

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

Version 2021				Introduction Typ	e: Post Launch Change		2 Final Version			Date:	10/19	/2023		
		PRODUCT INFORMA	TION				SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*				
Company Name:	mpany Name: Camber Pharmaceuticals. Inc. ANDA							rature range for t	his product.					
Application Number for NDA/ANI	DA/BLA (drug); PMA/510(k)(m	ed device):	091560				mperature Range	Controlled Room		and 25 C (68	° – 77° F)			
Medical Device Class, if applicable:														
DUNS:	11-856-3719					Oth	ner Temperature Range F	Requirement						
Proprietary Name (If Applicable) a	nd Established Name:	Abacavir Tablets USP, 300 mg					(write in)							
Selling Unit NDC:	31722-557-60	Unit of Use NDC	31722-557-60		31722557603	No	tes							
UDI		CVX Code:		MVX Code:										
Description:	Abacavir Tablets USP, 300 m	g					this product to be shipped				No			
Action learn directed by the shipped to customers on dry ice? No														
Active Ingredient(s): Abacavir b. Contact for temperature excursion questions:														
URL for Additional Product Inform	URL for Additional Product Information: www.camberpharma.com							Name: Soma Raju						
Address:	1031 Centennial Ave (and) 80			Address 2:			mber:		732-529-042	3				
City:	Piscataway		State:	NJ	Zip: 08854		oup E-mail:		somaraju@he					
Key Contact:	Customer Service		Email:	customerservice@cam	berpharma.com									
Phone Number:	1-866-827-3647		Fax:	732-562-8788		c. Special regulat	tions for product in any	states?			No			
Product Therapeutic Classification	n: Nucleoside	e reverse transcriptase inhibitorr				Sp	ecial returns requirement	s for this product?			No			
	ADDITIONAL PROD	DUCT INFORMATION		PRODUCT DE	SCRIPTION INFORMATION	-	(unit of sale) upright?				No			
The product is?		Is the Product	Direct-Ship Only				otect product (unit of sa	le) from light?			No			
a legend device?	No	Is the Product	Unit of Use	Size:	60 ct	e. Shelf life:					24	Months		
if yes, enter class # a product kit?	No	Orphan Drug Status				Init	tial shelf life at launch (i	t different):				Months		
if yes, list NDCs of	INO	FDA Approval Status		Strength:	300 mg			ORDER INFORM						
component parts		T DA Approval Guildo												
reverse numbered?	No			Dosage Form:	Film coated tablet	Un	it of Sale		What is the	NDC selling	unit?			
co-licensed?	No	Allergens Present					x Bottle		1 Bottle of 6	0 Tablets				
latex-free?	Yes			Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)			
preservative-free?	Yes			i roudot onapo	Capoulo		Ampule							
correctional institution block?	No	_		Product Color:	Yellow		Glass		Minimum or	der quantity	?	Yes		
opioid?	No	Country of Origin	India		H on one side and 139 on other		Tube							
Cannabinoid? If Unit Dose, is item bar coded to u	No No	Country of Origin	India	Product Imprin	t: side seperating 13 & 9 with score	e	Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of which	rh nackade f	vne?		
hospital scanning?		Is this product covered	under the		line		Vial Powder Sol			Each	in puckage i	ype :		
If Unit Dose, indicate NDC here:		Trade Agreements Act (Vial Power Multi			Inner/Carton/	Pack			
							Other: Write In			Case				
		FOR GENERIC DRUG PF	RODUCTS							-				
			Au		f Authorized Generic, other			ARMACY ORDER	/ BILL UNIT					
	AB			Se	ection fields are not applicable	Rec. sell unit to c	ustomer?		Rx billing u	nit to pharma	icy:			
II. Generic Equivalent to What Bran	nd?: Ziagen					Each								
(Write-in, e.g. 1 Vial) DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION										Gram Milliliter				
	BROC		(DOODA) IN ON MATION			-				winning				
Does supplier meet DSCSA definit	tion of manufacturer?	Yes	GLN:	0331722000000			ITEN	AND PACKING I	NFORMATION	N				
Is product exempt from DSCSA?		No												
If yes, select exemption:			GCP:				14/-1-1-1	Dimensi	ons (US msm	nts.)	Volume	Saleable #		
Other exemption - Write in:							Weight Lbs.	Depth	Width	Height	(Cube)	Pieces		
Is product repackaged?		No		riginal product purcha	ised	Item/Each:	0.2	1.75	1.75	3.5	10.72	1		
Is product sold by manufacturer's		Yes	direct from m											
Has FDA granted waiver/exception If yes, attach documentation from		No	Provide sour	ce manufacturer for r	epackaged product	Box/Carton/Bund Inner Pack:	le/							
in yes, attach documentation non						Case:								
		GTIN AND HIBCC PRODUCT	INFORMATION				11.4	11.25	8.25	9.38	870.12	48		
						Pallet:								
Saleable Unit of Measure	Saleable Qua	ntity HIBCC		N-14	Unit of Use GTIN-14									
X Item/Each														
Box/Carton/Bundle/Inner Pack	Bundle/Inner Pack 48 30331722557604					COST INFORMATION			WHOLESALER USE ONLY:					
X Case Pallet	48		303	31722557604		Regular Cost			Vendor #:					
r and						Invoice Cost (WA	C) (\$)	\$150.00	Whsl. Code	# ·				
							-/ (+/		Fineline Co					
						As of date:			1					
									1					
μ									I					
		Attach copy of SAFETY D	ATA SHEET (SDS) or non haza		SERT, LABEL AND PHOTO OF P									
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:														

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

Version 2021 For Designat	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HAZ	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No 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? C. Contact Hazard? C. Contact Hazard? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? (If yes, answer a-e below and provide SDS)	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Oxidizer Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No
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? No	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?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo Is this a reportable quantity?	Med Guide Required No Limited Distribution Requirement
RQ Threshold: No Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments
Is the Product	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 yes, indicate which: If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: No restriction: Yes	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: contact - customerservice@camberpharma.com
NO restriction: Select YEs if sold to retail pharmacy, hospitals, clinics and physician offices YES Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments:	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



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?