



Date: 5/4/2022

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212278							
Medical Device Class, if applicable:							
DUNS: 82-677-4775							
Proprietary Name (If Applicable) and Established Name: Atazanavir Capsules 300mg 30ct							
Selling Unit NDC: 31722-655-30				Unit of Use NDC:			
UDI				UPC: 331722655309			
CVX Code:				MXV Code:			
Description: Oral Solid - Capsule, Cap – Orange Opaque and Body – Green Opaque, 'H' on cap and 'A8' on body,							
Active Ingredient(s): Atazanavir							
URL for Additional Product Information:							
Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:			
City: Piscataway				State: NJ Zip: 08854			
Key Contact: Customer Service				Email: customerservice@camberpharma.com			
Phone Number: 1-866-827-3647				Fax: 732-562-8788			
Product Therapeutic Classification:							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?				Size: 30ct			
a legend device? No				Is the Product... Direct-Ship Only			
if yes, enter class #				Is the Product... Neither			
a product kit? No				Orphan Drug Status			
if yes, list NDCs of component parts				FDA Approval Status			
reverse numbered? No							
co-licensed? No				Allergens Present			
latex-free? Yes							
preservative-free? Yes							
correctional institution block?							
opioid? No				Product Shape: Capsule			
Cannabinoid? No				Product Color: Cap – Orange Opaque and			
If Unit Dose, is item bar coded to unit dose for hospital scanning? No				Product Imprint: 'H' on cap and 'A8' on bod			
If Unit Dose, indicate NDC here:				Country of Origin India			
				Is this product covered under the Trade Agreements Act (TAA)? No			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="checkbox"/> Authorized Generic <input type="checkbox"/> If Authorized Generic, other section fields are not applicable							
II. Generic Equivalent to What Brand?:							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes							
Is product exempt from DSCSA?							
If yes, select exemption:							
Other exemption - Write in:							
Is product repackaged? No							
Is product sold by manufacturer's exclusive distributor? No							
Has FDA granted waiver/exception/exemption for product? No							
If yes, attach documentation from FDA.							
Is product repackaged?							
Provide source manufacturer for repackaged product							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure							
Saleable Quantity							
HIBCC							
GTIN-14							
Unit of Use GTIN-14							
Regular Cost							
Invoice Cost (WAC) (\$)							
As of date:							
Signature:							
SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
a. Temperature – Indicate the USP temperature range for this product.							
Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Other Temperature Range Requirement (write in)							
Notes							
Is this product to be shipped to customers on ice? No							
Is this product to be shipped to customers on dry ice? No							
b. Contact for temperature excursion questions:							
Name: Soma Raju							
Number: 732-529-0423							
Group E-mail: somaraju@heterousa.com							
c. Special regulations for product in any states? No							
Special returns requirements for this product? No							
d. Store product (unit of sale) upright? No							
Protect product (unit of sale) from light? No							
e. Shelf life: 24 Months							
Initial shelf life at launch (if different): Months							
ORDER INFORMATION							
Unit of Sale							
What is the NDC selling unit?							
Minimum order quantity? Yes							
If Yes, how many of which package type?							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer?							
Rx billing unit to pharmacy:							
ITEM AND PACKING INFORMATION							
Weight Lbs.							
Dimensions (US msmts.)							
Volume (Cube)							
Saleable # Pieces							
Item/Each: 0.1							
Box/Carton/Bundle/Inner Pack:							
Case: 3.3							
Pallet:							
COST INFORMATION							
WHOLESALE USE ONLY:							
Regular Cost							
Invoice Cost (WAC) (\$)							
As of date:							
Signature:							

