HDAO

Version 2021						Introduction 1	ype: New Item		x Final Version			Date:	6/1/2	2024				
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOP	AGE REQUIR	EMENTS*						
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA								a Temperature -	a. Temperature – Indicate the USP temperature range for this product.									
	DA/ANDA/BLA (drug); PMA/510(k)(med device): 214571								Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicat					-								,					
DUNS:	11-856-3719							Oth	ner Temperature Range F	Requirement	Excursions p	ermitted to 15	5° to 30° C (5	9° – 86° F)				
Proprietary Name (If Applicable) a	nd Established Nar	ne: Varen	nicline Tablets 0.5 mg						(write in)					,				
Selling Unit NDC:	31722-678-56		Unit of Use NDC:		31722-678-56	UPC:	331722678568	No										
UDI			CVX Code:			MVX Code:												
Description:	Varenicline Tablets	0.5 mg						ls t	his product to be shipped	to customers on i	ce?	[No					
Is this product to be shipped to customers on dry ice? No											No							
Active Ingredient(s):		Varenicline tartrate	,															
									b. Contact for temperature excursion questions:									
URL for Additional Product Inform		on: www.camberpharma.com 00 Centennial Ave, Suite 1							Name:			Soma Raju						
Address:					Charles	Address 2:	7	Number:			732-529-0423							
City: Key Contact:	Customer Service					NJ	Zip: 08854 @camberpharma.com	Gro	Group E-mail: somaraju@heterousa.com									
Phone Number:	1-866-827-3647					732-562-8788	<u>scamberphama.com</u>	c. Special regulations for product in any states? No										
Product Therapeutic Classification		Nicotinic receptor p	partial agonist			102 002 0100			ecial returns requirement			-	No					
Frouder merapeutic classification								Op	ecial returns requirement	s for this product?		L	NO					
	ADDITIO	NAL PRODUCT IN	FORMATION			PRODUCT	DESCRIPTION INFORMATION	d Store product ((unit of sale) upright?			1	No					
The product is?			Is the Product	Direct-Ship C	Dnly				otect product (unit of sa	le) from light?		L	No					
a legend device?	ſ	No	is the Product	Unit of Use	y		56 ct	e. Shelf life:	Seet product (unit of Sa	ie, ironi light (24	Months				
if ves. enter class #			Orphan Drug Status			Size:	0000		tial shelf life at launch (f different):			24	Months				
a product kit?		No	orphan Drug olaiteo				0.5 mg			an annor or ny:		ļ		menne				
if yes, list NDCs of			FDA Approval Status			Strength:	5			ORDER INFORM	IATION							
component parts						Dosage Form	Film coated tablet											
reverse numbered?		No				Decageren			it of Sale		What is the M		unit?					
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 56							
latex-free?		Yes	Alc	ohol		Product Sha	pe: Capsular, biconvex		Box/Carton		(Write-in, e.g	. 1 Box of 10	Vials)					
preservative-free? correctional institution block?		Yes No					Pink		Ampule Glass		Minimum or	lor quantitu'		Yes				
opioid?		No				Product Cole	or:		Tube		Willing on the second second			res				
Cannabinoid?		No	Country of Origin	India			Debossed with 'H' on one side		Vial Liquid Sgl									
If Unit Dose, is item bar coded to u						Product Imp	rint: and 'V23' on the other side		Vial Liquid Multi		If Yes, how r	nany of whic	h package t	ype?				
hospital scanning?	[Is this product covered u	inder the					Vial Powder Sgl			Each						
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	FAA)?	No				Vial Powder Multi			nner/Carton/	Pack					
									Other: Write In			Case						
			FOR GENERIC DRUG PR	ODUCTS														
									DU									
			Authorized Generic *If Authorized Generic, other PHARMACY ORDER / BILL UNIT															
		I. Orange Book Rating: AB section fields are not applicable							Rec. sell unit to customer? Rx billing unit to pharmacy:									
II. Generic Equivalent to What Bra	II. Generic Equivalent to What Brand?: Chantix						section fields are not applicable	Rec. sell unit to c	ustomer?	1	Rx billing un							
							section fields are not applicable]		Each						
			Y CHAIN SECURITY ACT (section fields are not applicable]		Each Gram						
	indit.		LY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION		section fields are not applicable]		Each						
Does supplier meet DSCSA defini		DRUG SUPPL	LY CHAIN SECURITY ACT (Yes	DSCSA) INFOR		0331722498975	section fields are not applicable		ial)	AND PACKING I		Each Gram						
Does supplier meet DSCSA definit		DRUG SUPPL		DSCSA) INFOR	RMATION GLN:	0331722498975	section fields are not applicable		ial)	I AND PACKING I		Each Gram						
Is product exempt from DSCSA?		DRUG SUPPL	Yes	DSCSA) INFOR	GLN:	0331722498975	section fields are not applicable		ial) ITEN			Each Gram Milliliter	Volume	Saleable #				
		DRUG SUPPL	Yes	DSCSA) INFOR		0331722498975	section fields are not applicable		ial)		NFORMATION	Each Gram Milliliter	Volume (Cube)	Saleable # Pieces				
Is product exempt from DSCSA? If yes, select exemption:		DRUG SUPPL	Yes	DSCSA) INFOR	GLN: GCP:	0331722498975			ial) ITEN Weight Lbs.	Dimens Depth	NFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	(Cube)	Pieces				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacture	DRUG SUPPL	Yes No No Yes	DSCSA) INFOR	GLN: GCP: If yes, was ori direct from m	iginal product pure	chased	(Write-in, e.g. 1 Vi	ial) ITEN Weight Lbs. 0.07	Dimens	NFORMATION	Each Gram Milliliter						
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/exception	tion of manufacture exclusive distribut	DRUG SUPPL	Yes No No		GLN: GCP: If yes, was ori direct from m	iginal product pure		(Write-in, e.g. 1 Vi	ial) ITEN Weight Lbs. 0.07	Dimens Depth	NFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	(Cube)	Pieces				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	tion of manufacture exclusive distribut	DRUG SUPPL	Yes No No Yes		GLN: GCP: If yes, was ori direct from m	iginal product pure	chased	(Write-in, e.g. 1 Vi	ial) ITEN Weight Lbs. 0.07	Dimens Depth	NFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	(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/exception	tion of manufacture exclusive distribut	DRUG SUPPL er?	Yes No No Yes No		GLN: GCP: If yes, was ori direct from m	iginal product pure	chased	(Write-in, e.g. 1 Vi	ial) ITEN Weight Lbs. 0.07	Dimens Depth	NFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	(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/exception	tion of manufacture exclusive distribut	DRUG SUPPL er?	