

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

						Introduction 1	Type: New Item		x Final Version			Date:	11/7/	/2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceu	uticals, Inc.				Applica	tion: ANDA	a. Temperature	e – Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/ANI	DA/BLA; PMA/510(k	k): 216841				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:													
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ne: Rufinam	nide Oral Suspension 40 mg	g/mL				-	(write in)					
Selling Unit NDC:	31722-688-46		Unit of Use NDC:		31722-688-46	UPC: MVX Code:	331722688468		Notes					
UDI			CVX Code:			WVX Code.		-						1
Description:	Rufinamide Oral Su	uspension 40 mg/mL							Is this product to be shippe				No	
Active Ingredient(s):		Rufinamide, USP							Is this product to be shippe	d to customers on c	iry ice?		No	
Active ingredient(3).		Kumamude, 001						b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform	ation:	www.camberpharma.	com						Name:		Soma Raju			
Address:	800 Centennial Ave	a, Suite 1				Address 2:			Number:		732-529-042	23		
City:	Piscataway				State:	NJ	Zip: 08854		Group E-mail:		somaraju@h	neterousa.cor	<u>n</u>	
Key Contact:	Customer Service				Email:		@camberpharma.com							1
Phone Number:	1-866-827-3647				Fax:	732-562-8788			ulations for product in any				No	
Product Therapeutic Classification	r: /	Anticonvulsant							Special returns requiremen	ts for this product?			No	
		NAL PRODUCT INFO				PRODUCT	DESCRIPTION INFORMATION	d Store produ	ct (unit of sale) upright?				No	1
	ADDITIO	NAL PRODUCT IN		Disc of Ohim	2	PRODUCT] 1
The product is? a legend device?	Г	Na	Is the Product Is the Product	Direct-Ship (Unit of Use	Jniy		460 mL	e. Shelf life:	Protect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		No	Orphan Drug Status	onit of Use		Size:	400 IIIL		Initial shelf life at launch (if different).			24	Months Months
a product kit?		No	orphan Drug otatao			0	40 mg/mL			, and a second sec				montilo
if yes, list NDCs of			FDA Approval Status			Strength:	0			ORDER INFORM	IATION			
component parts						Dosage Form	n: Oral suspension							
reverse numbered?		No							Unit of Sale			NDC selling		
co-licensed? latex-free?		No	Allergens Present				N/A	1	x Bottle		1 Bottle of 4			
preservative-free?		Yes No	Alco	ohol		Product Sha	pe:		Box/Carton Ampule		(write-in, e.	g. 1 Box of 1	J viais)	
correctional institution block?		No					White		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				Product Cole	br:		Tube					
Cannabinoid?	1	No	Country of Origin	India		Product Imp	rint: N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					outorp			Vial Liquid Multi				ich package t	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered un Trade Agreements Act (T		Ne				Vial Powder Sgl		12	Each	/De els	
Il Unit Dose, Indicate NDC nere:			Trade Agreements Act (1	AA)?	No				Vial Powder Multi Other: Write In			Inner/Carton Case	Pack	
			FOR GENERIC DRUG PRO									louoo		
	<u>.</u>													
							*If Authorized Generic, other		DL					
I. Orange Book Rating:	AB				Aut	horized Generic	II Authonzeu Generic, other			IARMACT ORDER	/ BILL UNIT			
II. Occurring Environmental Million Device	AD				Aut	norized Generic	section fields are not applicable	Rec. sell unit t		TARMACT ORDER		nit to pharma	асу:	
II. Generic Equivalent to What Bran		Banzel		1	Aut	norized Generic		Rec. sell unit t		IARMACT ORDER		nit to pharma Each	асу:	
II. Generic Equivalent to what Brai					·	norized Generic		(Write-in, e.g.	to customer? 1 Vial)	TARMACT ORDER		Each Gram	acy:	
II. Generic Equivalent to what Brai			CHAIN SECURITY ACT (DSCSA) INFO	·	norized Generic			to customer? 1 Vial)			Each	acy:	
	nd?:	DRUG SUPPLY		DSCSA) INFO	RMATION			(Write-in, e.g.	to customer? 1 Vial) e:]	Rx billing u	Each Gram Milliliter	acy:	
Does supplier meet DSCSA definit Is product exempt from DSCSA?	nd?:	DRUG SUPPLY	Yes	DSCSA) INFO	·	0331722498975		(Write-in, e.g.	to customer? 1 Vial) e:	ARMACT OKDER	Rx billing u	Each Gram Milliliter	acy:	
Does supplier meet DSCSA definit Is product exempt from DSCSA?	nd?:	DRUG SUPPLY	Yes	DSCSA) INFO	RMATION GLN:			(Write-in, e.g.	io customer? 1 Vial) e: ITEN	AND PACKING I	Rx billing u	Each Gram Milliliter		Saleable #
Does supplier meet DSCSA definit	nd?:	DRUG SUPPLY	Yes	DSCSA) INFO	RMATION			(Write-in, e.g.	to customer? 1 Vial) e:	AND PACKING I	Rx billing u	Each Gram Milliliter	acy: Volume (Cube)	Saleable # Pieces
Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption:	nd?:	DRUG SUPPLY	Yes No No	DSCSA) INFO	RMATION GLN: GCP:		section fields are not applicable	(Write-in, e.g.	o customer? 1 Vial) e: TEI Weight Lbs.	A AND PACKING II Dimensi Depth	Rx billing u	Each Gram Milliliter N nts.) Height	Volume (Cube)	Pieces
Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacture	DRUG SUPPLY	Yes No No Yes	DSCSA) INFO	RMATION GLN: GCP: If yes, was or direct from m	0331722498975 ginal product pure fr?	section fields are not applicable	(Write-in, e.g. HCPCS J-Code	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36	AND PACKING I	Rx billing u	Each Gram Milliliter	Volume	
Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nd?:	DRUG SUPPLY	Yes No No	DSCSA) INFO	RMATION GLN: GCP: If yes, was or direct from m	0331722498975 ginal product pure fr?	section fields are not applicable	(Write-in, e.g. HCPCS J-Code	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36	A AND PACKING II Dimensi Depth	Rx billing u	Each Gram Milliliter N nts.) Height	Volume (Cube)	Pieces
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Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nd?:	DRUG SUPPLY	Yes No No Yes		RMATION GLN: GCP: If yes, was ori direct from m Provide source	0331722498975 ginal product pure fr?	section fields are not applicable	(Write-in, e.g. HCPCS J-Code	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36	A AND PACKING II Dimensi Depth	Rx billing u	Each Gram Milliliter N nts.) Height	Volume (Cube)	Pieces
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Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	nd?:	DRUG SUPPLY or? or? duct? GTIN	Yes No No Yes No AND HIBCC PRODUCT IN		RMATION GLN: GCP: If yes, was ori direct from m Provide sourc	0331722498975 Iginal product pure fr? ee manufacturer fc	section fields are not applicable chased r repackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case:	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36 undle/	A AND PACKING II Dimensi Depth 4	Rx billing u	Each Gram Milliliter N Height 7.5	Volume (Cube) 102.00	Pieces 1
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Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	nd?:	DRUG SUPPLY ir? or? duct? GTIN Saleable Quantity 1	Yes No No Yes No AND HIBCC PRODUCT IN		RMATION GLN: GCP: If yes, was ori direct from m Provide source GTIN 0032	0331722498975 iginal product pure fr? se manufacturer fc N-14 31722688468	section fields are not applicable chased r repackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case:	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36 undle/	A AND PACKING II Dimensi Depth 4	Rx billing u	Each Gram Milliliter nts.) Height 7.5 8.5	Volume (Cube) 102.00	Pieces 1 12
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Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	nd?:	DRUG SUPPLY ir? or? duct? GTIN Saleable Quantity 1	Yes No No Yes No AND HIBCC PRODUCT IN		RMATION GLN: GCP: If yes, was ori direct from m Provide source GTIN 0032	0331722498975 iginal product pure fr? se manufacturer fc N-14 31722688468	section fields are not applicable chased r repackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case:	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36 andle/ 18.15 COST INFORMATION	A AND PACKING I Dimensi Depth 4 16.5	Rx billing u	Each Gram Milliliter nts.) Height 7.5 8.5 8.5	Volume (Cube) 102.00 1507.69	Pieces 1 12
Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	nd?:	DRUG SUPPLY ir? or? duct? GTIN Saleable Quantity 1	Yes No No Yes No AND HIBCC PRODUCT IN		RMATION GLN: GCP: If yes, was ori direct from m Provide source GTIN 0032	0331722498975 iginal product pure fr? se manufacturer fc N-14 31722688468	section fields are not applicable chased r repackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code Item/Each: Box/Carton/Bt Inner Pack: Case: Pallet:	to customer? 1 Vial) e: ITEN Weight Lbs. 1.36 andle/ 18.15 COST INFORMATION WAC) (\$)	A AND PACKING I Dimensi Depth 4 16.5	Rx billing u	Each Gram Milliliter nts.) Height 7.5 8.5 8.5 WHOLESALL #:	Volume (Cube) 102.00 1507.69	Pieces 1 12
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Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	nd?:	DRUG SUPPLY ir? or? duct? GTIN Saleable Quantity 1 12	Yes No No Yes No AND HIBCC PRODUCT IN HIBCC		RMATION GLN: GCP: If yes, was ori direct from m Provide source GTIN 0033 2033	0331722498975 iginal product puri fr? æ manufacturer fo 	section fields are not applicable chased Unit of Use GTIN-14 331722688468	(Write-in, e.g. HCPCS J-Code Box/Carton/Bu Inner Pack: Case: Pallet: Regular Cost Invoice Cost (M As of date:	to customer? 1 Vial) e: ITEN Weight Lbs. I.36 Indle/ 18.15 COST INFORMATION WAC) (\$) 4/4/2024	A AND PACKING I Dimensi Depth 4 16.5	Rx billing u	Each Gram Milliliter nts.) Height 7.5 8.5 8.5 WHOLESALL #:	Volume (Cube) 102.00 1507.69	Pieces 1 12
Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	nd?:	DRUG SUPPLY or? or? duct? CTIN Saleable Quantity 1 12	Yes No No Yes No AND HIBCC PRODUCT IN HIBCC		RMATION GLN: GCP: If yes, was ori direct from m Provide source GTIN 0033 2033	0331722498975 iginal product pure fr? ee manufacturer fo N-14 31722688468 31722688462 d letter, PACKAGE	section fields are not applicable chased r repackaged product Unit of Use GTIN-14	(Write-in, e.g. HCPCS J-Code HCPCS J-Code Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet: Regular Cost (NAs of date: PRODUCT PACKAG	to customer? 1 Vial) e: ITEN Weight Lbs. I.36 Indle/ 18.15 COST INFORMATION WAC) (\$) 4/4/2024	A AND PACKING I Dimensi Depth 4 16.5	Rx billing u	Each Gram Milliliter nts.) Height 7.5 8.5 8.5 WHOLESALL #:	Volume (Cube) 102.00 1507.69	Pieces 1 12

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

Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level: Is the product a NIOSH hazardous drug? No
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If yes, indicate which: Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) (if Unit for the North Context of the Nor	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Is this a reportable quantity? No RQ Threshold: 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)	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: NCPDP#: Site Enrollment Number assigned NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments
SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes
	URL/Link to returns policy:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this
No No Restricted from US territories? (explain in comments) No	Special regulations of returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Comments:	
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



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

Version 2024 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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: 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:	PO Receipt Cut off time: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: EDI: Covernight Fees apply: Other fees apply: Image: Covernight 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?