

## **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	<b>nit to pharm</b> Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra	ind?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I Yes		·	0331722498975		(Write-in, e.g. 1	P o customer? 1 Vial) e:	HARMACY ORDER	Rx billing u	<b>nit to pharm</b> Each Gram Milliliter	acy:	
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		
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	ind?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I Yes		RMATION			(Write-in, e.g. 1	P o customer? 1 Vial) e:	M AND PACKING I Dimens	Rx billing u	nit to pharm Each Gram Milliliter N	Volume	Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ind?:	DRUG SUPPL	Y CHAIN SECURITY ACT (I Yes No		RMATION GLN: GCP:	0331722498975		(Write-in, e.g. 1 HCPCS J-Code	Pi o customer? 1 Vial) e: ITEI Weight Lbs.	M AND PACKING I Dimens Depth	Rx billing u	nit to pharm Each Gram Milliliter N nts.) Height	Volume (Cube)	Saleable # Pieces
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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?