



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

Version 2020

Introduction Type:  New Item

Final Version

Date:

### PRODUCT INFORMATION

Company Name:  Application:

Application Number for NDA/ANDA/BLA (drug); PMA/510(k) (med device):

DUNS:

Proprietary Name (If Applicable) and Established Name:

Selling Unit NDC:  Unit of Use NDC:  UPC:

UDI  CVX Code:  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:  Address 2:

City:  State:  Zip:

Key Contact:  Email:

Phone Number:  Fax:

Product Therapeutic Classification:

### SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range:   
 Other Temperature Range Requirement (write in):   
 Notes:   
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:  
 Name:   
 Number:   
 Group E-mail:

c. Special regulations for product in any states?  
 Special returns requirements for this product?

d. Store product (unit of sale) upright?  
 Protect product (unit of sale) from light?

e. Shelf life:  
 Initial shelf life at launch (if different):  Months

### ADDITIONAL PRODUCT INFORMATION

The product is?  
 a legend device?   
 If yes, enter class #   
 a product kit?   
 If yes, list NDCs of component parts   
 reverse numbered?   
 co-licensed?   
 latex-free?   
 preservative-free?   
 correctional institution block?   
 opioid?   
 Cannabinoid?   
 If Unit Dose, is item bar coded to unit dose for hospital scanning?   
 If Unit Dose, indicate NDC here:

Is the Product...  
 Is the Product...   
 Orphan Drug Status

Direct And Drop-Ship

FDA Approval Status

Allergens Present

Country of Origin

Is this product covered under the Trade Agreements Act (TAA)?

### PRODUCT DESCRIPTION INFORMATION

Size:

Strength:

Dosage Form:

Product Shape:

Product Color:

Product Imprint:

### 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

What is the NDC selling unit?  
  
 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

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

### FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:   Authorized Generic \*If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

### PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?   
 (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter

### DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  GLN:

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?  If yes, attach documentation from FDA.

Has FDA granted waiver/exception/exemption for product?

### ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	2.36	1.811023622	1.8110236	2.3622047	7.7475744	24
Case:	13.21	16.14173228	12.598425	9.8425197	2001.5788	96
Pallet:	442.7312775	47.24409449	39.370079	45.669291	84945.052	3456

### GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00372241029226	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	24		20372241029220	
<input checked="" type="checkbox"/> Case	96		40372241029224	
<input checked="" type="checkbox"/> Pallet	3456		50372241029221	

### COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:  
 Vendor #:   
 Whsl. Code #:   
 Finline Code:

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 and Medical Device Information (Rx Product Only)

Version 2020

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
    - Is the product a CA Prop 65 carcinogen?  No
    - Is the product a Paroxetine Extended-Release Tablets 12.5mg  No
    - Does the product label bear a CA Prop 65 warning?  No
  - c. Contact Hazard?  No
  - d. Does this product require special clean-up instructions?  No
 

(If yes, attach SDS with special instructions.)
  - e. Does the proc Paroxetine 12.5mg  No
- Is this product regulated for shipment by DOT?  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

- 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

- Is the product restricted for air shipment? If so, indicate restriction:
- Passenger
  - Cargo
  - Passenger & Cargo

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

### ADD'L STORAGE INFORMATION

- 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:
  - Schedule No.  Is it a scheduled listed chemical product?:  No

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes
- Restricted to retail pharmacy only:  No
- Restricted to hospital, clinics, and physician offices only:  No
- Restricted from US territories? (explain in comments)  037224102922
- Comments:  96  40372241029

### SDS Hazard Classification

- Organic
  - Inorganic
  - Steroid/Androgen
  - Corrosive
  - Oxidizer
  - Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug?  No  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

- Is there a REMS on this product?  No
- If Yes, is it managed with a pharmacy registry?
- Website URL:
- Med Guide Required  No
- Limited Distribution Requirement  No
- Comments / Details: (For example, iPledge program?)
- yellow
- REMS:  No
- REMS Program Manager Name:  Phone:
- Supplier Manages REMS registry exclusively:
- Wholesale distributor support:
- Provider Name:  DEA #:
- Site Enrollment Number assigned by Supplier:  PCPDP#:
- NPI #:
- Comments
- Registry:  No
- Registry Program Contact Name:  Phone:
- Comments

### RETURN INSTRUCTIONS

- Contact tel. # if product received damaged:  800-688-4697
- Is product returnable for credit:  Yes
- URL/Link to returns policy:
- Special regulations or returns requirements for this product in certain states?  No
- If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Paroxetine Exter: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></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><b>Overnight receipt available:</b> <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><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></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="text"/> yellow</p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><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>