

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

Version 2024						Introduction ³	Type: New	Item		x Final Version			Date:	11/20	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Applica	ition: AN	IDA	a. Temperature -	Indicate the USP temper	erature range for t	his product.			
Application Number for NDA/AN			107			NDA 505(b) Type				mperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical							·			· -					
DUNS:	11-856-3719								0	her Temperature Range I	Requirement	Do not freez	e. May be ref	rigerated.	
Proprietary Name (If Applicable) a		ame: Aba	acavir Oral Solution, USP 20 mg	J/mL						(write in)					
Selling Unit NDC:	31722-562-24		Unit of Use NDC:		31722-562-24		331722562249		No.	otes					
UDI			CVX Code:			MVX Code:									
Description:	Abacavir Oral So	olution, USP 20 mg/	mL						Is	this product to be shipped	d to customers on ic	ce?		No	
									Is	this product to be shipped	d to customers on o	Iry ice?		No	
Active Ingredient(s):		Abacavir sulfate,	, USP												
URL for Additional Product Inform	nation:	www.camberphar	rma com							nperature excursion qu ame:	estions:	Soma Raju			
Address:	800 Centennial A		mu.com		T	Address 2:				ımber:		732-529-042	23		
City:	Piscataway	-,			State:	NJ Zip : 08854			Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service	е			Email:	customerservice	@camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regula	tions for product in any	states?			No	
Product Therapeutic Classificatio	n:	Nucleoside analogue hu	man immunodeficiency virus (HIV-1) reverse	transcriptase inhibitor					Si	ecial returns requirement	s for this product?			No	
									. [
	ADDITI	IONAL PRODUCT	INFORMATION			PRODUCT	DESCRIPTION INFOR	MATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (Only	1				otect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	240 mL		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						ln In	itial shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	20 mg/mL				ORDER INFORM	IATION			
component parts			FDA Approvai Status				Clear oral solu	tion			ORDER IN ORI	IATION			
reverse numbered?		No				Dosage For	m:	uon	U	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle			40 mL Oral S		
latex-free?		Yes	Gluten, Corn,	Alashal When		Product Sha	N/A			Box/Carton			g. 1 Box of 10		
preservative-free?		No	Giuten, Com,	Alconol, Wilea		r roduct one				Ampule					
correctional institution block?		No				Product Col	or: Yellowish		_	Glass		Minimum o	rder quantity	?	Yes
opioid?		No		L. P.						Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	unit done for	No	Country of Origin	India		Product Imp	orint: N/A		-	Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ah naakaga (huno?
hospital scanning?	unit dose for		Is this product covered u	nder the					_	Vial Elquid Multi Vial Powder Sql			Each	сп раскаде і	type r
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No					Vial Powder Multi		- 10	Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
					Au	thorized Generic	*If Authorized Generic				IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA						section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Ziagen							Each								
		DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION				(Write-in, e.g. 1 \ HCPCS J-Code:	riai)			Gram Milliliter		
		5.100 00.		5000,1, 0.					nor oo o oode.		1		Ivillilitei		
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes		GLN:	0331722498975				ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.	Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										weight LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		iginal product pur	chased		Item/Each:	0.73	2.5	2.5	6	37.5	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Yes No	-	direct from m		or repackaged produc		Box/Carton/Bune	llo/					
If yes, attach documentation from		roduct?	NO		Provide sour	ce manuracturer to	or repackaged produc		Inner Pack:	ile/					
ii yoo, attaon accamentation not	27.11								Case:		11				
		G	TIN AND HIBCC PRODUCT I	NFORMATION						12.75	11	11	6.75	816.75	16
									Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use 0	STIN-14							
X Item/Each	N	Quantity 1			003	31722562249	0033172256	2249							
Box/Carton/Bundle/Inner Pack	IN	1			003	31122302249	0033172250	2243		COST INFORMATION			WHOLESALE	R USE ONL	Y:
X Case	N	16			303	31722562240									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost (W/	AC) (\$)	\$125.48	Whsl. Code			
												Fineline Co	de:		
									As of date:	9/15/2017		ļ			
			Attach copy of SAFETY DA	TA SHEET (OF)\$\ or non ha==	rd letter PACKACI	INCEDT I ADEL AND	DHOTO OF D	DODITOT BACKACI	NG and BARCODE		I			
l	formation on nage	_	Audul copy of SAFETT DA	IIA SHEET (SL	o non naza		r Designated Dron Shi		NODUCI FACKAGI	NO AND DARCODE.					



