

SAFETY DATA SHEET

hikma.

Alendronate Sodium Oral Solution, 70 mg/75 mL

Section 1. Identification

GHS product identifier : Alendronate Sodium Oral Solution, 70 mg/75 mL
 Chemical name : Alendronate Sodium
 Product code : Not available.
 Other means of identification : 70 mg/75 mL oral solution is supplied as a clear, colorless to pale pink solution with a raspberry flavor.
 Product type : Liquid.
 Container information : Bottle

Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Alendronate Sodium Oral Solution is for treatment of osteoporosis in postmenopausal women and to increase bone mass in men with osteoporosis.

Supplier's details : Hikma Pharmaceuticals USA Inc.
 1809 Wilson Road,
 Columbus, Ohio 43228
 Tel: (614) 276-4000

Emergency telephone number (with hours of operation) : CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3887
 24/7

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.
 Hazard statements : No known significant effects or critical hazards.

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statements

Prevention : Not applicable.
 Response : Not applicable.
 Storage : Not applicable.
 Disposal : Not applicable.
 Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Chemical name	: Alendronate Sodium
Other means of identification	: 70 mg/75 mL oral solution is supplied as a clear, colorless to pale pink solution with a raspberry flavor.

Active pharmaceutical ingredient	%	CAS number
4-Amino-1-hydroxy-1-phosphonobutyl phosphonic acid, monosodium salt trihydrate	0 - 0.1	121268-17-5

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

See Package Insert for further information.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin contact	: Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
Ingestion	: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician	: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	: No specific treatment.
Protection of first-aiders	: No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
- For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store at 20°C to 25°C (68°F to 77°F). Do not freeze. Store in original container protected from direct sunlight in a dry and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Clear.]
Color : Colorless to pale pink.
Odor : Not available.
Odor threshold : Not available.
pH : Not available.

Section 9. Physical and chemical properties

Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not applicable.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not applicable.
Lower and upper explosive (flammable) limits	: Not applicable.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Soluble in water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Section 11. Toxicological information**Reproductive toxicity**

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

Potential immediate effects : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity**Acute toxicity estimates**

There is no data available.

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

AERG : Not applicable.

Section 14. Transport information

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

FDA : Alendronate Sodium Oral Solution is an approved prescription medication.
 U.S. Federal regulations : **TSCA 4(a) proposed test rules:** 1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt
TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

SARA 313

There is no data available.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
Not classified.	

History

Revision date mm/dd/yyyy : 09/15/2018
 Version : 2
 Prepared by : KMK Regulatory Services Inc.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post-Launch Change Final Version Date: 10/17/2017

PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc. **Application:** ANDA

Application Number for NDA/ANDA/BLA, Med Device: A090520

Rx Product/Proprietary Name: Alendronate Sodium Oral Solution **UPC:**

NDC: 51224-0301-10 **MXV Code:**

Description: Alendronate Sodium Oral Solution

Active ingredients: Alendronate Sodium

URL for Additional Product Information: www.tagipharma.com

Address: 722 Progressive Lane **Address 2:** Room 205

City: South Beloit **State:** IL **Zip:** 61080

Key Contact: Melissa Bradley **Email:** mbradley@tagipharma.com

Phone Number: 815-624-7685 **Fax:** 815-624-7014

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AA **II. Brand Name:** Fosamax

III. Generic Equivalent for Brand: Alendronate Sodium Oral Solution

DRUG SUPPLY CHAIN SECURITY/ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No

Is product exempt from DSCSA? Yes No

If Yes, select exemption: Other exemption - Write in: _____

Is product repackaged? Yes No

Is product sold by manufacturer's exclusive distributor? Yes No

Are any waivers granted for product ID/barcode? Yes No

DUNS: 963322560

If Yes, attach documentation from FDA _____

ADDITIONAL PRODUCT INFORMATION

Is the Product... Legend Device? No

State Control? No

ARCOS reportable? No

Co-Licensed? No

Controlled Substance? No

Schedule No.? N/A

(incl. N for non-narcotic)

Controlled Substance Code: N/A

Hazardous Material/Cytotoxic Agent? No

Is Item... Neither

If Unit Dose, is item bar coded to unit dose for hospital scanning? _____

Is it reverse numbered? _____

ORDER INFORMATION

What is the NDC selling unit? 1 - 4 pack

Unit of Sale: Bottle Box/ Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sgl Vial Powder Multi Other: Write in _____

Minimum order quantity? Yes No

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

PHARMACY ORDER /BILL UNIT

Rec. sell unit to customer? _____

Size/Strength/Form: 70mg/75ml

Product Shape: _____

Product Color: Clear colorless to pale pink liquid.

Product Imprint: _____

WHOLESALE USE ONLY

Vendor #: _____

Whsl. Code #: _____

Freeline Code: _____

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 (write in) _____

VII. No Requirement

b. Contact for temperature excursion questions:

Name: Mat Mathis

Number: 815-624-7685

Is this product to be shipped to customers on ice? No

Is this product to be shipped to customers on dry ice? No

c. Special regulations for product in certain states?

Special returns requirements for this product? No

Special regulations for product in certain states? No

Special returns requirements for this product? No

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light? Yes

Protect product (unit of sale) from light? Yes

e. Shelf life:

Shelf life: 24 Months

Initial shelf life at launch (if different): _____

Months

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Depth	Height	Width:	Dimensions (US msms.)	Volume (Cube)	# Pieces:
Box/ Carton:	0.99	6.81	4.13	2.41			
Case:	30.65	14.43	13.11	12.87			
Pallet:							
UPC:							

COST INFORMATION

Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$191.65	

As of date: 9/15/2017

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

Signature: _____

See new p. 3 for Designated Drop Ship Only.

*Please provide any additional information on page 2.



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 No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 Carcinogen No
 Reproductive Toxicant No
 Both No
 Warning appears on label 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

EPA Hazardous Waste Code: _____

Hazardous Waste Identification _____

Is this product regulated for shipment by the DOT? No

Is this a reportable quantity?
 RQ Threshold: _____ No

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 No (if yes, identify method below) No

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# _____

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

Passenger

Cargo

Passenger & Cargo

ADD'L 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: _____

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) No

Comments: _____

(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 INFORMATION - Serialization

Serialized?	No	Yes	Level	Item	2D	2D	2D	2D	How?	RFID	RFID	RFID	RFID	GTIN-14
If not, when?	11/1/2017								Linear					
Items aggregated to case?									Linear					
									Linear					
									Linear					

REMS OF 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, IPledge program?) _____

RETURN INSTRUCTIONS

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

Is product returnable for credit: Yes No

URL/link to returns policy: _____

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

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

[Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@lagipharma.com]

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here: _____

_____ N/A

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
- b. Autofax
- c. Fax
- d. Phone only
- e. Supplier Web Site only

Minimum Order Quantity: _____
 Supplier's Customer Service Number: _____
 Contracted 3PL company / contact #: _____

Fax Number: _____
 Fax Number: _____
 Phone No.: _____
 Site Address: _____

Name: _____
 Phone: _____

Standard Order, Receipt and Processing

Purchase order daily receipt cut off time by supplier: _____
 Cut off time: _____ Central

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: _____
 Phone #: _____
 Order receipt method: _____ 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: _____

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 Program Contact Name: _____ Phone: _____
 Comments: _____

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? _____

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? _____
 Is product order for restocking purposes? _____

Other Data Information Required for Process PO

Patient Procedure Date: _____
 Physician Name: _____
 Physician/Clinic Phone #: _____
 Physician State License #: _____
 Physician/Clinic DEA #: _____
 Physician/Clinic Specialty: _____

Miscellaneous Notes:
