



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION

Company Name: Radha Pharmaceuticals Inc Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 205794
 DUNS: 117634222
 Proprietary Name (if Applicable) and Established Name: Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 100 mg, 500s
 Selling Unit NDC: 77771-174-05 Individual Unit NDC: 1 Bottle UPC: 377771174057
 UDI: CVX Code: MVX Code:
 Description: Blue, round, biconvex, film coated tablets, debossed with 'SG , 174' on one side and plain on other side.
 Active Ingredient(s): Bupropion Hydrochloride
 URL for Additional Product Information:
 Address: 330 Oser Avenue City: Hauppauge State: NY Address 2: Zip: 11788
 Key Contact: Siva Reddy, P.V. Email: sivareddy@radhapharm.com
 Phone Number: 631-424-2727 XT 107 Fax: 631-357-3178
 Product Therapeutic Classification: Antidepressant

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: Siva Reddy, P.V.
 Number: 631-424-2723 XT 107
 Group E-mail: sivareddy@radhapharm.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? No

e. Shelf life:
 Initial shelf life at launch (if different): 24 Months

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: USA
 Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size: 0.3543"
 Strength: 100mg
 Dosage Form: Tablet
 Product Shape: Round
 Product Color: Blue
 Product Imprint: SG 174'

ORDER INFORMATION

Unit of Sale
 Yes Bottle
 Box/ Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Powder Multi
 Other: Write In

What is the NDC selling unit?
 1 Bottle of 500 Tablets
 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?
 12 Bottles Each
 per Case Inner/ Carton/ Pack
 3 Cases Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB1
 II. Generic Equivalent to What Brand?: Wellbutrin SR
 Authorized Generic *If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
 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.

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.36	NA	4.3	2.5	#VALUE!	500 Tablets per Bottle
Box/ Carton/ Bundle/ Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	5	12.6	7.8	9.5	933.66	12 Bottles per Case
Pallet:	460	48	48	40	92160	84 Cases per Pallet
UPC:	Case:	377771174057				
	Carton:	20377771174051				

GTIN PRODUCT INFORMATION

Serialized?	Level	Item	Saleable Unit	Quantity		GTIN-14
				Serialized	Unit	
Yes	Item	Box/ Carton/ Bundle/ Inner Pack	X	1	1	00377771174057
If not, when?	Case	Pallet	X	12	12	20377771174051
Items aggregated?						

COST INFORMATION

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

WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 FineLine Code:

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? _____
 (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? No

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity? _____
 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? _____

Schedule No. (inc. N for non-narcotic) _____

Controlled Substance Code _____

Listed Chemical (List I or II) _____

If yes, indicate which: _____

Is it a scheduled listed chemical product? _____

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: _____

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: _____	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? No If yes, indicate which: _____

Hazardous Waste Identification	
EPA Hazardous Waste Code:	_____

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? No	
If Yes, is it managed with a pharmacy registry? _____	
Website URL: _____	
Comments / Details: (For example, iPledge program?) _____	
REMS: _____	
REMS Program Manager Name: _____	Phone: _____
Supplier Manages REMS registry exclusively: _____	
Wholesale distributor support: _____	
Provider Name: _____	
Site Enrollment Number assigned by Supplier: _____	DEA #: _____
	PCPDP #: _____
	NPI #: _____

Comments _____

Registry: _____

Registry Program Contact Name: _____ Phone: _____

Comments _____

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1877-671-4307

Is product returnable for credit: _____

URL/Link to returns policy: _____

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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></p> <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"/></p> <p>Phone: <input type="text"/></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="checkbox"/></p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/></p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 50px;" 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> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <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="checkbox"/></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="checkbox"/></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 style="width: 100%; height: 50px;" type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<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>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 style="width: 100%; height: 50px;" type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input style="width: 100%; height: 100px;" type="text"/>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>