

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

Version 2021						Introduction Type:	New Item		х	Final Version			Date:	17.10	0.2022		
			PRODUCT INF	ORMATION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*				
Company Name:	Strides Pharma, Inc. ANDA								a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):										Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applica			•	<u> </u>					•	Ū				,			
DUNS:	91-851-3263								Other Te	emperature Range	Requirement						
Proprietary Name (If Applicable)	and Established N	ame:	Hydrocortisone Tablets 10	mg, 100ct					(w	rite in)							
Selling Unit NDC:	64380-0971-06		Unit of Us				380971061		Notes								
UDI		hite to off-white oval tablets debossed on one side with a bisect and other side				MVX Code:											
Description:			Is this p	roduct to be shippe	ed to customers on i	ce?		No									
Active Ingredient(e):										Is this product to be shipped to customers on dry ice?							
Active Ingredient(s): Hydrocortisone Tablets, USP 10 mg										b. Contact for temperature excursion questions:							
URL for Additional Product Infor	D. Contact for	Michael Gargiulo															
Address:	1 Ram Ridge Rd.					Address 2:			Name: Number:				609-773-5004				
City:	Chestnut Ridge				State:				Group E-mail:								
Key Contact:	Walt Busbee				Email:										-		
Phone Number:	609-773-5008				Fax:	Fax: 609-935-0806			c. Special regulations for product in any states?					No			
Product Therapeutic Classification	Special returns requirements for this product?																
															7		
	ADDITIC	DNAL PRODUC	CT INFORMATION			PRODUCT DESCI	RIPTION INFORMATION	d. Store prod	-	of sale) upright?				No			
The product is?			Is the Product.		p Only			Ц	Protect	product (unit of s	sale) from light?			No			
a legend device?		No	Is the Product.			Size:	100	e. Shelf life:	luitiel el	aalf lifa at lawaah	(if different).			24	Months		
if yes, enter class # a product kit?			Orphan Drug S	tatus				-	initiai s	nelf life at launch	(ir different):				Months		
if yes, list NDCs of							10 mg				ORDER INFORM	IATION					
component parts			FF -			December Forms	Tablets										
reverse numbered?		No				Dosage Form:	Tablets		Unit of	Sale			NDC sellin	g unit?			
co-licensed?		No	Allergens Pres	ent				Ц	х	Bottle		Bottle x 100					
latex-free?		Yes				Product Shape:	oval tablets			Box/Carton		(Write-in, e	g. 1 Box of	10 Vials)			
preservative-free? correctional institution block?		No						-		Ampule Glass		Minimum c	order quanti	tv2	Yes		
opioid?		No				Product Color:	White to off-white			Tube		William	nuei quanti	ty:	163		
Cannabinoid?		No	Country of Origin	India		But had becaused	depossed on one side with			Vial Liquid Sgl							
If Unit Dose, is item bar coded to	unit dose for					Product Imprint:	a bisect and other side with			Vial Liquid Multi		If Yes, how	many of wl	hich package	type?		
hospital scanning?				overed under the						Vial Powder Sql			Each				
If Unit Dose, indicate NDC here:			Trade Agreeme	nts Act (TAA)?	No					Vial Power Multi			Inner/Carto	n/Pack			
				Ue propueto				<u> </u>		Other: Write In		1	Case				
			FOR GENERIC DR	UG PRODUCTS													
NO Authorized Generic *If Authorized Generic, other								PHARMACY ORDER / BILL UNIT									
I. Orange Book Rating: AB Authorized Generic in Authorized Generic, other section fields are not applicable								Rec. sell unit to customer? Rx billing unit to pharmacy:									
II. Generic Equivalent to What Brand?: CORTEF® (Pharmacia and Upjohn) N008697								Bottle			x Each						
in control Equitation to What Brand									(Write-in, e.g. 1 Vial)				Gram				
		DRUG SL	JPPLY CHAIN SECURIT	ACT (DSCSA) INFO	ORMATION								Milliliter				
		_															
Does supplier meet DSCSA defin		irer?	Yes		GLN:			ITEM AND PACKING INFORMATION									
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msi	-	Volume	Saleable #		
Other exemption - Write in: Is product repackaged?			No		If was was a	original product		Item/Each:			Depth	Width	Height	(Cube)	Pieces		
Is product repackaged? Is product sold by manufacturer!	s exclusive distrib	utor?	No			lirect from mfr?		itorii/Lacii.		0.093901	1.772	1.772	3.504	11.002504	1		
Has FDA granted waiver/exception			No		•	rce manufacturer for rep	packaged product	Box/Carton/B	Bundle/	NIA	NIA	NIA	NIA	NIA	NIA		
If yes, attach documentation from		_				•	•	Inner Pack:		NA	NA	NA	NA	NA	NA		
								Case:		9.275778	14.764	9.252	7.874	1075.5611	80		
			GTIN AND HIBCC PRO	DUCT INFORMATION	N			Delle:					1.5.				
Saleable Unit of Measure	0	alaahla Quantii	ty HIBCC		CT	IN-14	Unit of Use CTIN 14	Pallet:		489.3273	47.992	39.09	40	75040.291	3840		
x Item/Each	5	aleable Quanti	ц ПВСС			B64380971061	Unit of Use GTIN-14										
Box/Carton/Bundle/Inner Pack	NA NA							COST INFORMATION				WHOLESALER USE ONLY:					
x Case		80			503	364380971066											
x Pallet		3840			703	364380971060		Regular Cost				Vendor #:					
								Invoice Cost	(WAC) (\$)	\$85.75	Whsl. Code					
								As of data:		9/14/2020		Fineline Co	ode:				
								As of date:		3/ 14/2020		1					
	_																
			Attach copy of SAFI	TY DATA SHEET (S	DS) or non haza	rd letter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACK	AGING a	nd BARCODE.		•					
*Please provide any additional in	formation on page	2.	.,	(-			gnated Drop Ship Only.		Signatu								