



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:

Final Version

Date:

**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) 200 mg, 60s

Selling Unit NDC: 7771-176-60 Individual Unit NDC: 1 Bottle UPC: 37771176600

UDI:  CVX Code:  MVX Code:

Description: Pink, round, biconvex, film coated tablets, debossed with oSG, 176' 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 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?  No

Special returns requirements for this product?  No

d. Store product (unit of sale) upright?  Yes

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: 0.4685"

Strength: 200mg

Dosage Form: Tablet

Product Shape: Round

Product Color: Pink

Product Imprint: SG 176'

**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 60 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?  Yes

If Yes, how many of which package type?

24 Bottles	Each
per Case	Inner/ Carton/ Pack
3 Cases	Case

**FOR GENERIC DRUG PRODUCTS**

Authorized Generic

\*If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB1

II. Generic Equivalent to What Brand?: Wellbutrin SR

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?

Rx billing unit to pharmacy:

<input type="checkbox"/>	Each
<input type="checkbox"/>	Gram
<input type="checkbox"/>	Milliliter

(Write-in, e.g. 1 Vial)

**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

Is product sold by manufacturer's exclusive distributor?  No

Has FDA granted waiver/exception/exemption for product?  No

GLN: 037771000000

If Yes, was original product purchased direct from mfr?

If yes, attach documentation from FDA.

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.13	NA	3	1.74	#VALUE!	60 Tablets per Bottle
Box/ Carton/ Bundle/ Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	3.75	12.1	4.5	8.4	457.38	24 Bottles per Case
Pallet:	650	48	48	40	92160	160 Cases per Pallet
UPC:	Case:	37771176600				
	Carton:					

**GTIN PRODUCT INFORMATION**

Serialized?	Yes	Level	Item	Saleable Unit	Quantity	GTIN-14
Serialized?	<input checked="" type="checkbox"/>	Item	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	1	00377771176600
If not, when?	<input type="checkbox"/>	Case		<input checked="" type="checkbox"/>	24	20377771176604
Items aggregated?	<input type="checkbox"/>	Pallet				

**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?  
 (if yes, answer a-e below and provide SDS) No

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><input style="width: 100%; height: 100px;" type="text"/></p>
ADDITIONAL INFORMATION	
<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	