HDA

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

Version 2020 | Introduction Type: | | Final Version | Date: | 6/26/2020

PRODUCT INFORMATION

Company Name:	Amneal Specialty, a Division of Amneal Pharmaceuticals, LLC	Application:	NDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	17-078		
DUNS:	827748190		
Proprietary Name (If Applicable) and Established Name:	Dexedrine Dextroamphetamine Sulfate Spansule Sustained-Release Capsules 10mg		
Selling Unit NDC:	64896-674-10	Unit of Use NDC:	UPC: 3-6489667410-4
UDI		CVX Code:	MVX Code:
Description:	Each capsule, with brown cap and natural body, contains dextroamphetamine sulfate. The 10-mg capsule is imprinted in white with IX and 10 mg on the brown cap and is imprinted in white with 674 and 10 mg on the natural body		
Active Ingredient(s):	dextroamphetamine sulfate		
URL for Additional Product Information:			
Address:	400 Crossing Blvd. Third Floor	Address 2:	
City:	Bridgewater	State: NJ	Zip: 08807
Key Contact:		Email:	
Phone Number:	866-525-7270	Fax:	866-525-7271
Product Therapeutic Classification:	Cerebral Stimulants		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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

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: 877-835-5472 option 1
Group E-mail:

c. Special regulations for product in any states? No
Special returns requirements for this product? No

d. Store product (unit of sale) upright? No
Protect product (unit of sale) from light? Yes

e. Shelf life: 36 Months
Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is?		
a legend device?	No	Is the Product… Direct-Ship Only
if yes, enter class #		Is the Product…
a product kit?	No	Orphan Drug Status
if yes, list NDCs of component parts		FDA Approval Status
reverse numbered?	No	
co-licensed?	No	Allergens Present
latex-free?		
preservative-free?		
correctional institution block?	No	
opioid?	No	
Cannabinoid?	No	Country of Origin USA
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)? No
If Unit Dose, indicate NDC here:		

PRODUCT DESCRIPTION INFORMATION

Size:	90
Strength:	10 mg
Dosage Form:	Capsules
Product Shape:	capsule shaped
Product Color:	brown cap and natural body
Product Imprint:	imprinted in white with IX and 10 mg on the brown cap and is imprinted in white with 674 and 10 mg on the natural body

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?
x	Bottle	1 bottle of 90 capsules
	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
	Ampule	
	Glass	Minimum order quantity? Yes
	Tube	
	Vial Liquid Sgl	
	Vial Liquid Multi	If Yes, how many of which package type?
	Vial Powder Sql	24 Each
	Vial Power Multi	Inner/Carton/Pack
	Other: Write In	Case

PHARMACY ORDER / BILL UNIT

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

FOR GENERIC DRUG PRODUCTS

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:
Is product exempt from DSCSA?	No	
If yes, select exemption:		
Other exemption - Write in:		
Is product repackaged?	No	If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor?	No	
Has FDA granted waiver/exception/exemption for product?	No	If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	49.04 gm	2.875"	1.75"	4.0625"		1
Box/Carton/Bundle/Inner Pack:						
Case:	3.25 lbs	11.875"	10.8125"	4.875"		24
Pallet:	508 lbs	47.5"	33.5"	63.5"		144

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00364896674104	
	Box/Carton/Bundle/Inner Pack				
x	Case	24		50364896674109	
	Pallet				

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$2,109.72
As of date:	

WHOLESALER 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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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?
  - 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? — No
  - (If yes, attach SDS with special instructions.)
- 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#

SDS Hazard Classification

☐ Organic	☐ Corrosive
☒ Inorganic	☐ Oxidizer
☐ Steroid/Androgen	☐ 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
Limited Distribution Requirement
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   PCPDP#:
    by Supplier: NPI #:

  Comments

Registry: — No
  Registry Program Contact Name: Phone:
  Comments

ADD'L STORAGE INFORMATION

Is the Product…
Controlled Substance?	Yes	Controlled Substance Code: 1100
Controlled by State(s)?	No	Listed Chemical (List I or II): No
ARCOS Reportable?	Yes	If yes, indicate which:
Schedule No.	2	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 — 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:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 866-525-7270
  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 and/or Image of Product Barcode:

Release DATE

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Version 2020   **FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:
- a. EDI
- b. Autofax — Fax Number:
- c. Fax — Fax Number:
- d. Phone only — Phone No.:
- e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #:   Name:
Phone:

Standard Order Receipt and Processing

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:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:
- ☐ Monday
- ☐ Tuesday
- ☐ Wednesday
- ☐ Thursday
- ☐ Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:

Other fees apply:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

Return Instructions

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?

Is product order for restocking purposes?