

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

Application Number for NOAMANGAL (Large): PRAINTS (Applicate) and a product of the first of the product of the	Version 2021						Introduction Type:	New Item	X	Final Version			Date:	5.20.	.2022
Application before the DANADORAN CANADORAN CANDER SECTION 1997 1997 1997 1997 1997 1997 1997 199				PRODUCT INFORMA	ATION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Application before the DANADORAN CANADORAN CANDER SECTION 1997 1997 1997 1997 1997 1997 1997 199	Company Name:	Strides Pharma I	nc.				Application:	ANDA	a. Temperature – Indi	icate the USP temp	erature range for	r this product			
Charles Char	Application Number for NDA/A	NDA/BLA (drug); F	PMA/510(k)(med de	vice):	201	087								38° – 77° F)	
Part	Medical Device Class, if application	able:													
Section Control Cont	DUNS:	11-8344-504							Other T	emperature Range	Requirement	Excursions r	permitted to	15° to 30°C (5	59° to 86°F)
## ACT Code: Provide by Particle by Part			Name: Amlo	•		ablets				vrite in)					
## PROOF Is Spritten file or product for the product on the product on the product of the product on the product of the produc	_	64380-199-01			:			380199014	Notes						
Address lagred eithorise (1) Address lagred eithorise (1) Figure 125 Face 1	UDI			CVX Code:			MVX Code:								
Additional Content Service	Description:	Peach to light bro	own, film coated, ova	al shaped biconvex tablets, o	debossed with 'P	on one side	of the tablet and '174' on	the other	1						-
Contract for importance excession operations Contract for Special Contract for Specia	Anthon Louis Points		Analadiaina Daada		lt				Is this p	product to be shippe	d to customers on	dry ice?		No]
Section Product Information Product In	Active ingredient(s):		Amiodipine Besyla	ate; Hydrochlorothlazide; vai	Isartan				h Contact for tompor	aturo ovourcion a	loctions:				
Market Product Produ	URL for Additional Product Infor	rmation·								-	lestions.	Petronia An	derson		
State Control Contro	Address:		ad				Address 2:		- 1						
Part	City:	Chestnut Ridge				State:	NY Zip	10977	Group	E-mail:		petronia.and	lerson@stric	desusa.com	
Authorized States Product The reposite Classification Separate frame position Separate	Key Contact:					1		rvice@stridesusa.com]						
ADDITIONAL PRODUCT INFORMATION It is the Product. It is the Product is the Vice of State of	Phone Number:					Fax:	609-935-0806		- · · · ·	-					4
The product is?	Product Therapeutic Classificati	ion:	anti-anginal; anti-h	nypertensive; diuretic					Special	returns requiremen	ts for this product	?		No	
The product is?									, , , , , , , , , , , , , , , , , , ,						1
a lagrand device? No Orphan Dup Shares FOA Approach Status FOA Status FOA Approach Status		ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (uni	t of sale) upright?					1
Sec.	-				· ·	nly			11	t product (unit of s	ale) from light?				
Strongth: 10mg / 15mg /	_		No		Neither		Size:	30	11		CC PCC ()			36	Months
## Second Component parts Table Component parts Component pa			No	Orpnan Drug Status				10mg / 160mg / 12 5mg	Initial s	sneif life at launch	(if different):				Months
Dosage Form: Tablet Dosa			INO	FDA Approval Status			Strength:	Tomg / Toomg / T2.5mg			ORDER INFOR	MATION			
Allorgens No. Allorgens Present No. Product Color: Product Imprint: P774 No. No. Authorized General: other No. Autho	_ =			. элгирричин опини			D	Tablet						<u> </u>	
Product Shape: Product Color: Page Product Shape: Product Shape: Product Color: Page Product Color: Product Imprint: Product			No				Dosage Form:		Unit of	Sale		What is the	NDC selling	g unit?	
Product Stage:	co-licensed?		No	Allergens Present					х	_					
Canabilitide block? Open Country of Origin US Product Color: Product Imprint: Product Impri							Product Shape:	Oval		_		(Write-in, e.	g. 1 Box of	10 Vials)	
Authorized Genetic Equivalent to What Brand's Country of Origin US Froduct Cooperage Froduct Cooperag	•	2						pooch to light brown		- ·		Minimum	rdor aucontit		Voc
Country of Origin US Product Imprine: P174		f					Product Color:	peach to light brown		_		Willimum Or	ruer quantit	y r	168
If Unit Does, indicate NDC here: Tade Agreements Act (TAA)? Vest	1			Country of Origin	US		1 .	P 174							
FOR GENERIC DRUG PRODUCTS Authorized Generic If Authorized Generic, other section fields are not applicable section fields are not applic	If Unit Dose, is item bar coded to	unit dose for		, 0			Product Imprint:					If Yes, how	many of wh	nich package	type?
FOR GENERIC DRUG PRODUCTS Authorized Genetic, other section fields are not applicable (Write-in, e.g. 1 Vial) Exclore HCT 1 Solite 1 So	'														
Authorized Generic Transport Section Federate Section fields are not applicable Section fields are not appli	If Unit Dose, indicate NDC here:			Trade Agreements Act	(TAA)?	Yes								n/Pack	
Authorized Generic Hauthorized Generic									<u> </u>	Other: Write In			Case		
