



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

Version 2021

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Strides Pharma Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	75671
Medical Device Class, if applicable:	
DUNS:	11-8344-504
Proprietary Name (If Applicable) and Established Name:	Megestrol Acetate Oral Suspension, USP 240mL
Selling Unit NDC:	64380-0160-01
Unit of Use NDC:	
UPC:	364380160014
UDI	
CVX Code:	
MVX Code:	
Description:	Milky white, lemon-lime flavored oral suspension.
Active Ingredient(s):	Megestrol Acetate
URL for Additional Product Information:	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fd97ca46-3f69-440b-80f1-28fed4544f2a
Address:	2 Tower Center Blvd
City:	East Brunswick
Key Contact:	Walt Busbee
Phone Number:	609-773-5008
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
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="Controlled Room – between 20 and 25 C (68° – 77°)"/>
Notes	
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
b. Contact for temperature excursion questions:	
Name:	<input type="text" value="Michael Gargiulo"/>
Number:	<input type="text" value="609-773-5004"/>
Group E-mail:	
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="36"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Is the Product... Orphan Drug Status	
a legend device?	<input type="text" value="No"/>		Size:
if yes, enter class #			<input type="text" value="8"/>
a product kit?	<input type="text" value="No"/>		Strength:
if yes, list NDCs of component parts reverse numbered?			<input type="text" value="40 mg/mL"/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value="Milliliter"/>
latex-free?			Dosage Form:
preservative-free?		Allergens Present	<input type="text" value="N/A"/>
correctional institution block?			Product Shape:
opioid?		Country of Origin	<input type="text" value="White (milky white)"/>
Cannabinoid?			Product Color:
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="N/A"/>
If Unit Dose, indicate NDC here:			Product Imprint:

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="BOTTLE of 8 Ounces"/>
<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="text" value="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="text" value="12"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text" value=""/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text" value=""/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic <small>*If Authorized Generic, other section fields are not applicable</small>
II. Generic Equivalent to What Brand?:	<input type="text" value="Megace / N020264"/>

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value=""/> (Write-in, e.g. 1 Vial)	<input type="text" value=""/> Each
	<input type="text" value=""/> Gram
	<input type="text" value=""/> Milliliter

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=""/>
If yes, select exemption:	GLN: <input type="text" value="0359556421464"/>
Other exemption - Write in:	GCP: <input type="text" value=""/>
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.	Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.67	2.41	5.25	2.41	1.089	1
Box/Carton/Bundle/Inner Pack:	4.1	4.85	5.75	7.5	3.5	6
Case:	8.4	9.75	6	7.75	7.624	12
Pallet:	1550	48	49.63	40	1562.749	2100

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			00364380160014	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack			20364380160018	
<input checked="" type="checkbox"/> Case			50364380160019	
<input checked="" type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	<input type="text" value="\$36.00"/>	Whsl. Code #:	
As of date:		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: