



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

Version 2021

Introduction Type:

Final Version

Date:

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="40350"/>		Medical Device Class, if applicable: <input type="text"/>		Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>		Other Temperature Range Requirement (write in): <input type="text" value="15° to 30°C (59° to 86°F)"/>	
DUNS: <input type="text" value="11-8344-504"/>		Proprietary Name (If Applicable) and Established Name: <input type="text" value="Methimazole Tablets, USP"/>		Notes: <input type="text"/>		Is this product to be shipped to customers on ice? <input type="text" value="No"/>	
Selling Unit NDC: <input type="text" value="64380-0212-02"/>		Unit of Use NDC: <input type="text"/>		UPC: <input type="text" value="364380212027"/>		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"/>		MVX Code: <input type="text"/>		b. Contact for temperature excursion questions:	
Description: <input 5"="" and="" em="" on="" one="" other."="" plain="" side="" the="" type="text" value="White to off white, round, flat-faced, bevelled-edged tablets, scored with "/>				Name: <input type="text" value="Michael Gargiulo"/>		Number: <input type="text" value="609-773-5004"/>	
Active Ingredient(s): <input type="text" value="Methimazole"/>				Group E-mail: <input type="text"/>		c. Special regulations for product in any states?	
URL for Additional Product Information: <input type="text" value="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca8c1028-216d-485a-90df-b54818451bc3"/>				Special returns requirements for this product? <input type="text" value="No"/>		d. Store product (unit of sale) upright?	
Address: <input type="text" value="1 Ram Ridge Rd"/>		Address 2: <input type="text"/>		Protect product (unit of sale) from light? <input type="text" value="No"/>		e. Shelf life:	
City: <input type="text" value="Chestnut Ridge"/>		State: <input type="text" value="NY"/>		Zip: <input type="text" value="10977"/>		Initial shelf life at launch (if different):	
Key Contact: <input type="text" value="Walt Busbee"/>		Email: <input type="text" value="stridescustomerservice@stridesusa.com"/>		36 Months		24 Months	
Phone Number: <input type="text" value="609-773-5008"/>		Fax: <input type="text" value="609-935-0806"/>		24 Months			
Product Therapeutic Classification: <input type="text"/>				ORDER INFORMATION			
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"/>		Size: <input type="text" value="500"/>		Unit of Sale	
if yes, enter class # <input type="text"/>		Is the Product... <input type="text" value="Neither"/>		Strength: <input type="text" value="5 mg"/>		X Bottle	
a product kit? <input type="text" value="No"/>		Orphan Drug Status <input type="text"/>		Dosage Form: <input type="text" value="Tablets"/>		Box/Carton	
if yes, list NDCs of component parts <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text" value="Round"/>		Ampule	
reverse numbered? <input type="text" value="No"/>		Allergens Present <input type="text"/>		Product Color: <input type="text" value="White to off-white"/>		Glass	
co-licensed? <input type="text" value="No"/>		Country of Origin <input type="text" value="USA"/>		Product Imprint: <input type="text" value="EM;5"/>		Tube	
latex-free? <input type="text"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/>				Vial Liquid Sgl	
preservative-free? <input type="text"/>						Vial Liquid Multi	
correctional institution block? <input type="text" value="No"/>						Vial Powder Sgl	
opioid? <input type="text" value="No"/>						Vial Powder Multi	
Cannabinoid? <input type="text" value="No"/>						Other: Write In	
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>						If Yes, how many of which package type?	
If Unit Dose, indicate NDC here: <input type="text"/>						24 Each	
FOR GENERIC DRUG PRODUCTS				Minimum order quantity? <input type="text" value="Yes"/>			
I. Orange Book Rating: <input type="text" value="AB"/>		Authorized Generic <input type="text" value="No"/>		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Methimazole"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				PHARMACY ORDER / BILL UNIT			
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0359556421464"/>		Rec. sell unit to customer? <input type="text" value="1 Bottle"/>		Rx billing unit to pharmacy:	
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text"/>		(Write-in, e.g. 1 Vial)		X Each	
If yes, select exemption: <input type="text"/>						Gram	
Other exemption - Write in: <input type="text"/>						Milliliter	
Is product repackaged? <input type="text" value="No"/>		If yes, was original product purchased direct from mfr? <input type="text"/>		ITEM AND PACKING INFORMATION			
Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION				COST INFORMATION			
Selling Unit of Measure		Selling Quantity		HIBCC		GTIN-14	
X Item/Each		1				Unit of Use GTIN-14	
X Box/Carton/Bundle/Inner Pack		12				00364380212027	
X Case		24				20364380212021	
Pallet						50364380212022	
				WHOLESALE USE ONLY:		Regular Cost	
				Invoice Cost (WAC) (\$)		\$117.55	
				As of date: <input type="text"/>		Vendor #:	
						Whsl. Code #:	
						Fineline Code:	

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: