indicate N	DC nere:		1							Glass Tube		Minimum o	rder quantity	/ ?	Yes	
Country of Origin		India	r I	Product 0	olor:	Cap: White	opaque; Bod	ly: White opaque		Vial Liquid Sgl						
			•						Vial Liquid Ggi Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under the Trade Agreements Act (TAA)?				Product I	Product Imprint: I' on cap and '105' on body			Vial Powder Sql 24 Each				.,,,,,,				
								Vial Power Multi			Inner/Carton	/Pack				
									Other: Write In	_		Case				
FOR GENERIC DRUG PRODUCTS																
					Luthorized Co	onorio :	*If Authorized	Conorio other costion		DHAD	MACY ORDE	P/RIII IINI	т			
			′	Authorized Generic *If Authorized Generic, other section fields are not applicable												
I. Orange Book Rating: AB				notes are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?:  Strattera								(Write-in, e.g. 1 Vial)				Each Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(vviite-iii, e.g. i viai)				Milliliter				
			()	,												
Does supplier meet DSCSA	definition of manufact	turer?	Yes	GLN:	033172	22000000				ITEM A	ND PACKING	INFORMAT	ION			
Is product exempt from DSC	n DSCSA? No															
If yes, select exemption:										Weight Lbs.		nsions (US m		Volume	# Pieces:	
Other exemption - Write in:			Ma	1634						1	Depth	Height	Width	(Cube)		
Is product repackaged? Is product sold by manufacti	urar'e avalueiva diatri	hutor?	No No	If Yes, was of from mfr?	iginal produ	ıct purchase	ea direct		Item:	0.02	1.51	2.34	1.51		1	
Has FDA granted waiver/exc			No	If yes, attach	documentati	ion from ED	^		Box/Carton/Bundle/							
inas i DA granteu waiver/exc	opuomevembnom 10t	product:		ii yes, allacii	aocumentati	.on nom FD/	Α.		Inner Pack:							
			GTIN PRODUCT INFORMAT	TION					Case:	1.24	0.010	0.70	0.400		0.	
			Se	leabl						1.24	9.646	3.78	6.496		24	
			Level e	Unit				GTIN-14	Pallet:						225	
Serialized?	Yes	Х	Item	X 2		Linear	1	00331722714303							223	
If not, when?			Box/Carton/Bundle/Inner Pack	21		Linear			UPC:	Case:						
Items aggregated?	Yes	Х		<b>X X</b> 2		Linear	24	20331722714307		Carton:						
		<u> </u>	Pallet	21		Linear			COOT	INFORMATION			WHOLECA	ER USE ONI	V	
				21		Linear			COST	INFORMATION			WHOLESAL	ER USE UNI	. I .	
		<del>                                     </del>		21		Linear			Regular Cost			Vendor #:				
				21		Linear			Invoice Cost (WAC) (\$)		\$55.00		#:			
									Federal Excise Tax Pe		ψοσ.σσ	Fineline Co				
									As of date:		1	1				
			Attach copy of SAFETY DATA S	SHEET (SDS) or non	hazard letter,	, PACKAGE I	INSERT, LAB	BEL AND PHOTO OF PR	ODUCT PACKAGING and E	BARCODE.						
*Please provide any addition	nal information on pag							rop Ship Only.	Signatu							



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? SDS Hazard Classification No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No X Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c Contact Hazard? Nο Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes URL/Link to returns policy: No Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



## **Standard Pharmaceutical Product Information (Page 3)**

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	Purchase order daily receipt cut off time by supplier Cut off time:  Eastern
b. Autofax c. Fax d. Phone only  Fax Number: Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time: Eastern
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:  Phone: 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/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?