Company AB Section fields are not applicable Bottle Bott				FOR GENERIC DRUG PR	RODUCTS										
Company AB Section fields are not applicable Bottle Bott						Δι	ithorized Generic *If A	uthorized Generic other		PH	ARMACY ORDER	R / BILL LINIT			
Compress	I Onen no Book Botin no	AD			_ '	AC		•	Dec cell unit to quet		AKMAOTOKDEK				
Does supplier meet DSCSA definition of manufacturer? Yes GCP: If yes, select exempt from DSCSA? No GCP: Weight Lbs. Dimensions (Us meets) Dimensions (Us meets) Dimensions (Us meets) Dimensions (Us meets) Selected the legation of manufacturers exclusive distributor? No If yes, was original product of purchased direct from Infr? Provide source manufacturer for repackaged product If yes, attach documentation from FDA. GTIN AND HIBCC PRODUCT INFORMATION GTIN 14 Unit of Use GTIN-14 Dimensions (Us meets) Dimensions (Us meets) Volume Saleable Unit of Measure As Beor-Carton-Bundle/Inner Pack: Case: 2.7 13.25 9 4.25 506.8125 24 Pallet: 470 48 40 51.75 99380 3698 COST INFORMATION Regular Cost Invoice Cost (WAC) (\$) S221.45 Whist-Code #: Fineline Code: As of date: As of date: As of date:			Exforce HCT					• • • • • • • • • • • • • • • • • • • •			1	KX billing u		iacy:	
Does supplier meet DSCSA definition of manufacturer? Yes GLN: OSS9556421464 ITEM AND PACKING INFORMATION Weight Lbs. Dimensions (US minute) Weight Lbs. Dimensions (US minute) Depth Width Height (Cube) Plece is product repackaged? If yes, select exemption: Sis product repackaged? No No If yes, was original product purchased direct from mif? Provide source manufacturer for repackaged product If yes, and waiver/exception/exemption for product? No Saleable Unit of Measure Saleable Unit of Measure Saleable Unit of Measure Saleable Ouanity Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.	ii. Generic Equivalent to What Bi	rana : .	Exiolge 1101							itto	1				
If yes, salect exemption:			DRUG SUPPL	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION									
If yes, salect exemption:					_										
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Case Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Saleable Unit of Use GTIN-14 Saleable Uni	• • •		urer?			GLN:	0359556421464			ITEM	AND PACKING I	NFORMATIO	N		
Saleable Unit of Measure Saleable Unit of Unit of Use GTIN-14 Unit of Use GTIN-14 Saleable Unit o	Is product exempt from DSCSA?	?		No					-						
Sproduct repackaged? No If yes, was original product purchased direct from mfr? No Provide source manufacturer for repackaged product If yes, attach documentation from FDA. Tem/Each 1.2 6.5 8.5 3.75 207.1875 12						GCP:				Weight Lbs.		•	•		Saleable
Seproduct sold by manufacturer's exclusive distributor? No Provide source manufacturer for repackaged product	-			No		If you was a	riginal product		Itom/Each:		Depth	Width	Height	(Cube)	Pieces
Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Provide source manufacturer for repackaged product Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Unit of Use GTIN-14 Source from FDA Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Source from FDA Source from FDA Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Cost (Invoice Cost (WAC) (S) Source from FDA Source		r'e avelusiva distrib	hutor?						item/Each:	0.09	2.05	2.05	3.37	14.162425	1
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Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14								.		1.2	6.5	8.5	3.75	207.1875	12
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14									Case:	2.7	13.25	Q	4 25	506 8125	24
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14			GTI	IN AND HIBCC PRODUCT I	INFORMATION					2.1	10.20	J	4.20	300.0123	24
X	Octobby How of Manager			LUDGO		0.71		11 % (11 OTN) (4	Pallet:	470	48	40	51.75	99360	3696
X Box/Carton/Bundle/Inner Pack 12 20364380199018 50364380199019 Regular Cost Invoice Cost (WAC) (\$) \$271.45 Fineline Code: Substituting the company of the company of the copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		S	saleable Quantity	HIBCC				Unit of Use G FIN-14							
X Case Pallet Regular Cost Invoice Cost (WAC) (\$) As of date: Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.			12						COS	ST INFORMATION		1	WHOLESAL	ER USE ONL	Y:
Pallet Regular Cost Invoice Cost (WAC) (\$) S271.45 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.															
Invoice Cost (WAC) (\$) \$271.45 Whsl. Code #: Fineline Code: As of date: Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.									Regular Cost			Vendor #:			
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.									11 -	\$)	\$271.45				
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.												Fineline Co	de:		
									As of date:			4			
	1			Attach	TA CUEET (22.2	\\ a=== !	rd lawer DAOMAGE INC.	DT LADEL AND BUCTO OF	III						
A PERSON DESCRIPTION OF THE PROPERTY OF THE PR	*Please provide any additional in	nformation on no-		Attach copy of SAFETY DA	IA SHEET (SDS	o) or non haza									



