



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: Months

Initial shelf life at launch (if different): Months

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|--|--|--|---|
| The product is a legend device? <input type="text" value="No"/> | Is the Product... <input type="text"/> | Direct-Ship Only <input type="text"/> | Size: <input type="text" value="88g net content - 60 metered pump actuations"/> |
| if yes, enter class # a product kit? <input type="text"/> | Is the Product... <input type="text"/> | Neither <input type="text"/> | |
| if yes, list NDCs of component parts reverse numbered? <input type="text"/> | Orphan Drug Status <input type="text"/> | FDA Approval Status <input type="text"/> | Strength: <input type="text" value="1.62%"/> |
| co-licensed? <input type="text"/> | Allergens Present <input type="text"/> | Country of Origin <input type="text" value="Spain"/> | Dosage Form: <input type="text" value="Gel"/> |
| latex-free? <input type="text"/> | <input type="text" value="Not made with natural rubber latex."/> | Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="Yes"/> | Product Shape: <input type="text" value="n/a"/> |
| preservative-free? <input type="text"/> | | | Product Color: <input type="text" value="Clear Colorless Gel"/> |
| correctional institution block? <input type="text"/> | | | Product Imprint: <input type="text" value="n/a"/> |
| opioid? <input type="text"/> | | | |
| Cannabinoid? <input type="text"/> | | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> | | | |
| If Unit Dose, indicate NDC here: <input type="text"/> | | | |

ORDER INFORMATION

Unit of Sale

| | |
|-------------------------------------|-------------------|
| <input type="checkbox"/> | Bottle |
| <input checked="" type="checkbox"/> | Box/Carton |
| <input type="checkbox"/> | Ampule |
| <input type="checkbox"/> | Glass |
| <input type="checkbox"/> | Tube |
| <input type="checkbox"/> | Vial Liquid Sgl |
| <input type="checkbox"/> | Vial Liquid Multi |
| <input type="checkbox"/> | Vial Powder Sgl |
| <input type="checkbox"/> | Vial Power Multi |
| <input type="checkbox"/> | Other: Write In |

What is the NDC selling unit?

Minimum order quantity?

If Yes, how many of which package type?

| | |
|---------------------------------|-------------------|
| <input type="text" value="28"/> | Each |
| <input type="text"/> | Inner/Carton/Pack |
| <input type="text"/> | 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:

| | |
|-------------------------------------|------------|
| <input checked="" type="checkbox"/> | Each |
| <input type="checkbox"/> | Gram |
| <input type="checkbox"/> | Milliliter |

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?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?

GLN:

If Yes, was original product purchased direct from mfr?

If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-----------|
| | | Depth | Width | Height | | |
| Box/Carton/Bundle/Inner Pack: | 0.4 | 2.6 | 2.6 | 7.4 | 50.024 | 1 |
| Case: | 11.35 | 12.1 | 19.6 | 9.4 | 2229.304 | 28 |
| Pallet: | | | | | 0 | |

GTIN AND HIBCC PRODUCT INFORMATION

| Saleable Unit of Measure | Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|--|----------|-------|----------------|---------------------|
| Item/Each | 1 | | 00370700112212 | 00370700112212 |
| Box/Carton/Bundle/Inner Pack | | | | |
| <input checked="" type="checkbox"/> Case | 28 | | 10370700112219 | |
| Pallet | | | | |

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline 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:



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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?
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No
 - c. Contact Hazard? Yes
 - d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) Yes
 - e. Does the product contain DEHP? 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? Yes No Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

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

SDS Hazard Classification

- Organic
 - Inorganic
 - Steroid/Androgen
 - Corrosive
 - Oxidizer
 - Contact Hazard
- Aerosol Class; Identify NFPA Storage Level:
- Is the product a NIOSH hazardous drug? Yes 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 Yes
- If Yes, is it managed with a pharmacy registry? Yes No
Website URL:
- Med Guide Required Yes No
- Limited Distribution Requirement Yes No
- Comments / Details: (For example, iPledge program?)
- REMS:**
- REMS Program Manager Name: Phone:
- Supplier Manages REMS registry exclusively: Yes No
- Wholesale distributor support: Yes No
- Provider Name: DEA #:
- Site Enrollment Number assigned by Supplier: PCPDP#:
- NPI #:
- Comments
- Registry:**
- Registry Program Contact Name: Phone:
- Comments

RETURN INSTRUCTIONS

- Contact tel. # if product received damaged:
- Is product returnable for credit: Yes No
- 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 and/or Image of Product Barcode:



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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 <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="checkbox"/> Drop Ship service fee billed with each order: <input type="checkbox"/> Drop Ship miscellaneous fees billed: <input type="checkbox"/> 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"/> | |
| Other Data Information Required to Process PO: | Return Instructions |
| 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"/> | 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"/> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <input type="text"/> | Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/> |