

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

Version 2021

Introduction Type: New Item

Final Version

Date: 1/20/2023

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: SOLA Pharmaceuticals Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A215417
 Medical Device Class, if applicable:
 DUNS: 080121345
 Proprietary Name (if Applicable) and Established Name: Cyanocobalamin- Cyanocobalamin Injection
 Selling Unit NDC: 70512-840-25 Unit of Use NDC: 70512-840-01 UPC: 070512840258
 UDI
 Description: Cyanocobalamin Injection, USP 1,000 mcg/mL; 25 vials; is a sterile solution of Cyanocobalamin for intramuscular or subcutaneous injections.
 Active Ingredient(s): Cyanocobalamin
 URL for Additional Product Information:
 Address: 655 Highlandia Dr. City: Baton Rouge State: LA Address 2: Zip: 70810
 Key Contact: Email: info@solameds.us
 Phone Number: 866-747-7365 Fax: 800-754-9550
 Product Therapeutic Classification: Synthetic form of vitamin B12

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: (Controlled Room – between 20 and 25 C (68° – 77° F))
 Other Temperature Range Requirement (write in):
 Notes: Protect from light.
 Is this product to be shipped to customers on ice? No
 Is this product to be shipped to customers on dry ice? No
 b. Contact for temperature excursion questions:
 Name: Number: 866-747-7365 Group E-mail: info@solameds.us
 c. Special regulations for product in any states? Special returns requirements for this product? No
 d. Store product (unit of sale) upright? Yes
 Protect product (unit of sale) from light? Yes
 e. Shelf life: 24 Months
 Initial shelf life at launch (if different):

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? <input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status <input type="checkbox"/> Neither	Direct-Ship Only <input type="checkbox"/>	Size: 25 x 1mL IM or SC vials
if yes, enter class #	FDA Approval Status		Strength: 1000mcg/mL
if yes, list NDCs of component parts reverse numbered?	Allergens Present		Dosage Form: Injectable Solution
co-licensed? <input type="checkbox"/> No	Country of Origin <input type="checkbox"/> India		Product Shape: NA
latex-free? <input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		Product Color: Clear Red Solution
preservative-free? <input type="checkbox"/> No			Product Imprint: NA
correctional institution block? <input type="checkbox"/> No			
opioid? <input type="checkbox"/> No			
Cannabinoi? <input type="checkbox"/> No			
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>			
If Unit Dose, indicate NDC here:			

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? 1 box of 25 vials (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

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

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AP Authorized Generic If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Cyanocobalamin Injection, USP

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 25 vials (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? Yes No
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? No
 Is product sold by manufacturer's exclusive distributor? No
 Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.
 GLN: 0370512000004
 GCP: 0370512
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Depth	Dimensions (US msmts.) Width	Height	Volume (Cube)	Saleable # Pieces
Box/Carton/Bundle/Inner Pack:	0.4	3.54	3.54	1.57	19.674612	25
Case:	30.55	15.35	11.61	7.87	1402.5402	72
Pallet:	1102.3	46.06	34.84	44.09	70752.563	2592

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	25		00370512840259	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	72		50370512840254	
<input checked="" type="checkbox"/> Pallet	2592		70370512840258	

COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$) \$89.00
 As of date: 8/5/22

WHOLESALE USE ONLY:
 Vendor #: Whst. Code #: FineLine Code:

*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. 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? No

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

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT?
 (if yes, answer a-e below and provide SDS) No

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?
 (if yes, answer a-e below and provide SDS) No

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: No

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#

SDS Hazard Classification

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, No
 identify NFPA Storage Level:
 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? No
 Website URL:

Med Guide Required No
 Limited Distribution Requirement No
 Comments / Details: (For example, iPledge program?)

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 866-747-7365

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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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"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> 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"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <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: 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 and Priority Overnight PO Processing 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"/>	Return Instructions 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: 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"/>	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
Miscellaneous Notes: <input type="text"/>	