Yes No No Yes		GLN: GCP: If yes, was ori direct from m	iginal product pure	chased	(Write-in, e.g. 1 Vi	ial) ITEN Weight Lbs. 0.07 Ie/	Dimensi Depth 1.5	NFORMATION ons (US msm Width 1.5	Each Gram Milliliter ts.) Height 2.5	(Cube) 5.63	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/exception	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL er?	Yes No No Yes No		GLN: GCP: If yes, was ori direct from m	iginal product pur fr? ee manufacturer fo	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case:	ial) ITEN Weight Lbs. 0.07 Ie/	Dimensi Depth 1.5	NFORMATION ons (US msm Width 1.5	Each Gram Milliliter ts.) Height 2.5	(Cube) 5.63	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/exception If yes, attach documentation from	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL er?	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was ori direct from m Provide source	iginal product pur fr? ee manufacturer fo	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case:	ial) ITEN Weight Lbs. 0.07 Ie/	Dimensi Depth 1.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter Lis.) Height 2.5 4	(Cube) 5.63 250.8	Pieces 1 24				
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/exception If yes, attach documentation from Saleable Unit of Measure	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL er? ior? oduct? GTI aleable Quantity	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was ori direct from m Provide source	iginal product pure fr? e manufacturer fo	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case:	ial) ITEN Weight Lbs. 0.07 Ie/	Dimensi Depth 1.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter ts.) Height 2.5	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL er? ior? oduct? GTI aleable Quantity	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTIN 0033	iginal product pure fr? e manufacturer fo	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	ial) ITEN Weight Lbs. 0.07 le/ 2.15	Dimensi Depth 1.5	NFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter Lis.) Height 2.5 4	(Cube) 5.63 250.8	Pieces 1 24				
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/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Catron/Bundle/Inner Pack	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL or? cor? pduct? GTI aleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTIN 0033	iginal product pur fr? ee manufacturer fo 4-14 11722678568	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter Is.) Height 2.5 4 4	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL or? cor? pduct? GTI aleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTIN 0033	iginal product pur fr? ee manufacturer fo 4-14 11722678568	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet:	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter s.) Height 2.5 4 4 VHOLESALE	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL or? cor? pduct? GTI aleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTIN 0033	iginal product pur fr? ee manufacturer fo 4-14 11722678568	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION C) (\$)	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter s.) Height 2.5 4 4 VHOLESALE	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL or? cor? pduct? GTI aleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTIN 0033	iginal product pur fr? ee manufacturer fo 4-14 11722678568	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter s.) Height 2.5 4 4 VHOLESALE	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL or? cor? pduct? GTI aleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or direct from m Provide source GTIN 0033	iginal product pur fr? ee manufacturer fo 4-14 11722678568	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION C) (\$)	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter s.) Height 2.5 4 4 VHOLESALE	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA.	DRUG SUPPL or? cor? pduct? GTI aleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT IN HIBCC		GLN: GCP: If yes, was ori direct from m Provide source GTIN 0033 2033	iginal product puri fr? æ manufacturer fo N-14 11722678568 31722678562	Unit of Use GTIN-14 00331722678568	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA As of date:	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION C) (\$) 1/31/2024	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter s.) Height 2.5 4 4 VHOLESALE	(Cube) 5.63 250.8	Pieces 1 24				
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X IntervEach Box/Catron/Bundle/Inner Pack X Case	tion of manufacture exclusive distribut n/exemption for pro n FDA. Sa	DRUG SUPPL or? oduct? GTI aleable Quantity 1 24 24	Yes No No Yes No IN AND HIBCC PRODUCT IN HIBCC		GLN: GCP: If yes, was ori direct from m Provide source GTIN 0033 2033	iginal product pure fr? re manufacturer fo N-14 31722678568 31722678562 d letter, PACKAGE	chased	(Write-in, e.g. 1 Vi Item/Each: Box/Carton/Bund Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WA As of date:	ial) ITEN Weight Lbs. 0.07 le/ 2.15 COST INFORMATION C) (\$) 1/31/2024	Dimensi Depth 1.5 9.5	VFORMATION ons (US msm Width 1.5 6.6	Each Gram Milliliter s.) Height 2.5 4 4 VHOLESALE	(Cube) 5.63 250.8	Pieces 1 24				

HDA🔾

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

Version 2021 For Designa	ted Drop Ship Only Products, Please Use Page 3				
MATERIAL HA	ZARD 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? 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? No Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which:				
a. On/definition for holder b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:				
(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? 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?)				
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: 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 Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No Registry Program Contact Name: Comments				
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes				
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com				
No No 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 If so, which states? Other requirements? Comments?				
MISCELLANE	OUS NOTES and/or Image of Product Barcode:				



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
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:
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 co
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:	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?