



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION

Company Name: Application:
 Application Number for NDA/ANDA/BLA, Med Device:
 DUNS:
 Rx Product/Proprietary Name:
 NDC: UPC:
 CVX Code: MVX Code:
 Description:
 Active ingredients:
 URL for Additional Product Information:
 Address: Address 2:
 City: State: Zip:
 Key Contact: Email:
 Phone Number: Fax:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

I. Freezer – between -25 and -10 C (-13° – 14° F)
 II. Cold – between 2 and 8 C (36° – 46° F)
 III. Cool – between 8 and 15 C (46° – 59° F)
 IV. Controlled Room – between 20 and 25 C (68° – 77° F)
 allows for excursions between 15 and 30 C (59° – 86° F)
 V. Avoid Excessive Heat – above 40 C (>104° F)
 VI. Other Temperature Range Requirement
 (write in)
 VII. No Requirement

b. Contact for temperature excursion questions:
 Name:
 Number:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: II. Brand Name:
 III. Generic Equivalent for Brand:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? If Yes, was original product purchased direct from mfr?
 Is product sold by manufacturer's exclusive distributor?
 Are any waivers granted for product ID/barcode? If yes, attach documentation from FDA

c. Special regulations for product in certain states?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life:

Months
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 Legend Device?
 State Control?
 ARCOS reportable?
 Co-Licensed?
 Controlled Substance?
 Schedule No. ?
 (incl. N for non-narcotic)
 Controlled Substance Code:
 Hazardous Material/Cytotoxic Agent?
 Is Item...
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 Is it reverse numbered?

ORDER INFORMATION

Unit of Sale
 Bottle
 Box/ Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Power Multi
 Other: Write In
 SD infusion bag

What is the NDC selling unit?

 Minimum order quantity?
 If Yes, how many of which package type?
 Each
 Inner/ Carton/ Pack
 Case

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Height	Width:			
Box/ Carton:	0.30823 (1 Triple)	11.42 (1 Triple)	0.5905 (1 Triple)	8.27 (1 Triple Laminated)		1 Triple Laminated	
Case:	4.276	12.5984	7.0866	8.66141		Case (10 Triple)	
Pallet:	375.077 (For Sea)	48	41.42 (For Sea)	40		For Sea (80 Shippers or	
UPC:	Case:						
	Carton:	355150246472					

WHOLESALE USE ONLY:

Vendor #:
 Whsl. Code #:
 Fineline Code:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

Other Product Information

Size/Strength/Form:
 Product Shape:
 Product Color:
 Product Imprint:

COST INFORMATION

Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$185.00	
As of date: <input type="text" value="1/5/2017"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT?

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization						
Serialized?	Level	How?	RFID	GTIN-14		
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	NA		
If not, when?	Box/Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	NA		
Items aggregated to case?	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	50355150246477		
	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	70355150246471		

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product 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?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

CLASS OF TRADE RESTRICTION:

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
REMS or Registry Restrictions	Return Instructions
REMS: <input type="checkbox"/> REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="checkbox"/> Wholesale distributor support: <input type="checkbox"/> Provider Name: <input type="text"/> Site Enrollment Number assigned by Supplier: <input type="text"/> DEA #: <input type="text"/> PCPDP #: <input type="text"/> NPI #: <input type="text"/> Comments: <input type="text"/> Registry: <input type="checkbox"/> Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Miscellaneous Notes: <input type="text"/>



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION

Company Name: Application:
 Application Number for NDA/ANDA/BLA, Med Device:
 DUNS:
 Rx Product/Proprietary Name:
 NDC: UPC:
 CVX Code: MVX Code:
 Description:
 Active ingredients:
 URL for Additional Product Information:
 Address: Address 2:
 City: State: Zip:
 Key Contact: Email:
 Phone Number: Fax:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

I. Freezer – between -25 and -10 C (-13° – 14° F)
 II. Cold – between 2 and 8 C (36° – 46° F)
 III. Cool – between 8 and 15 C (46° – 59° F)
 IV. Controlled Room – between 20 and 25 C (68° – 77° F)
 allows for excursions between 15 and 30 C (59° – 86° F)
 V. Avoid Excessive Heat – above 40 C (>104° F)
 VI. Other Temperature Range Requirement
 (write in)
 VII. No Requirement

b. Contact for temperature excursion questions:
 Name:
 Number:
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: II. Brand Name:
 III. Generic Equivalent for Brand:

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? If Yes, was original product purchased direct from mfr?
 Is product sold by manufacturer's exclusive distributor?
 Are any waivers granted for product ID/barcode? If yes, attach documentation from FDA

c. Special regulations for product in certain states?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life:

Months
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

Is the Product...
 Legend Device?
 State Control?
 ARCOS reportable?
 Co-Licensed?
 Controlled Substance?
 Schedule No. ?
 (incl. N for non-narcotic)
 Controlled Substance Code:
 Hazardous Material/Cytotoxic Agent?
 Is Item...
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 Is it reverse numbered?

ORDER INFORMATION

Unit of Sale: Bottle Box/ Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Power Multi Other: Write In SD infusion bag

What is the NDC selling unit?

 Minimum order quantity?
 If Yes, how many of which package type?
 Each
 Inner/ Carton/ Pack
 Case

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Height	Width:			
Box/ Carton:	0.30823 (1 Triple)	11.42 (1 Triple)	0.5905 (1 Triple)	8.27 (1 Triple Laminated)		1 Triple Laminated	
Case:	4.276	12.5984	7.0866	8.66141		Case (10 Triple)	
Pallet:	375.077 (For Sea)	48	41.42 (For Sea)	40		For Sea (80 Shippers or	
UPC:	Case:						
	Carton:	355150247479					

WHOLESALE USE ONLY:

Vendor #:
 Whsl. Code #:
 Fineline Code:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy:
 Each Gram Milliliter

Other Product Information

Size/Strength/Form:
 Product Shape:
 Product Color:
 Product Imprint:

COST INFORMATION

Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$300.00	
As of date: <input type="text" value="1/5/2017"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT?

