



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

Version 2021

Introduction Type: New Item

Final Version

Date: 17.10.2022

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Strides Pharma, Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="207029"/>				Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in) <input type="text"/>			
DUNS: <input type="text" value="91-851-3263"/>				Notes <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Hydrocortisone Tablets 5mg, 50"/>				Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="64380-0970-25"/>		Unit of Use NDC: <input type="text"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
UDI <input type="text"/>		CVX Code: <input type="text"/>		b. Contact for temperature excursion questions:			
Description: <input h5""="" type="text" value="White to off-white oval tablets debossed on one side with a bisect and other side with "/>		MVX Code: <input type="text"/>		Name: <input type="text" value="Michael Gargiulo"/>			
Active Ingredient(s): <input type="text" value="Hydrocortisone Tablets, USP 5 mg"/>				Number: <input type="text" value="609-773-5004"/>			
URL for Additional Product Information: <input type="text"/>				Group E-mail: <input type="text"/>			
Address: <input type="text" value="1 Ram Ridge Rd."/>		Address 2: <input type="text"/>		c. Special regulations for product in any states?			
City: <input type="text" value="Chestnut Ridge"/>		State: <input type="text" value="NY"/>		Special returns requirements for this product? <input type="text"/>			
Key Contact: <input type="text" value="Walt Busbee"/>		Zip: <input type="text" value="10977"/>		d. Store product (unit of sale) upright? <input type="text"/>			
Phone Number: <input type="text" value="609-773-5008"/>		Email: <input type="text" value="Stridescustomerservice@stridesusa.com"/>		Protect product (unit of sale) from light? <input type="text"/>			
Product Therapeutic Classification: <input type="text"/>		Fax: <input type="text" value="609-935-0806"/>		e. Shelf life: <input type="text" value="18"/> Months			
				Initial shelf life at launch (if different): <input type="text"/>			
ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION				
The product is? a legend device? <input type="text" value="No"/>			Is the Product... <input type="text" value="Direct-Ship Only"/>				
if yes, enter class # <input type="text"/>			Is the Product... <input type="text" value="Neither"/>				
a product kit? <input type="text"/>			Orphan Drug Status <input type="text"/>				
if yes, list NDCs of component parts reverse numbered? <input type="text"/>			FDA Approval Status <input type="text"/>				
co-licensed? <input type="text" value="No"/>			Allergens Present <input type="text"/>				
latex-free? <input type="text"/>			Country of Origin <input type="text" value="India"/>				
preservative-free? <input type="text"/>			Size: <input type="text" value="50"/>				
correctional institution block? <input type="text"/>			Strength: <input type="text" value="5 mg"/>				
opioid? <input type="text"/>			Dosage Form: <input type="text" value="Tablets"/>				
Cannabinoid? <input type="text"/>			Product Shape: <input type="text" value="oval tablets"/>				
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>			Product Color: <input type="text" value="White to off-white"/>				
If Unit Dose, indicate NDC here: <input type="text"/>			Product Imprint: <input type="text" value="debossed on one side with a"/>				
Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>							
ORDER INFORMATION							
Unit of Sale			What is the NDC selling unit?				
<input type="checkbox"/> Bottle			<input type="text" value="Bottle x 50 Tablets"/>				
<input type="checkbox"/> Box/Carton			(Write-in, e.g. 1 Box of 10 Vials)				
<input type="checkbox"/> Ampule			Minimum order quantity? <input type="text" value="Yes"/>				
<input type="checkbox"/> Glass							
<input type="checkbox"/> Tube			If Yes, how many of which package type?				
<input checked="" type="checkbox"/> Vial Liquid Sgl			<input type="text" value="1"/> Each				
<input type="checkbox"/> Vial Liquid Multi			<input type="text"/> Inner/Cartron/Pack				
<input type="checkbox"/> Vial Powder Sgl			<input type="text"/> Case				
<input type="checkbox"/> Vial Power Multi							
<input type="checkbox"/> Other: Write In							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer?			Rx billing unit to pharmacy:				
<input type="text" value="Bottle"/>			<input checked="" type="checkbox"/> Each				
(Write-in, e.g. 1 Vial)			<input type="checkbox"/> Gram				
			<input type="checkbox"/> Milliliter				
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.066351	1.772	1.772	3.504	11.002504	1	
Box/Cartron/Bundle/Inner Pack:	NA	NA	NA	NA	NA	NA	
Case:	7.071778	14.764	9.252	7.874	1075.5611	80	
Pallet:	383.5353	47.992	39.09	40	75040.291	3840	
COST INFORMATION							
Regular Cost			Vendor #:				
Invoice Cost (WAC) (\$)			Whsl. Code #:				
As of date: <input type="text"/>			Fineline Code: <input type="text"/>				
WHOLESALE USE ONLY:							
Signature: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> NO Authorized Generic *If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?: <input type="text" value="CORTEF® (Pharmacia and Upjohn) N008697"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>							
Is product exempt from DSCSA? <input type="text" value="No"/>							
If yes, select exemption: <input type="text"/>							
Other exemption - Write in: <input type="text"/>							
Is product repackaged? <input type="text" value="No"/>							
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>							
If yes, attach documentation from FDA. <input type="text"/>							
Provide source manufacturer for repackaged product <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC			
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>		<input type="text"/>			
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack		<input type="text" value="NA"/>		<input type="text"/>			
<input checked="" type="checkbox"/> Case		<input type="text" value="80"/>		<input type="text"/>			
<input checked="" type="checkbox"/> Pallet		<input type="text" value="3840"/>		<input type="text"/>			
				GTIN-14			
				<input type="text" value="00364380970255"/>			
				<input type="text" value="NA"/>			
				<input type="text" value="50364380970250"/>			
				<input type="text" value="70364380970254"/>			
				Unit of Use GTIN-14 <input type="text"/>			

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: