

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

						Introduction 7	ype: New Item		x Final Version			Date:	3/11/	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharma	ceuticals, Inc.				Applica	ion: ANDA	a. Temperature	e - Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/AN						NDA 505(b) Type:			Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical									· -					
DUNS:	11-856-3719							_	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Finaster	eride Tablets, USP 1 mg					T	(write in)					
Selling Unit NDC:	31722-526-30		Unit of Use NDC:		31722-526-30		331722526302		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Finasteride Table	ets, USP 1 mg						T	Is this product to be shipped	to customers on ic	e?		No	
·									Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		Finasteride, USP												
								b. Contact for temperature excursion questions:						
URL for Additional Product Inforn		www.camberpharma.	<u>.com</u>						Name:		Soma Raju	_		
Address:		nial Ave, Suite 1			Ctata	Address 2: State: NJ Zin: 08854						2-529-0423 maraju@heterousa.com		
City: Key Contact:	Piscataway Customer Servic				State: Email:	-	Zip: 08854	-	Group E-mail:		somaraju@r	neterousa.com	1	
Phone Number:	1-866-827-3647				Email: customerservice@camberpharma.com 732-562-8788			c Special regu	lations for product in any	etatos?			No	
		5 alpha-reductase inl	hibitor		l ax.	732-302-0700								
Product Therapeutic Classificatio	on:	5 alpha-reductase ini	Allibitor						Special returns requirement	s for this product?			No	
	ADDIT	IONAL PRODUCT INF	OPMATION			PPODUCT	DESCRIPTION INFORMATION	d Store produ	ct (unit of sale) upright?				No	1
	ADDIT	IONAL I RODUCT INI		Di . Ol . 6		TRODUCT	DESCRIPTION IN ORMATION	- 1						-
The product is?			Is the Product	Direct-Ship (Only		20 -1		Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product Orphan Drug Status	Unit of Use		Size:	30 ct	e. Shelf life:	Initial shelf life at launch (i	f different).			24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				1 mg		initial shelf life at launch (ramerent):				Months
if yes, list NDCs of		INU	FDA Approval Status			Strength:	i ilig			ORDER INFORM	ATION			
component parts			1 DA Approvai Glatas				Film coated tablet							
reverse numbered?		No				Dosage Forn	n:		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 3	0 Tablets		
latex-free?		Yes	Dairy, Lactose, D	Duo Corn Alor	hal	Product Sha	Round		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?		Yes	Dairy, Lactose, L	Jye, Corn, Aicc	onoi	Froduct Sna			Ampule					
correctional institution block?		No				Product Cole	Brown		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	Debossed with "H" on one side and "36" on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		la thia anadust assumed .						Vial Liquid Multi Vial Powder Sql			many of whi	ch package t	type?
If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No			-	Vial Powder Sgi Vial Powder Multi		24	Inner/Carton	/Pack	
ii onii bose, indicate Nbo nere.			_ made rigidements rick (i		140				Other: Write In			Case	1 dok	
			FOR GENERIC DRUG PR	ODUCTS								1		
			TON OZNZKIO BROOT K	0500.0							l			
					Au	thorized Generic	*If Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit t	o customer?		Rx hilling u	nit to pharma	acv.	
II. Generic Equivalent to What Bra								Each						
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		II. Generic Equivalent to What Brands.						(Write-in, e.g. 1 Vial)				Each		
		Поробіц						(Write-in, e.g. 1	1 Vial)					
			Y CHAIN SECURITY ACT ((DSCSA) INFO	RMATION			(Write-in, e.g. 1	1 Vial)	ı				
		DRUG SUPPLY	,	(DSCSA) INFO	RMATION			(Write-in, e.g. 1	e:			Gram Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	DRUG SUPPLY	Yes	(DSCSA) INFO	RMATION GLN:	0331722498975		(Write-in, e.g. /	e:	AND PACKING IN	IFORMATIO	Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA?	ition of manufactu	DRUG SUPPLY	,	(DSCSA) INFO		0331722498975		(Write-in, e.g. / HCPCS J-Code	e:	AND PACKING IN	IFORMATIO	Gram Milliliter		
	ition of manufactu	DRUG SUPPLY	Yes	(DSCSA) INFO		0331722498975		(Write-in, e.g. / HCPCS J-Code	e: ITEN		ons (US msn	Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ition of manufactu	DRUG SUPPLY	Yes No	(DSCSA) INFO	GLN: GCP:			HCPCS J-Code	e:			Gram Milliliter	Volume (Cube)	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes No	(DSCSA) INFO	GLN: GCP: If yes, was or	iginal product pure	chased	(Write-in, e.g. / HCPCS J-Code	e: ITEN	Dimensio	ons (US msn	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distrib	DRUG SUPPLY	Yes No No Yes	(DSCSA) INFO	GLN: GCP: If yes, was or direct from m	iginal product pure		HCPCS J-Code	Weight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distrib on/exemption for p	DRUG SUPPLY	Yes No	(DSCSA) INFO	GLN: GCP: If yes, was or direct from m	iginal product pure	chased rrepackaged product	Item/Each:	Weight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distrib on/exemption for p	DRUG SUPPLY	Yes No No Yes	DSCSA) INFO	GLN: GCP: If yes, was or direct from m	iginal product pure		Item/Each: Box/Carton/Bu Inner Pack:	Weight Lbs. 0.06	Dimension Depth 1.5	ons (US msn Width 1.5	Gram Milliliter	(Cube) 6.75	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	s exclusive distrib on/exemption for p	DRUG SUPPLY urer? butor? product?	Yes No No Yes No		GLN: GCP: If yes, was or direct from m	iginal product pure		Item/Each:	Weight Lbs.	Dimensio Depth	ons (US msn Width	Gram Milliliter	(Cube)	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation froi Saleable Unit of Measure X	s exclusive distrib infexemption for p m FDA. RFID tag(Y/N)	DRUG SUPPLY urer? Duttor? GTIN Saleable Quantity 1	Yes No No Yes No No A AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTII	iginal product pure fr? ce manufacturer fo N-14	r repackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/Bu Inner Pack: Case:	Weight Lbs. 0.06	Dimension Depth 1.5	ons (US msn Width 1.5	Gram Milliliter Nuts.) Height 3	(Cube) 6.75	Pieces 1 24
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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 HAZ	ARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? 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? No Does the product label bear a CA Prop 65 warning? 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?	SDS Hazard Classification X Organic Corrosive Oxidizer Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which: Yes Group 3 items (primarily adverse reproductive effects)
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? (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?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? 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?)
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) Special Permit; DOT-SP	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NCPDP#: NPI #:
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION Is the Product Controlled Substance? No Controlled Substance Code	Comments RETURN INSTRUCTIONS
Controlled by State(s)? ARCOS Reportable? No Schedule No. Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: 1-866-827-3647 Yes
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No Comments:	product in certain states? If so, which states? Other requirements? Comments?
	DUS NOTES and/or Image of Product Barcode: or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus.



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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?