



October 26, 2018

Tagi Pharma
722 Progressive Lane
South Beloit, IL, 61080

Attn: Mr. Richard Waggoner

Dear Valued Customer:

In response to your Safety Data Sheet (SDS) request, according to OSHA Hazard Communications Standards 1910.1200(b)(6)(vii) and 1910.1200(b)(5)(iii), an SDS is not required for the requested product(s), as they are exempt from the Hazard Communications Standard.

NDC	Description
51224-102-50	Hydromorphone Hydrochloride Tablets, USP 8 mg, (100 Tablets)
51224-206-30	Naltrexone Hydrochloride Tablets, USP 50 mg, (30 Tablets)
51224-206-50	Naltrexone Hydrochloride Tablets, USP 50 mg, (100 Tablets)
51224-203-50	Phentermine Hydrochloride Capsules, USP 15 mg (100 Capsules)
51224-203-70	Phentermine Hydrochloride Capsules, USP 15 mg (1000 Capsules)
51224-202-50	Phentermine Hydrochloride Capsules, USP 30 mg (100 Capsules)
51224-202-70	Phentermine Hydrochloride Capsules, USP 30 mg (1000 Capsules)
51224-101-50	Phentermine Hydrochloride Tablets, USP 37.5 mg (100 Tablets)
51224-101-70	Phentermine Hydrochloride Tablets, USP 37.5 mg (1000 Tablets)

The above products are stored, prescribed, prepared, dispensed, administered, and disposed of according to the directions included within the product labeling and product packaging. The products are regulated by the Food and Drug Administration according to 21 CFR § 211.132.

If you have any questions or require additional product information, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Nadim Chaaoui", is written over a light blue horizontal line.

Nadim Chaaoui
Sr. Manager QA and Compliance
Elite Pharmaceuticals
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Fax: 201-660-7915
Email: nchaaraoui@elitepharma.com



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post Launch Change Final Version Date: 9/1/2016

PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc. Application: ANDA

Application Number for NDANDA/ABLA, Med Device: ANDA/075274

Rx Product/Proprietary Name: Naltrexone Hydrochloride Tablets, USP

NDC: 51224-206-50

CVV Code: UPC: MX Code:

Description: Naltrexone Hydrochloride Tablets, USP 50mg

Active ingredients: Naltrexone Hydrochloride

URL for Additional Product Information: www.tagipharma.com

Address: 722 Progressive Lane

City: South Beloit

Key Contact: Melissa Bradley

Phone Number: 815-624-7685

State: IL

Email: mbradley@tagipharma.com

Fax: 815-624-7014

Address 2: Room 205

Zip: 61080

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB

II. Brand Name: ReVia and Depzate

III. Generic Equivalent for Brand: Naltrexone HCL

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes

Is product exempt from DSCSA? No

Is product exempt from DSCSA? No

If Yes, select exemption:

Other exemption - Write in:

Is product repackaged? No

Is product sold by manufacturer's exclusive distributor? No

Are any waivers granted for product ID/barcode? No

If Yes, was original product purchased direct from mfr?

If Yes, attach documentation from FDA

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?

Direct Ship Item

Unit of Sale

What is the NDC selling unit?

Minimum order quantity?

If Yes, how many of which package type?

Each

Inner/ Carton/Pack

Case

UPC:

Carton:

WHOLESALE USE ONLY

Vendor #:

Whsi. Code #:

Each

Gram

Milliliter

Rx billing unit to pharmacy:

Product Shape:

Product Color:

Product Imprint:

Round film-coated

Yellow

EL and 15

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

VII. No Requirement (write in)

CONTACT FOR TEMPERATURE EXCURSION QUESTIONS:

Name: Matt Mathis

Number: 815-624-7685

b. Contact for temperature excursion questions:

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

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: 24 Months

Initial shelf life at launch (if different):

Months

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Depth	Height	Width:	Volume (Cube)	# Pieces:
Box/ Carton:	1.7oz		2.5"		1.75"	
Case:	20.3oz	7.5"	1.75"		5.5"	
Pallet:						
Case:						
Carton:						

PHARMACY ORDER/BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Other Product Information

Size/Strength/Form:

Product Shape:

Product Color:

Product Imprint:

Round film-coated

Yellow

EL and 15

COST INFORMATION

Regular Cost Per Unit of Sale (\$)

Invoice Cost (WAC) (\$)

Federal Excise Tax Per Unit of Sale

As of date: 9/1/2016

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

c. Warning appears on label? No

d. Contact Hazard? No

e. 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 the DOT?

Is this a reportable quantity? No

RO 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)

Limitied 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# _____

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL STORAGE INFORMATION

Please check as appropriate for this product:

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class: Identify NFPA Storage Level: _____

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

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (>2.2%)

Other: _____

GLASS OR PLASTIC RESTRICTION

No restriction: Select "YES" if sold to retail pharmacy, hospital, clinics and physician offices

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments: _____

Hazardous Waste Identification

EPA Hazardous Waste Code: _____

(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 IDENTIFICATION - Serialized

Serialized?	Level	How?	GTIN-14
If not, when? <input type="checkbox"/> No	Item	Linear	
Items aggregated to case? <input type="checkbox"/> 1/1/2017	Box/Case	Linear	
	Case	Linear	
	Pallet	Linear	
		RFID	
		RFID	
		RFID	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? _____

Website URL: _____

Comments / Details: (For example, Pledge program?) _____

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 800-397-9228

Is product returnable for credit: Yes

URL/Link to returns policy: N/A

Special regulations or returns requirements for this product in certain states? Yes

If so, which states? Other requirements? Comments? _____

Georgia, Mississippi and North Carolina. Request can be made via fax: 815-624-7887 or email: customercare@agpharma.com

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: _____

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

Purchase orders may be accepted by:

a. EDI Yes

b. Autolox Yes

c. Fax Yes

d. Phone only Yes

e. Supplier Web Site only No

12 Bottles

Minimum Order Quantity: 800-397-9228

Supplier's Customer Service Number: 815-624-7687

Contracted 3PL company / contact #: 815-624-7687

Name: 815-624-7687

Phone: 800-397-9228

Fax Number: 815-624-7687

Fax Number: 815-624-7687

Phone No.: 800-397-9228

Site Address:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order: Yes

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

REMS or Registry Restrictions

REMS: No

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: _____

Wholesale distributor support: _____

Provider Name: _____

Site Enrollment Number assigned by Supplier: _____

DEA #: _____

PCPDP #: _____

NPI #: _____

Comments:

Registry: _____

Registry Program Contact Name: _____ Phone: _____

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: _____

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier: 12:00 PM Central

Cut off time: _____

Shipping lead time of PO: _____ Hours _____ Days

Ships same day for next day receipt: No

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: Yes

Overnight and Priority/Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: 12:00 PM Central

Days of week overnight is available:

<input checked="" type="checkbox"/>	Monday
<input checked="" type="checkbox"/>	Tuesday
<input checked="" type="checkbox"/>	Wednesday
<input checked="" type="checkbox"/>	Thursday
<input checked="" type="checkbox"/>	Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 12:00 PM

Return Instructions

Contact # if product is received damaged: 800-397-9228

Is product returnable for credit: Yes

URL/link to returns policy: N/A

Special regulations or returns requirements for this product in certain states? Yes

If so, which states? Other requirements? Comments? _____

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? _____

Is product order for restocking purposes? _____

Miscellaneous Notes: _____