



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

Version 2021

Introduction Type: New Item

Final Version

Date: 17.06.2024

PRODUCT INFORMATION	
Company Name:	Strides Pharma Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	202330
Medical Device Class, if applicable:	
DUNS:	91-851-3263
Proprietary Name (If Applicable) and Established Name:	Buspirone Hydrochloride tablets USP [5mg][500's][VA]
Selling Unit NDC:	42543-0741-07
Unit of Use NDC:	
UPC:	342543741072
UDI	
CVX Code:	
MX Code:	
Description:	White to Off white ovoid-rectangular uncoated tablet with score line on one side and engraved '5' on the other side.
Active Ingredient(s):	Buspirone Hydrochloride Tablets, USP 5 mg
URL for Additional Product Information:	
Address:	1 Ram Ridge Rd.
City:	Chestnut Ridge
State:	NY
Address 2:	
Zip:	10977
Key Contact:	
Email:	Stridescustomerservice@stridesusa.com
Phone Number:	609-773-5008
Fax:	609-935-0806
Product Therapeutic Classification:	

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)	
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	Nagesh Majeti
Number:	609-770-5004
Group E-mail:	
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="checkbox"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/>
e. Shelf life:	
Initial shelf life at launch (if different):	36 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Size:	500
a legend device?	<input type="checkbox"/> No	Strength:	5 mg
if yes, enter class #		Dosage Form:	Tablets
a product kit?		Product Shape:	Ovoid-Rectangular
if yes, list NDCs of component parts		Product Color:	White to Off white
reverse numbered?	<input type="checkbox"/> No	Product Imprint:	Uncoated tablet with score line on one side and engraved '5' on the other
co-licensed?	<input type="checkbox"/> No		
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	<input type="checkbox"/>		
Is the Product... Neither	<input type="checkbox"/>		
Orphan Drug Status			
FDA Approval Status			
Allergens Present			
Country of Origin	India		
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> 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	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> 1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	BUSPAR / 018731
<input type="checkbox"/> NO	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:
<input type="checkbox"/> Bottle	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
If yes, attach documentation from FDA.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	2.095	7.598	5.827	4.134	183.03	12
Case:	26.902	18.701	8.465	17.717	2804.67	144
Pallet:	582.141	48	40	40.669	78084.48	2880

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00342543741072	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	12		20342543741076	
<input checked="" type="checkbox"/> Case	144		50342543741077	
<input checked="" type="checkbox"/> Pallet	2,880		70342543741071	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
As of date:		Fineline Code:	

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature: