



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

Version 2024

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION

Company Name: CREEKWOOD PHARMACEUTICALS LLC Application: ANDA
 Application Number for NDA/ANDA/BLA; PMA/510(k): A218162 NDA 505(b) Type:
 Medical Device Class, if applicable:
 DUNS: 118582565
 Proprietary Name (If Applicable) and Established Name: Haloperidol Tablets, USP 1 mg
 Selling Unit NDC: 82619-106-01 Unit of Use NDC: 82619-106-01 UPC: 382619106015
 UDI: CVX Code: MVX Code:
 Description: Yellow, round shaped flat faced beveled edge uncoated tablets scored on one side and debossed with '299' on other side
 Active Ingredient(s): Haloperidol, USP
 URL for Additional Product Information:
 Address: 1130 US 46 W Address 2: Suite 21
 City: Parsippany State: NJ Zip: 07054
 Key Contact: Paul Thomas Email: paul@creekwoodpharma.com
 Phone Number: 1-732-344-022 Fax:
 Product Therapeutic Classification: Antipsychotic

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement (write in):
 Notes:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?
 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?
 d. Store product (unit of sale) upright?
 Protect product (unit of sale) from light?
 e. Shelf life:
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is?
 a legend device?
 if yes, enter class #
 a product kit?
 if yes, list NDCs of component parts reverse numbered?
 co-licensed?
 latex-free?
 preservative-free?
 correctional institution block?
 opioid?
 Cannabinoid?
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose, indicate NDC here:
 Is the Product... Direct-Ship Only
 Is the Product... Unit of Use
 Orphan Drug Status
 FDA Approval Status
 Allergens Present: Not present
 Country of Origin: INDIA
 Is this product covered under the Trade Agreements Act (TAA)?

PRODUCT DESCRIPTION INFORMATION

Size: 6 mm
 Strength: 1 mg
 Dosage Form: Tablet
 Product Shape: Round shaped
 Product Color: Yellow
 Product Imprint: 299

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?:

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?

 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity?
 If Yes, how many of which package type?
 Each
 Inner/Carton/Pack Case

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? GLN: 850045940003
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 GCP: 850045940
 Is product repackaged?
 Is product sold by manufacturer's exclusive distributor?
 If yes, was original product purchased direct from mfr?
 Has FDA granted waiver/exception/exemption for product?
 Provide source manufacturer for repackaged product:
 If yes, attach documentation from FDA:

PHARMACY ORDER / BILL UNIT

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

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each		1		00382619106015	382619106015
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				20382619106019	
<input checked="" type="checkbox"/> Case		60			
<input checked="" type="checkbox"/> Pallet		112			

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.05	1.5	8.07	2.35	3.53	1
Box/Carton/Bundle/Inner Pack:						
Case:	4.16	9.6	8.07	6.8	526.81	60
Pallet:	466.75	38.5	32.28	48.22	59926.85	112

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$)
 As of date:
 Vendor #:
 Whsl. Code #:
 Fineline Code:

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																									
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="background-color: #002060; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify <input type="text"/> No</p> <p>NFPA Storage Level: <input type="text"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/></p>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard																		
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Hazardous Waste Identification																									
EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/>																									
REMS or REGISTRY RESTRICTIONS																									
<p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/> No</p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p> <p>Registry:</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/> IT IS NOT A REMS PRODUCT</p>																									
ADD'L STORAGE INFORMATION																									
<p>Is the Product...</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;">Controlled Substance?</td> <td style="width: 10%;"><input type="checkbox"/> No</td> <td style="width: 20%;">Controlled Substance Code</td> <td style="width: 10%;"><input type="text"/></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>Controlled by State(s)?</td> <td><input type="checkbox"/> No</td> <td>Listed Chemical (List I or II)</td> <td><input type="checkbox"/> No</td> <td></td> <td></td> </tr> <tr> <td>ARCOS Reportable?</td> <td><input type="checkbox"/> No</td> <td>If yes, indicate which:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>Schedule No.</td> <td><input type="text"/></td> <td>Is it a scheduled listed chemical product?:</td> <td><input type="checkbox"/> No</td> <td></td> <td></td> </tr> </table>		Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	<input type="text"/>			Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No			ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>			Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No		
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Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No																						
CLASS OF TRADE RESTRICTION:																									
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>																									
RETURN INSTRUCTIONS																									
<p>Contact tel. # if product received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: https://creekwoodpharma.com/wp-content/uploads/2023/07/Return-Goods-Policy.pdf</p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>																									
MISCELLANEOUS NOTES and/or Image of Product Barcode:																									
Release DATE																									



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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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/> Direct customer solutions (R & S)</p> <p>Phone: <input type="text"/> 1-800-655-7556</p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	