



Date: 4/18/2023

SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
<b>a. Temperature – Indicate the USP temperature range for this product.</b>						
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>b. Contact for temperature excursion questions:</b>						
Name:		Soma Raju				
Number:		732-529-0423				
Group E-mail:		somaraju@heterousa.com				
<b>c. Special regulations for product in any states?</b>						
Special returns requirements for this product?		No				
<b>d. Store product (unit of sale) upright?</b>						
Protect product (unit of sale) from light?		No				
<b>e. Shelf life:</b>						
Initial shelf life at launch (if different):		24 Months				
<b>ORDER INFORMATION</b>						
<b>Unit of Sale</b>		<b>What is the NDC selling unit?</b>				
Bottle		1 carton of 28 Unit-dose tablets				
x Box/Carton		(Write-in, e.g. 1 Box of 10 Vials)				
Ampule						
Glass		<b>Minimum order quantity?</b>				
Tube		Yes				
Vial Liquid Sgl						
Vial Liquid Multi		<b>If Yes, how many of which package type?</b>				
Vial Powder Sgl		1 Each				
Vial Power Multi		Inner/Carton/Pack				
Other: Write In		Case				
<b>PHARMACY ORDER / BILL UNIT</b>						
<b>Rec. sell unit to customer?</b>		<b>Rx billing unit to pharmacy:</b>				
		Each				
(Write-in, e.g. 1 Vial)		Gram				
		Milliliter				
<b>ITEM AND PACKING INFORMATION</b>						
	<b>Weight Lbs.</b>	<b>Dimensions (US msmts.)</b>			<b>Volume (Cube)</b>	<b>Saleable # Pieces</b>
	<b>Depth</b>	<b>Width</b>	<b>Height</b>			
Item/Each:	0.06	5.81	0.75	4	17.43	1
Box/Carton/Bundle/ Inner Pack:						
Case:	8.75	15.5	12.5	12.75	2,470.31	114
Pallet:						
<b>COST INFORMATION</b>						<b>WHOLESALE USE ONLY:</b>
<b>Regular Cost</b>			<b>Vendor #:</b>			
<b>Invoice Cost (WAC) (\$)</b>		\$325.70	<b>Whsl. Code #:</b>			
<b>As of date:</b>		4/17/2023	<b>FineLine Code:</b>			

ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device?	No	Is the Product... Direct-Skip Only	Unit Dose	Size:	28 Unit-dose Tablets (1x28)
if yes, enter class #		Orphan Drug Status		Strength:	250mcg
a product kit?	No	FDA Approval Status		Dosage Form:	Tablet
if yes, list NDCs of component parts reverse numbered?		Allergens Present		Product Shape:	round, flat bevel edged tablets
co-licensed?	No	Gluten, wheat, corn, alcohol		Product Color:	white to off white
latex-free?	Yes	Country of Origin	India	Product Imprint:	debossed with "H" on one side and "T" on the other side
preservative-free?	Yes				
correctional institution block?	No				
opioid?	No				
Cannabinoid?	No				
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No	Is this product covered under the Trade Agreements Act (TAA)?	No		
If Unit Dose, indicate NDC here:	31722-676-35				

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Daliresp
	<input type="checkbox"/> Authorized Generic      *If Authorized Generic, other section fields are not applicable

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption: Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	Yes
Has FDA granted waiver/exception/exemption for product?	No
If yes, attach documentation from FDA.	
GLN:	0331722000000
GCP:	
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION			
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14
x Item/Each	1		00331722676366
x Box/Carton/Bundle/Inner Pack			
x Case	114		20331722676360
x Pallet			

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):		208213	
Medical Device Class, if applicable:			
DUNS:		82-677-4775	
Proprietary Name (If Applicable) and Established Name:		Roflumilast Tablets 250mcg	
Selling Unit NDC:		31722-676-36	
UDI		Unit of Use NDC:	
		CVX Code:	
		MVX Code:	
Description:		Roflumilast Tablets 250mcg	
Active Ingredient(s):		Roflumilast	
URL for Additional Product Information:		www.camberpharma.com	
Address:		1031 Centennial Ave (and) 800 Centennial Ave, Suite 1	
City:		Piscataway	
Key Contact:		Customer Service	
Phone Number:		1-866-827-3647	
Product Therapeutic Classification:		Selective Phosphodiesterase-4 Enzyme Inhibitor	
State:		NJ	
Email:		customerservice@camberpharma.com	
Fax:		732-562-8788	
Address 2:		Zip: 08854	

Company Name:		Camber Pharmaceuticals, Inc.	
Application:		ANDA	

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?	
Special returns requirements for this product?	
No	
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	
No	
e. Shelf life:	
Initial shelf life at launch (if different):	
24 Months	
Months	

The product is? a legend device?		No
if yes, enter class #		
a product kit?		No
if yes, list NDCs of component parts reverse numbered?		
co-licensed?		No
latex-free?		Yes



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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

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



# 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
<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><b>Purchase order daily receipt cut off time by supplier</b></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><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></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><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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><b>Class of Trade Restriction:</b></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><b>Other Data Information Required to Process PO:</b></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><b>Return Instructions</b></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><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>