

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

Version 2021				Introduction Ty	pe: Pos	t Launch Change	1	Final Version			Date:	7/12/	2023
		PRODUCT INFORMATION						SPECIAL HAN	DLING AND STOP	AGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANI	DA/BLA (drug); PMA/510(k)(me	d device):	216229				Tempera	ature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:													
DUNS:	11-856-3719							emperature Range F	Requirement				
Proprietary Name (If Applicable) an Selling Unit NDC:	31722-030-32	Deferasirox Oral Granules 180mg Unit of Use NDC:		UPC: 3	331722030328		(wi Notes	rite in)					
UDI	31722-030-32	CVX Code:		MVX Code:	551722050520	)	notes						
Description:	Deferasirox Oral Granules 180r						la thia pr	oduct to be shipped	d to quotomoro on i			No	
Description.	Dererasilox Oral Granules 1001	iig						oduct to be shipped				No	
Active Ingredient(s): Deferasirox										.,			
	b. Contact for temperature excursion questions:												
URL for Additional Product Inform Address:		rpharma.com		Address 2:			Name: Number	_		Soma Raju 732-529-042	2		
City:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 Piscataway State:			NJ Zip: 08854			Group E	somaraju@heterousa.com					
Key Contact:	Customer Service Email:			customerservice@camberpharma.com			o oup 1			<u>oomaraja on</u>	010100000.001	<u>.</u>	
Phone Number:	1-866-827-3647		Fax:	732-562-8788			c. Special regulations	for product in any	states?			No	
Product Therapeutic Classification	n: Iron-Chelatir	ng Agent					Special	returns requirement	ts for this product?			No	
				DDODUOT-DE	September							N	
	ADDITIONAL PROD			PRODUCT DE	SCRIPTION	NFORMATION	d. Store product (unit	,				No	
The product is?			rect-Ship Only hit Dose		<b>60</b> ·			product (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #	No	Is the Product Ur Orphan Drug Status		Size:	30ct		e. Shelf life:	nelf life at launch (	if different).			24	Months Months
a product kit?	No				180mg		initial si	ion me at launch (	n amerenty.				months
if yes, list NDCs of		FDA Approval Status		Strength:	1				ORDER INFORM	IATION			
component parts				Dosage Form:	Granula	ar powder							
reverse numbered?	No						Unit of S	-		What is the		unit?	
co-licensed? latex-free?	No Yes	Allergens Present			N/A		1	Bottle Box/Carton		1 carton of 3	0 sachets g. 1 Box of 1	) Viele)	
preservative-free?	Yes			Product Shape	e:			Ampule		(write-in, e.	y. I BUX UI II	J Vidis)	
correctional institution block?	No			Bredwet Color	white to	off white		Glass		Minimum or	der quantity	?	Yes
opioid?	No			Product Color:				Tube					
Cannabinoid?	No	Country of Origin Inc	dia	Product Imprin	nt: N/A			Vial Liquid Sgl					
If Unit Dose, is item bar coded to un hospital scanning?	nit dose for No	Is this product covered under	the	-				Vial Liquid Multi Vial Powder Sol		If Yes, how	many of whi Each	ch package t	sype?
If Unit Dose, indicate NDC here:	31722-030-3							Vial Power Multi			Inner/Carton	/Pack	
								Other: Write In			Case		
		FOR GENERIC DRUG PRODU	CTS										
							PHARMACY ORDER / BILL UNIT						
			Au			Generic, other are not applicable			IARMACY ORDER				
I. Orange Book Rating: AB						are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:				acy:		
II. Generic Equivalent to What Brand?: Jadenu Sprinkle							(Write-in, e.g. 1 Vial) Each						
	DRUG	SUPPLY CHAIN SECURITY ACT (DSC	SA) INFORMATION				,				Milliliter		
Deserved in the second second second				000470000000				17221	I AND PACKING I	FORMATION			
Does supplier meet DSCSA definit Is product exempt from DSCSA?	non of manufacturer?	Yes	GLN:	0331722000000				TEN	FAND PACKING I	NFORMATION	V		
If yes, select exemption:			GCP:						Dimensi	ons (US msm	nts)	Volume	Saleable #
Other exemption - Write in:			GUF.					Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No		riginal product purch	ased		Item/Each:	0.1	4.06	2.125	3.25	. ,	1
Is product sold by manufacturer's		Yes	direct from m					0.1	4.00	2.120	0.20		· · · ·
Has FDA granted waiver/exception If yes, attach documentation from		No	Provide source	ce manufacturer for I	repackaged p	roduct	Box/Carton/Bundle/ Inner Pack:						
i yes, attach documentation non							Case:	4.45	47.40	44.75			0.1
		GTIN AND HIBCC PRODUCT INFOR	RMATION					4.15	17.13	11.75	5.5		24
Only the line's of Management							Pallet:						
Saleable Unit of Measure	Saleable Quan	tity HIBCC		N-14	Unit o	f Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack	1 00331722030328						COS	T INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case													
Pallet							Regular Cost			Vendor #:			
							Invoice Cost (WAC) (\$)	)	\$2,000.00	Whsl. Code			
	-						As of data:	1/30/2023		Fineline Coo	de:		
							As of date:	1/30/2023					
		Attach copy of SAFETY DATA S	SHEET (SDS) or non haza	rd letter, PACKAGE IN	NSERT, LABE	L AND PHOTO OF P	RODUCT PACKAGING an	d BARCODE.		•			
*Please provide any additional info	ormation on page 2.			See new p. 3 for D	esignated Dr	op Ship Only.	Signatu	re:					

## **HDA** Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 For Des	rop Ship Only Products, Please Use Page 3					
MATERIA	L HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? N b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? N Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? C. Contact Hazard? C. Contact Hazard? C. Contact require special clean-up instructions? (If yes, attach SDS with special instructions.) E. Does the product contain DEHP? N Is this product regulated for shipment by DOT? (If yes, answer a-e below and provide SDS)	X     Organic     Corrosive       Do     Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard       Does the product have an Aerosol class? If yes, identify NFPA Storage Level:     No       NFPA Storage Level:     Image: Contact Hazard					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? N	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? N	No       If Yes, is it managed with a pharmacy registry?       Website URL:					
Is the product restricted for air shipment? If so, indicate restriction:          No         No	Med Guide Required     No       Limited Distribution Requirement     Image: Comments / Details: (For example, iPledge program?)       REMS:     No					
RQ Threshold:       NO         Is this a marine pollutant?       No         Is this product shipped utilizing an authorized DOT exception or Special Permit?         No       (if yes, identify method below)         Limited Quantity         Consumer Commodity, ORM-D         Small Quantity (49 CFR 173.4)         Special Permit; DOT-SP         Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS     REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Site Enrollment Number assigned     DEA #:       by Supplier:     NPI #:					
SP# ADD'L STORAGE INFORMATION	Registry:     No       Registry Program Contact Name:     Phone:       Comments					
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) N ARCOS Reportable? Schedule No. CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy:					
No restricted to retail pharmacy only:     N       Restricted to retail pharmacy only:     N       Restricted to hospital, clinics, and physician offices only:     N       Restricted from US territories? (explain in comments)     N       Comments:     N	D     Special regulations or returns requirements for this       p     product in certain states?					
	ANEOUS NOTES and/or Image of Product Barcode:					
MISCELL						



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