



Date: 09/22/2026

PRODUCT INFORMATION			
Company Name:		CREEKWOOD PHARMACEUTICALS LLC	Application:
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):		A213423	ANDA
Medical Device Class, if applicable:			
DUNS:	118582565		
Proprietary Name (If Applicable) and Established Name:		Pregabalin Capsules 300 mg	
Selling Unit NDC:	82619-129-01	Unit of Use NDC:	82619-129-01
UDI	NA	CVX Code:	NA
Description:	Pregabalin 300 mg capsules are "Size 1" White body and Orange cap, hard-gelatin capsule printed with black ink "CW" on the cap, and "300" on the body containing white to off-white crystalline powder.		
Active Ingredient(s):	Pregabalin		
URL for Additional Product Information:			
Address:	1130 US 46 W	State:	NJ
City:	Parsippany	Address 2:	Suite 21
Key Contact:	Paul Thomas	Email:	paul@creekwoodpharma.com
Phone Number:	1-732-344-022	Fax:	
Product Therapeutic Classification:	Anticonvulsant		

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?	No	Is the Product... Direct-Ship Only	Size:
a legend device?	No	Is the Product... Unit of Use	Strength:
if yes, enter class #		Orphan Drug Status	Dosage Form:
a product kit?	No	FDA Approval Status	Product Shape:
if yes, list NDCs of component parts		Allergens Present	Product Color:
reverse numbered?	No	Country of Origin	Product Imprint:
co-licensed?	No		
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
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?:	LYRICA

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
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 AND HIBCC PRODUCT INFORMATION	
Saleable Unit of Measure	Saleable Quantity
X Item/Each	1
X Box/Carton/Bundle/Inner Pack	24
X Case	2016
X Pallet	

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?	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):	24 Months

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
x Bottle	1 bottle of 90 Capsules
Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
Ampule	
Glass	
Tube	
Vial Liquid Sgl	
Vial Liquid Multi	
Vial Powder Sgl	
Vial Power Multi	
Other: Write In	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 bottle of 90 capsules	X Each
(Write-in, e.g. 1 Vial)	Gram
	Milliliter

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.19	NA	2.20	4.72	10.38	1
Box/Carton/Bundle/ Inner Pack:						
Case:	5.6	13.85	9.37	6.14	796.81543	24
Pallet:	471.16	47.24	39.37	42.99	79954.47	2016

COST INFORMATION		WHOLESALE 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:

Paul Thomas



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 ☐ Organic ☐ Corrosive ☐ Inorganic ☐ Oxidizer # ☐ Steroid/Androgen ☐ Contact Hazard Does the product have an Aerosol class? If yes, ☐ No identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? ☐ No If yes, indicate which:	
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: Phone: Supplier Manages REMS registry exclusively: ☐ Wholesale distributor support: ☐ Provider Name: DEA #: Site Enrollment Number assigned by Supplier: NCPDP#: NPI #: Comments IT IS NOT A REMS PRODUCT Registry: Registry Program Contact Name: Phone: Comments IT IS NOT A REMS PRODUCT			
ADD'L STORAGE INFORMATION Is the Product... 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. 5 Is it a scheduled listed chemical product?: ☐ Yes 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:			



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: <table border="0"><tr><td>a. EDI</td><td>☐</td><td>Fax Number:</td><td> </td></tr><tr><td>b. Autofax</td><td>☐</td><td>Fax Number:</td><td> </td></tr><tr><td>c. Fax</td><td>☐</td><td></td><td></td></tr><tr><td>d. Phone only</td><td>☐</td><td>Site Address:</td><td> </td></tr><tr><td>e. Supplier Web Site only</td><td>☐</td><td></td><td></td></tr></table> Minimum Order Quantity: Units Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Direct customer solutions (R & S) Phone: 1-800-655-7556		a. EDI	☐	Fax Number:		b. Autofax	☐	Fax Number:		c. Fax	☐			d. Phone only	☐	Site Address:		e. Supplier Web Site only	☐			Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships for second day receipt: Ships regular ground for 3-10 days receipt:	
a. EDI	☐	Fax Number:																					
b. Autofax	☐	Fax Number:																					
c. Fax	☐																						
d. Phone only	☐	Site Address:																					
e. Supplier Web Site only	☐																						
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: Days of week overnight is available: <table border="0"><tr><td>☐</td><td>Monday</td></tr><tr><td>☐</td><td>Tuesday</td></tr><tr><td>☐</td><td>Wednesday</td></tr><tr><td>☐</td><td>Thursday</td></tr><tr><td>☐</td><td>Friday</td></tr></table> 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:		☐	Monday	☐	Tuesday	☐	Wednesday	☐	Thursday	☐	Friday										
☐	Monday																						
☐	Tuesday																						
☐	Wednesday																						
☐	Thursday																						
☐	Friday																						
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:		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?																					