



# 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):	204559
Medical Device Class, if applicable:	
DUNS:	91-851-3263
Proprietary Name (If Applicable) and Established Name:	PEG 3350, Sodium Bicarbonate, Sodium Chloride, Potassium Chloride for Oral Solution with Lemon Flavour [1's][Strides]
Selling Unit NDC:	64380-0769-21
Unit of Use NDC:	
UPC:	364380769217
UDI	
CVX Code:	
MXV Code:	
Description:	A White to almost white powder.
Active Ingredient(s):	PEG 3350, Sodium Bicarbonate, Sodium Chloride, Potassium Chloride for Oral Solution with Lemon Flavour
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*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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>b. Contact for temperature excursion questions:</b>	
Name:	Nagesh Majeti
Number:	609-770-5004
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/>
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	36 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	<input type="checkbox"/>
a legend device?	<input type="checkbox"/> No	Is the Product... Neither	<input type="checkbox"/>
if yes, enter class #		Orphan Drug Status	<input type="checkbox"/>
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	<input type="checkbox"/> No	Allergens Present	
co-licensed?	<input type="checkbox"/> No	Country of Origin	India
latex-free?	<input type="checkbox"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
preservative-free?	<input type="checkbox"/>		
correctional institution block?	<input type="checkbox"/>	Size:	1
opioid?	<input type="checkbox"/>	Strength:	NA
Cannabinoid?	<input type="checkbox"/>	Dosage Form:	Powder for Oral Solution
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Product Shape:	Powder
If Unit Dose, indicate NDC here:		Product Color:	A White to almost white powder
		Product Imprint:	NA

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle
<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:	AA
II. Generic Equivalent to What Brand?:	NULYTELY & NULYTELY FLAVOURED / N019797
<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:	NA	NA	NA	NA	NA	NA
Case:	13.387	22.441	15.748	11.220	3965.158	8
Pallet:	244.905	48	40	38.307	73549.440	120

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		00364380769217	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	NA		NA	
<input checked="" type="checkbox"/> Case	8		50364380769212	
<input checked="" type="checkbox"/> Pallet	120		70364380769216	

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: