



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Sciegen Pharmaceuticals Inc
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	207479
DUNS:	0793912286
Proprietary Name (If Applicable) and Established Name:	Bupropion Hydrochloride Extended- Release Tablets, USP (XL) 300 mg, 500s per Bottle
Selling Unit NDC:	50228-145-05
Individual Unit NDC:	1 Bottle
UPC:	350228145053
UDI	
CVX Code:	
MVX Code:	
Description:	white to pale yellow, Modified Capsule Shape, biconvex, film coated tablets, debossed with 0145' on one side and plain on other side.
Active Ingredient(s):	Bupropion Hydrochloride, USP
URL for Additional Product Information:	
Address:	89 Arkay Drive
City:	Hauppauge
Key Contact:	Siva Reddy, P.V.
Phone Number:	631-424-2727 XT 107, 631-524-5509
Product Therapeutic Classification:	Antidepressant
Application:	ANDA
State:	NY
Zip:	11788
Email:	sivareddy@sciegenpharm.com
Fax:	631-357-3178

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Temperature Range	
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, 631-524-5509
Group E-mail:	sivareddy@sciegenpharm.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:	24 Months
Initial shelf life at launch (if different):	

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:	0.6800 X0.2750"
Strength:	300mg
Dosage Form:	Tablets
Product Shape:	Modified Capsule Shape
Product Color:	White to pale yellow
Product Imprint:	Debossed with 145 on one side

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Yes Bottle	1 Bottle of 500 Tablets
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	
	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:	AB3
II. Generic Equivalent to What Brand?:	Wellbutrin XL 300
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> 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
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	035022800000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.73	NA	5.6	3.2	#VALUE!	500 Tablets per Bottle
Box/Carton/Bundle/Inner Pack:	NA	NA	NA	NA	#VALUE!	NA
Case:	9.5	12.6	7.8	9.5	933.66	12 Bottles per Case
Pallet:	355	48	48	40	92160	33 Cases per Pallet
UPC:	Case:	350228145903				
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
Yes	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00350228145053		
If not, when?	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack					
Items aggregated?	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	12	20350228145057		
	<input type="checkbox"/> Pallet					

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