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

Version 2021 For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):						
a. Cytotoxic?	No	SDS Hazard (Classification			
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?						
Is the product a CA Prop 65 carcinogen?	No	Organic Corrosiv	e			
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic Oxidizer				
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen Contact	Hazard			
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,				
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:				
(If yes, attach SDS with special instructions.)		NFPA Storage Level:				
e. Does the product contain DEHP?	No					
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?				
(if yes, answer a-e below and provide SDS)		If yes, indicate which:				
a. UN/Identification Number		, , , , , , , , , , , , , , , , , , , ,				
b. Proper Shipping Name						
c. DOT Hazard Class		Hazardous Waste Identification				
d. Packing Group						
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics			
Is this product regulated for shipment by IATA?	No					
(if yes, answer a-e below and provide SDS)	-	REMS or REGISTR	Y RESTRICTIONS			
a. UN/Identification Number						
b. Proper Shipping Name		Is there a REMS on this product?				
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?				
d. Packing Group		Website URL:				
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required				
Passenger		Limited Distribution Requirement				
Cargo		Comments / Details: (For example, iPledge program?)				
Passenger & Cargo						
Is this a reportable quantity? No		REMS:				
RQ Threshold:		REMS Program Manager Name:	Phone:			
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:	T Hono.			
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:				
No (if yes, identify method below)		Provider Name:	DEA #:			
Limited Quantity		Site Enrollment Number assigned	NCPDP#:			
Consumer Commodity, ORM-D		by Supplier:	NPI#:			
Small Quantity (49 CFR 173.4)						
Special Permit; DOT-SP		Comments				
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#		Registry:				
		Registry Program Contact Name:	Phone:			
ADD'L STORAGE INFORMATION		Comments				
Is the Product						
Controlled Substance? No Controlled Substance Code		RETURN INS	TRUCTIONS			
Controlled by State(s)? No Listed Chemical (List I or II)	No					
ARCOS Reportable? No If yes, indicate which:		Contact tel. # if product received damaged:				
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:				
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices						
Restricted to retail pharmacy only:		Special regulations or returns requirements for this				
Restricted to hospital, clinics, and physician offices only:		product in certain states?				
Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?				
Comments:						
MIRAL		IS NOTES and/or Image of Product Barcode:				
IVIISC		TO THE PER AND THE ANGLE OF THE OLD COLOR				



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

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by:	Purchase order daily receipt cut off time by supplier				
a. EDI	Cut off time:				
b. Autofax Fax Number:					
c. Fax Fax Number:	Shipping lead time of PO: Hours Days				
d. Phone only					
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:				
Minimum Order Quantity:	Ships for second day receipt:				
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:				
Contracted 3PL company / contact #: Name:					
Phone:					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order:	Overnight receipt available:				
Drop Ship service fee billed with each order:	PO Receipt cut off time:				
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday				
Comments:	Tuesday				
	Wednesday				
	Thursday				
	Friday				
	Priority Overnight receipt available:				
Class of Trade Restriction:	PO Receipt Cut off time:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:				
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	PO Receipt Cut off time: Phone: Phone #:				
Restricted to Hospital, clinics, and physician offices only. Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax: Friorie: Friorie				
Comments:	EDI:				
Commonto.	Overnight Fees apply:				
	Other fees apply:				
Other Data Information Required to Process PO:	Return Instructions				
Patient Procedure Date:	Contact # if product is received damaged:				
Physician Name:	Is product returnable for credit: URL/Link to returns policy:				
Physician/Clinic Phone # Physician State License #	ORL/Link to returns policy.				
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?				
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?				
Miscellaneous Notes:	in so, minor states of state requirements.				
Miscentificous Notes.					
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure?				
	Is product order for restocking purposes?				