Is this a reportable quantity?
RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?
(if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

ADDITIONAL PRODUCT INFORMATION - Serialization					
Serialized?	Level	How?	RFID	GTIN-14	
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	NA	
If not, when?	Box/Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	NA	
Items aggregated to case?	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	50355150247474	
	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	70355150247478	

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

Comments / Details: (For example, iPledge program?)

RETURN INSTRUCTIONS

Contact tel. # if product 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?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

CLASS OF TRADE RESTRICTION:

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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
REMS or Registry Restrictions	Return Instructions
REMS: <input type="checkbox"/> REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/> Supplier Manages REMS registry exclusively: <input type="checkbox"/> Wholesale distributor support: <input type="checkbox"/> Provider Name: <input type="text"/> Site Enrollment Number assigned by Supplier: <input type="text"/> DEA #: <input type="text"/> PCPDP #: <input type="text"/> NPI #: <input type="text"/> Comments: <input type="text"/> Registry: <input type="checkbox"/> Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/> Comments: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	<input type="text"/>
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	AuroMedics Pharma LLC		Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	207160		
DUNS:	<input type="text"/>		
Rx Product/Proprietary Name:	Levetiracetam in 0.54% Sodium Chloride injection for intravenous Infusion only 1500mg/100mL (15mg/mL)		
NDC:	55150-248-47	UPC:	355150248476
CVX Code:	<input type="text"/>	MXV Code:	<input type="text"/>
Description:	Levetiracetam in 0.54% Sodium Chloride injection for intravenous Infusion only 1500mg/100mL (15mg/mL)		
Active ingredients:	<input type="text"/>		
URL for Additional Product Information:	www.auromedics.com		
Address:	6 Wheeling Road	Address 2:	<input type="text"/>
City:	Dayton	State:	NJ
Key Contact:	<input type="text"/>	Zip:	08810
Phone Number:	888-238-7880	Email:	<input type="text"/>
		Fax:	732-355-9449

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input checked="" type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/> Recommended storage: At or below 25°C
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	Steve Lucas
Number:	732-823-4122
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain 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:	
<input type="text"/> 24	Months
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Brand Name:	Keppra
III. Generic Equivalent for Brand:	levetiracetam

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:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	What is the NDC selling unit?
Legend Device?	No	<input type="checkbox"/> Bottle	10 No's of single use flexible containers in one case pack. The Case pack NDC No. is 55150-
State Control?	No	<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	No	<input type="checkbox"/> Ampule	Minimum order quantity? Yes
Co-Licensed?	No	<input type="checkbox"/> Glass	
Controlled Substance?	No	<input type="checkbox"/> Tube	If Yes, how many of which package type?
Schedule No. ?	<input type="text"/>	<input type="checkbox"/> Vial Liquid Sgl	<input type="text"/> 10 Each
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	<input type="text"/> 1 Inner/ Carton/ Pack
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> 1 Other: Write In
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Power Multi	<input type="text"/> 1 Case
Is Item...	<input type="text"/>	<input checked="" type="checkbox"/> Other: Write In	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	<input type="checkbox"/> SD infusion bag	
Is it reverse numbered?	<input type="text"/>		

ITEM AND PACKING INFORMATION							
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Height	Width:			
Box/ Carton:	0.30823 (1 Triple)	11.42 (1 Triple)	0.5905 (1 Triple)	8.27 (1 Triple Laminated)		1 Triple Laminated	
Case:	4.276	12.5984	7.0866	8.66141		Case (10 Triple)	
Pallet:	375.077 (For Sea)	48	41.42 (For Sea)	40		For Sea (80 Shippers or	
UPC:	Case:						
	Carton:	355150248476					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text"/>	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	<input type="text"/>		\$400.00	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input type="text"/>	Product Color:	<input type="text"/>			
		<input type="checkbox"/> Each		Product Imprint:	<input type="text"/>			
		<input type="checkbox"/> Gram						
		<input type="checkbox"/> Milliliter						

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$400.00	
As of date: <input type="text"/> 1/5/2017		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT?

Is this a reportable quantity?
RQ Threshold: _____

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);
SP# _____

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class _____

b. UN/ID Number _____

c. Packing Group _____

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization					
Serialized?	Level	How?	RFID	GTIN-14	
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	NA	
If not, when? _____	Box/Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	NA	
Items aggregated to case? <input type="checkbox"/>	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	50355150248471	
	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	70355150248475	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL: _____

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level: _____

RETURN INSTRUCTIONS

Contact tel. # if product 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? _____

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other: _____

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: _____

CLASS OF TRADE RESTRICTION:

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: _____

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address: <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>Purchase order daily receipt cut off time by supplier</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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<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>Overnight receipt available: <input type="checkbox"/></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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p>
Class of Trade Restriction:	Saturday Overnight receipt available:
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	<p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="checkbox"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="checkbox"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
REMS or Registry Restrictions	Return Instructions
<p>REMS: <input type="checkbox"/></p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p>Wholesale distributor support: <input type="checkbox"/></p> <p>Provider Name: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/></p> <p>DEA #: <input type="text"/></p> <p>PCPDP #: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="checkbox"/></p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<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>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	<p><input type="text"/></p>