



Introduction Type:

Date: 09/22/2026

PRODUCT INFORMATION						
Company Name:		CREEKWOOD PHARMACEUTICALS LLC	Application:	ANDA		
Application Number for NDA/ANDA/BLA; PMA/510(k):		218875	NDA 505(b) Type:			
Medical Device Class, if applicable:						
DUNS:	118582565					
Proprietary Name (If Applicable) and Established Name:		Atomoxetine Capsules USP 100 mg				
Selling Unit NDC:	82619-121-01	Unit of Use NDC:	82619-121-01	UPC:	382619121018	
UDI		CVX Code:		MVX Code:		
Description:	White opaque body, orange opaque cap, size "O" hard gelatin capsule. Imprinted with "387" on cap and "100" on body in black ink, filled with white to off white powder					
Active Ingredient(s):	Atomoxetine Hydrochloride USP					
URL for Additional Product Information:						
Address:	1130 US 46 W Parsippany Paul Thomas 1-732-344-0222		State: NJ	Address 2: Suite 21	Zip: 07054	
Phone Number:			Email:	paul@creekwoodpharma.com		
Fax:						
Product Therapeutic Classification:	Attention-Deficit/Hyperactivity Disorder (ADHD)					
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device?	No	Is the Product... Direct-Ship Only	Size:			21 mm
If yes, enter class #		Is the Product... Orphan Drug Status	Strength:			100 mg
a product kit?	No	FDA Approval Status	Dosage Form:			Capsule
If yes, list NDCs of component parts reverse numbered?	No	Allergens Present	Product Shape:			Capsule shaped
co-licensed?	No	Not present	Product Color:			orange (Orange Opaque)
latex-free?	Yes		Product Imprint:			387 on cap and 100 on body
preservative-free?	Yes					
correctional institution block?	No					
cannabinoid?	No	Country of Origin	INDIA			
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No	Is this product covered under the Trade Agreements Act (TAA)?	No			
If Unit Dose, indicate NDC here:						
FOR GENERIC DRUG PRODUCTS						
I. Orange Book Rating:						
II. Generic Equivalent to What Brand?:	Strattera					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						
Does supplier meet DSCSA definition of manufacturer?	Yes		GLN:	850045940003		
Is product exempt from DSCSA?			GCP:	850045940		
If yes, select exemption: Other exemption - Write in:						
Is product repackaged?	No		If yes, was original product purchased direct from mfr?			
Has FDA granted waiver/exception/exemption for product?	No		Provide source manufacturer for repackaged product			
If yes, attach documentation from FDA.						
GTIN AND HIBCC PRODUCT INFORMATION						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
X Item/Each		1		00382619121018	00382619121018	
x Box/Carton/Bundle/Inner Pack						
x Case		60		20382619121012		
x Pallet		5760				
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) Notes 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: SUJIT SAKPAL Number: 551-303-9330 Group E-mail: sujit@creekwoodpharma.com						
c. Special regulations for product in any states? Special returns requirements for this product? No						
d. Store product (unit of sale) upright?	Protect product (unit of sale) from light?					
e. Shelf life:	Initial shelf life at launch (if different):					
ORDER INFORMATION						
Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Power Multi Other: Write In What is the NDC selling unit? 1 bottle of 30 Tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? Yes If Yes, how many of which package type? 60 Each Inner/Carton/Pack 1 Case						
PHARMACY ORDER / BILL UNIT						
Rec. sell unit to customer? 1 bottle of 30 tablets (Write-in, e.g. 1 Vial) HCPCS J-Code: Rx billing unit to pharmacy: x Each Gram Milliliter						
ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Box/Carton/Bundle/ Inner Pack:	0.14	1.61	1.61	3.11	8.06	1
Case:	9.54	10.03	8.46	8.07	684.77	60
Pallet:	763.11	40.15	33.85	48.42	65806.53	5760
COST INFORMATION WHOLEALER USE ONLY:						
Regular Cost		Vendor #:				
Invoice Cost (WAC) (\$)		Whsl. Code #:				
As of date:		Fineline Code:				

*Please provide any additional information on page 2.

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

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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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? No Does the product label bear a CA Prop 65 warning? No 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? 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? No Is this product regulated for shipment by 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? No 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 <table><tr><td>☐ Organic</td><td>☐ Corrosive</td></tr><tr><td>☐ Inorganic</td><td>☐ Oxidizer</td></tr><tr><td>☐ Steroid/Androgen</td><td>☐ Contact Hazard</td></tr></table> Does the product have an Aerosol class? If yes, identify No NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No If yes, indicate which:		☐ Organic	☐ Corrosive	☐ Inorganic	☐ Oxidizer	☐ Steroid/Androgen	☐ Contact Hazard										
☐ Organic	☐ Corrosive																		
☐ Inorganic	☐ Oxidizer																		
☐ Steroid/Androgen	☐ Contact Hazard																		
Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics																			
REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL: Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: DEA #: NCPDP#: NPI #: Comments IT IS NOT A REMS PRODUCT Registry: Registry Program Contact Name: Comments IT IS NOT A REMS PRODUCT																			
ADD'L STORAGE INFORMATION Is the Product... <table><tr><td>Controlled Substance?</td><td> No </td><td>Controlled Substance Code</td><td> </td></tr><tr><td>Controlled by State(s)?</td><td> No </td><td>Listed Chemical (List I or II)</td><td> No </td></tr><tr><td>ARCOS Reportable?</td><td> No </td><td>If yes, indicate which:</td><td> </td></tr><tr><td>Schedule No.</td><td> </td><td>Is it a scheduled listed chemical product?:</td><td> No </td></tr></table>				Controlled Substance?	No	Controlled Substance Code		Controlled by State(s)?	No	Listed Chemical (List I or II)	No	ARCOS Reportable?	No	If yes, indicate which:		Schedule No.		Is it a scheduled listed chemical product?:	No
Controlled Substance?	No	Controlled Substance Code																	
Controlled by State(s)?	No	Listed Chemical (List I or II)	No																
ARCOS Reportable?	No	If yes, indicate which:																	
Schedule No.		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 Yes Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:																			
RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?																			
MISCELLANEOUS NOTES and/or Image of Product Barcode:																			

Release DATE



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) Phone: 1-800-655-7556	Purchase order daily receipt cut off time by supplier Cut off time: 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: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone #: Phone #: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply:
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:	
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: 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?