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
Is this product (check all that apply):			
a. Cytotoxic?	<input type="text" value="No"/>		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="text" value="No"/>		
Is the product a CA Prop 65 carcinogen?	<input type="text" value="No"/>		
Is the product a CA Prop 65 reproductive toxicant?	<input type="text" value="No"/>		
Does the product label bear a CA Prop 65 warning?	<input type="text" value="No"/>		
c. Contact Hazard?	<input type="text" value="No"/>		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="text" value=""/>		
e. Does the product contain DEHP?	<input type="text" value=""/>		
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text" value=""/>		
b. Proper Shipping Name	<input type="text" value=""/>		
c. DOT Hazard Class	<input type="text" value=""/>		
d. Packing Group	<input type="text" value=""/>		
e. Inhalation Hazard?	<input type="text" value="No"/>		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text" value=""/>		
b. Proper Shipping Name	<input type="text" value=""/>		
c. DOT Hazard Class	<input type="text" value=""/>		
d. Packing Group	<input type="text" value=""/>		
e. Inhalation Hazard?	<input type="text" value="No"/>		
Is the product restricted for air shipment? If so, indicate restriction:			
<input type="checkbox"/> Passenger	<input type="text" value=""/>		
<input type="checkbox"/> Cargo	<input type="text" value=""/>		
<input type="checkbox"/> Passenger & Cargo	<input type="text" value=""/>		
Is this a reportable quantity? <input type="text" value=""/>			
RQ Threshold: <input type="text" value=""/>			
Is this a marine pollutant? <input type="text" value="No"/>			
Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below)			
<input type="checkbox"/> Limited Quantity	<input type="text" value=""/>		
<input type="checkbox"/> Consumer Commodity, ORM-D	<input type="text" value=""/>		
<input type="checkbox"/> Small Quantity (49 CFR 173.4)	<input type="text" value=""/>		
<input type="checkbox"/> Special Permit; DOT-SP	<input type="text" value=""/>		
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);	<input type="text" value=""/>		
SP#	<input type="text" value=""/>		
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="text" value="No"/>	Controlled Substance Code	<input type="text" value=""/>
Controlled by State(s)?	<input type="text" value="No"/>	Listed Chemical (List I or II)	<input type="text" value="No"/>
ARCOS Reportable?	<input type="text" value=""/>	If yes, indicate which:	<input type="text" value=""/>
Schedule No.	<input type="text" value=""/>	Is it a scheduled listed chemical product?:	<input type="text" value="No"/>
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="text" value="Yes"/>	
Restricted to retail pharmacy only:		<input type="text" value="No"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="text" value="No"/>	
Restricted from US territories? (explain in comments)		<input type="text" value="No"/>	
Comments:		<input type="text" value=""/>	
SDS Hazard Classification			
<input checked="" type="checkbox"/> Organic	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input type="checkbox"/> Inorganic	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
<input type="checkbox"/> Steroid/Androgen	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:		<input type="text" value=""/>	
NFPA Storage Level:		<input type="text" value=""/>	
Is the product a NIOSH hazardous drug?		<input type="text" value="No"/>	
If yes, indicate which:		<input type="text" value=""/>	
Hazardous Waste Identification			
EPA Hazardous Waste Code:		Waste Characteristics <input type="text" value=""/>	
REMS or REGISTRY RESTRICTIONS			
Is there a REMS on this product?		<input type="text" value="No"/>	
If Yes, is it managed with a pharmacy registry?		<input type="text" value=""/>	
Website URL:		<input type="text" value=""/>	
Med Guide Required		<input type="text" value=""/>	
Limited Distribution Requirement		<input type="text" value=""/>	
Comments / Details: (For example, iPledge program?)		<input type="text" value=""/>	
REMS:		<input type="text" value="No"/>	
REMS Program Manager Name:		Phone: <input type="text" value=""/>	
Supplier Manages REMS registry exclusively:		<input type="text" value=""/>	
Wholesale distributor support:		<input type="text" value=""/>	
Provider Name:		DEA #: <input type="text" value=""/>	
Site Enrollment Number assigned by Supplier:		NCPDP#: <input type="text" value=""/>	
NPI #: <input type="text" value=""/>			
Comments		<input type="text" value=""/>	
Registry:		<input type="text" value="No"/>	
Registry Program Contact Name:		Phone: <input type="text" value=""/>	
Comments		<input type="text" value=""/>	
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:		1-866-827-3647	
Is product returnable for credit:		<input type="text" value="Yes"/>	
URL/Link to returns policy:		<input type="text" value="contact - customerservice@camberpharma.com"/>	
Special regulations or returns requirements for this product in certain states?		<input type="text" value="No"/>	
If so, which states? Other requirements? Comments?		<input type="text" value=""/>	
MISCELLANEOUS NOTES and/or Image of Product Barcode:			
<input type="text" value=""/>			



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