



# 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) 150 mg, 500s  
 Selling Unit NDC:  7771-175-05 Individual Unit NDC:  1 Bottle UPC:  37771175054  
 UDI  CVX Code:  MVX Code:   
 Description:  Purple, round, biconvex tablets, debossed with 'SG 175' on one side and plain on other side.  
 Active Ingredient(s):  Bupropion Hydrochloride  
 URL for Additional Product Information:   
 Address:  330 Oser Avenue Address 2:   
 City:  Hauppauge State:  NY 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?  Yes  
 e. Shelf life:  24 Months Initial shelf life at launch (if different):  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:  0.4291  
 Strength:  150mg  
 Dosage Form:  Tablet  
 Product Shape:  Round  
 Product Color:  Purple  
 Product Imprint:  SG 175'

**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  
 (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  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?:  Wellbutrin SR

**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 GLN:  03777100000  
 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 If yes, attach documentation from FDA.  
 Has FDA granted waiver/exception/exemption for product?  No

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.55	NA	5.3	2.9	#VALUE!	500 Tablets per Bottle
Case:	7.5	12.9	8.5	9.8	1074.57	12 Bottles per Case
Pallet:	570	48	48	40	92160	70 cases per Pallet
UPC:	Case:	37771175054				
	Carton:	2037771175058				

**GTIN PRODUCT INFORMATION**

Serialized?	Yes	Level		Quantity	GTIN-14
		Item	Saleable Unit		
If not, when?	<input type="text"/>	X	Box/ Carton/ Bundle/ Inner Pack	1	0037771175054
Items aggregated?	No	X	Case	12	2037771175058
			Pallet		

**COST INFORMATION**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 Federal Excise Tax Per Unit of Sale   
 As of date:   
 WHOLESALE USE ONLY:  
 Vendor #:   
 Whsl. Code #:   
 Fine Line 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

Organic  Corrosive

Inorganic  Oxidizer

Steroid/Androgen  Contact Hazard

Aerosol Class; Identify NFPA Storage Level: \_\_\_\_\_

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 #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></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><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> 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:	Return Instructions
<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>	<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>
Other Data Information Required to Process PO:	Miscellaneous Notes:
<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 style="text-align: center;"><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>