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Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

Series Product (selected at the stage by) Series Se	MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION						
Does the product a CA Prop 65 reprositive touland? Does the product based ears A CA Prop 65 reprositive Touland? a. C. Corract Heaterd? (if yes, attach 550 with appoint interactions) (if yes, attach 550 with appoint product regulated for enjoyenet by DOT? (if yes, attach 550 with appoint product regulated for enjoyenet by DOT? b. The product regulated for enjoyenet by DOT? a. In Nichellandian Number a. Experiment by DOT? b. The product regulated for enjoyenet by IATA? no c. DOT Heater Class	a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
d. Does the product require special dense up instructions? (if yes, submits 90 km) explored point instructions) (if yes, submits 90 km) explored provide SDS) (if yes, submits 90 km) explored SDS) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes) (if yes, submits 90 km) explored SDS (if yes)	Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Gi yes, native a ne below and provide SDS	d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	identify NFPA Storage Level:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product registed for shipment by IATA? (if yes, answer are below and provides Ush product shipped ush produc	(if yes, answer a-e below and provide SDS) a. UN/Identification Number							
Second content of the product regulated for shipment by ATA? No REMS or REGISTRY RESTRICTIONS	c. DOT Hazard Class d. Packing Group							
If yes, answer a-below and provide SDS SPAPE SP								
b. Propore Shipping Name c. DOT Hazard Class d. Packing Group l. Inhalation Hazard?	. ,	REMS or REGISTRY RESTRICTIONS						
Passenger Cargo Passenger & Cargo Phone: Phon	b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry?						
RQ Threshold: Is this a martine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No Consumer Commodity, QRM-D Small Quantity (49 CFR 173.4) Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION Is the Product Controlled Substance? Controlled Substance? Controlled Substance? No If yes, indicate which: Special Provision (listed in certain pharmacy, hopetas, derice and physician offices only: No restriction: Seed-YES # 204 to retail pharmacy, only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Supplier Manages REMS registry Provider Name: Supplier Manages Registry Provider Name: Supplier Manages Registry Provider Name: Support Name: Supplier Manages Registry Provider Name: Supplier Manage	Passenger Cargo	Limited Distribution Requirement						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION Is the Product Controlled Substance? Controlled Substance? Controlled Substance? No Schedule No. Is it a scheduled listed chemical product?: No Restricted to retail pharmacy only: Restricted to retail pharmacy only: Restricted from US territories? (explain in comments) Comments Comments Comments Comments Registry: No Registry Program Contact Name: Comments Registry Program Contact Name: Comments Registry: No Registry Program Contact Name: Comments Registry Program Contact Name: Comments Comments Registry: No Registry Program Contact Name: Comments Registry Program Contact Name: Comments Comments Registry: No Registry Program Contact Name: Comments Registry Program Contact Name: Comments Comments Registry: No Registry Program Contact Name: Comments Registry Program Contact Name: Comments Comments Registry: No Registry Program Contact Name: Comments Registry Program Contact Name: Comments Comments Registry: No Registry Program Contact Name: Comments No Registry Program Contact Name: Comments No Registry Program Contact Name: Comments No Registry Program Contact Name: Comments No Registry Program Contact Name: Comments Registry Program Contact Name: Comments No Registry Program Contact Name: N	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	REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned Phone: DEA #: NCPDP#:						
Registry: ADD'L STORAGE INFORMATION Is the Product Controlled Substance? Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices only: Restricted to no pairal, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special Permit; DOT-SP	Comments						
Registry Program Contact Name: Phone: Controlled Substance? No Listed Chemical (List 1 or II) No ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No Schedule No. CLASS OF TRADE RESTRICTION: Vestricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Registry Program Contact Name: Phone: Comments Registry Program Contact Name: Phone: Comments Registry Program Contact Name: Phone: Registry Program Contact Name: Phone: Comments Registry Program Contact Name: Phone: Registry Program Contact Name: Phone: Comments Registry Program Contact Name: Phone: Registry Program Contact Name: Phone: Comments Registry Program Contact Name: Phone: Comments Registry Program Contact Name: Phone: Registry		Device.						
Is the Product Controlled Substance? No Controlled Substance Code Listed Chemical (List I or II) ARCOS Reportable? Schedule No. No If yes, indicate which: Is it a scheduled listed chemical product?: No Restriction: Select YES # 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 Comments Comments Comments RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: URL/Link to returns requirements for this product in certain states? No Special regulations or returns requirements for this Product in certain states? If so, which states? Other requirements? No If so, which states? Other requirements?	5P#							
Controlled Substance? Controlled Substance? Controlled Substance? Controlled Substance? No ARCOS Reportable? Schedule No. CLASS OF TRADE RESTRICTION: No restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: Controlled Substance Code Listed Chemical (List I or II) No No If yes, indicate which: Is it a scheduled listed chemical product?: No No If yes, indicate which: Is it a scheduled listed chemical product?: No Is product returnable for credit: URL/Link to returns policy: Contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? If so, which states? Other requirements? Comments?	ADD'L STORAGE INFORMATION							
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: No 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: On If yes, indicate which: Is it a scheduled listed chemical product?: No URL/Link to returns policy: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?	Controlled Substance Code Controlled Substance Code	RETURN INSTRUCTIONS						
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: URL/Link to returns policy: contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? If so, which states? Other requirements?		Contact tel. # if product received damaged: 1-866-827-3647						
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) No Roments: Comments: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No No No No No No No If so, which states? Other requirements? Comments? Comments:		Is product returnable for credit: Yes						
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No No If so, which states? Other requirements? Comments?	CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? If so, which states? Other requirements? Comments?	No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com						
Restricted from US territories? (explain in comments) Comments: If so, which states? Other requirements? Comments?								
	Restricted from US territories? (explain in comments) No	·						
MISCELLANEOUS NOTES and/or Image of Product Barcode:	Comments:							
	MISCELLA	NEOUS NOTES and/or Image of Product Barcode:						



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

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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:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 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: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	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? Is product order for restocking purposes?