

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

						Introduction 1	ype: New Item		x Final Version			Date:	10/29	9/2024
			PRODUCT INFORMAT	FION					SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN			7			NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat	ble:									-				
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Erlotin	ib Tablets 25 mg					_	(write in)					
Selling Unit NDC:	31722-263-30		Unit of Use NDC:		31722-263-30	UPC: MVX Code:	331722263306	-	Notes					
UDI			CVX Code:			WIVA Code:								1
Description:	Erlotinib Tablets 2	5 mg							Is this product to be shippe				No	
Active Ingredient(s): Erlotinib hydrochloride Is this product to be shipped to customers on dry ice? No														
riouro ingiourorido).		2.notime rigaroomor						b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform	nation:	www.camberpharm	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:		-	Number:		732-529-04			
City:	Piscataway				State:	NJ	Zip: 08854	_	Group E-mail:		somaraju@	neterousa.coi	<u>n</u>	
Key Contact:	Customer Service 1-866-827-3647				Email: Fax:	732-562-8788	@camberpharma.com	. Creatial range	lations for product in any				Nie	1
Phone Number:		Kinggo inhihitor			Fax:	/32-302-8/88			• •				No	
Product Therapeutic Classification	n:	Kinase inhibitor							Special returns requirement	its for this product?			No	
		ONAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPTION INFORMATION	d Store produ	ct (unit of sale) upright?				No	1
The product is 2				Direct-Ship (Only	- I NODUCITI				ala) from Kabia			No	1
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	Unity	1	30 ct	e. Shelf life:	Protect product (unit of s	aie) from light?			N0 18	Months
if yes, enter class #		110	Orphan Drug Status			Size:			Initial shelf life at launch	(if different):			10	Months
a product kit?		No				Ctronethy	25 mg			(
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFOR	MATION			
component parts						Dosage Form	n: Film-coated tablet							
reverse numbered?		No						r.	Unit of Sale			NDC selling	unit?	
co-licensed? latex-free?		No	Allergens Present				Round, biconvex		x Bottle Box/Carton		1 Bottle of 3	g. 1 Box of 1		
preservative-free?		Yes	Dairy, I	Lactose		Product Sha	pe:		Ampule		(write-iii, e	g. i bux ui i	U VIAIS)	
correctional institution block?		No					White		Glass		Minimum o	rder quantity	?	Yes
opioid?		No				Product Col	or:		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	Debossed with 'H' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					i roudet imp	and '28' on the other side		Vial Liquid Multi		If Yes, how	many of wh	ch package	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl		1	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	IAA)?	No				Vial Powder Mult Other: Write In	I		Inner/Cartor Case	/Pack	
				ODUCTO				<u></u>	Other: write in			Tener		
			FOR GENERIC DRUG PRO	ODUCTS					Other: white in			1		
			FOR GENERIC DRUG PRO	ODUCTS	Aut	thorized Generic	*If Authorized Generic, other			HARMACY ORDER	/ BILL UNIT	1		
L Orange Book Rating:	AB		FOR GENERIC DRUG PRO	DDUCTS	Aut	horized Generic	*If Authorized Generic, other section fields are not applicable	Rec. sell unit t	Pł	HARMACY ORDER			acv.	
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	Tarceva	FOR GENERIC DRUG PRO	DDUCTS	Aut	horized Generic		Rec. sell unit t	Pł	HARMACY ORDER		nit to pharm	acy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Tarceva			·	horized Generic		Rec. sell unit to	Pi o customer?	HARMACY ORDER			acy:	_
			FOR GENERIC DRUG PRO		·	horized Generic			PI o customer? 1 Vial)	HARMACY ORDER		nit to pharm	acy:	
II. Generic Equivalent to What Bra	ind?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I		RMATION			(Write-in, e.g. 1	P o customer? 1 Vial) e:		Rx billing u	nit to pharm Each Gram Milliliter	acy:	
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	ind?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I		RMATION GLN:			(Write-in, e.g. 1	P o customer? 1 Vial) e:	M AND PACKING I	Rx billing u	nit to pharm Each Gram Milliliter		
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HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 For Designate	ed 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? 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? (if yes, answer a-e below and provide SDS) a. UN/Identification Number	Does the product have an Aerosol class? If yes, identify No NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? Yes If yes, indicate which: Group 1 items (antineoplastic)
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? No (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?	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 Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: No
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: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No Registry Program Contact Name: Comments Phone:
Is the Product	
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: Isted Chemical (List I or II) No Schedule No. Is it a scheduled listed chemical product?: No Isted Chemical (List I or II) No	RETURN INSTRUCTIONS 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
Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: No	Special regulations or returns requirements for this product in certain states? No
MISCELLANEC	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 - in	f 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 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:	
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 second
	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: Order receipt method: 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 State License # 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?