

AADA No.	Drug	Applicant
60-128	Ampicillin Trihydrate	IBI, Giovanni Lorenzini S.p.A., 20139 Milano, Italy.
60-130	Ampicillin	Do.
61-659	Erythromycin Delayed-Release Tablets, U.S.P., 250 milligrams (mg)	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
61-818	Cephalexin Monohydrate	IBI.
61-923	Amoxicillin Trihydrate	Do.
62-052	Nystatin Ointment, U.S.P.	Lemmon Co., 650 Cathill Rd., Sellersville, PA 18960.
62-430	Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment, U.S.P.	Pharmafair, Inc., 110 Kennedy Dr., Hauppauge, NY 11788.
62-449	Cephalothin Sodium	IBI.
62-666	Cephalothin Sodium for Injection, U.S.P., 1 gram (g) and 2 g	Fujisawa USA, Inc., Parkway North Center, Three Parkway North, Deerfield, IL 60015-2548
62-710	Cephalothin Sodium	IBI.
62-747	Clindamycin Phosphate Injection, U.S.P., 150 mg/milliliters (mL)	Fujisawa USA, Inc.
ANDA No.	Drug	Applicant
80-041	Trisulfapyrimidines Oral Suspension, U.S.P., 0.5 g/5 mL ..	Solvay Pharmaceuticals, Inc.
80-921	Vitamin A Capsules, U.S.P., 50,000 units	Lemmon Co.
83-993	Phendimetrazine Tartrate Tablets, U.S.P., 35 mg	Solvay Pharmaceuticals, Inc.
84-435	Meprobamate Tablets, U.S.P., 200 mg	Do.
85-897	Phendimetrazine Tartrate Capsules, U.S.P., 35 mg	Do.
87-074	Diatrizoate Meglumine and Diatrizoate Sodium Injectin, U.S.P.	Mallinckrodt Medical, Inc., P.O. Box 5840, St. Louis, MO 63134.
87-113	Triamcinolone Acetonide Cream, U.S.P. 0.1%	Solvay Pharmaceuticals, Inc.
87-210	Reserpine, Hydralazine Hydrochloride, and Hydrochlorothiazide Tablets, U.S.P., 0.1 mg/25 mg/15 mg	Do.
87-833	Prednisone Tablets, U.S.P., 25 mg	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216-6532
88-071	Dexamethasone Sodium Phosphate Ophthalmic Ointment, U.S.P., 0.05%	Pharmafair, Inc.
88-612	Phentermine Hydrochloride Capsules, U.S.P., 30 mg	Lemmon Co.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective March 31, 1995.

Dated: February 16, 1995.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 95-5060 Filed 2-28-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95N-0050]

Drug Export; Sandostatin (Octreotide Acetate) Lar® Injection; 10-Milligram (mg), 20-mg, and 30-mg Vials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sandoz Pharmaceuticals Corp. has

filed an application requesting conditional approval for the export of the human drug Sandostatin (octreotide acetate) LAR® Injection 10-mg, 20-mg, and 30-mg vials to Switzerland for further packaging and marketing.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently

approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Sandoz Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936-1080, has filed an application requesting approval for the export of the human drug Sandostatin (octreotide acetate) LAR® Injection 10-mg, 20-mg, and 30-mg vials to Switzerland. This product is a new formulation of octreotide acetate manufactured by a different process which is indicated for arremgaly, malignant carcinoid syndrome, and vipoma. The firm does have approval for Sandostatin Injection. The

application was received and filed in the Center for Drug Evaluation and Research on December 27, 1994, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 13, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: February 9, 1995.

Edward Miracco,

Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95-5059 Filed 2-28-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95N-0049]

Drug Export; Zyluprim (Allopurinol Sodium) for Injection Equivalent to 500 Milligrams Allopurinol Sterile Lyophilized Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Burroughs Wellcome Co. has filed an application requesting approval for the export of the human drug Zyluprim (allopurinol sodium) for Injection equivalent to 500 milligrams (mg) allopurinol to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Burroughs Wellcome Co., 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709-2700, has filed an application requesting approval for the export of the human drug Zyluprim (allopurinol sodium) for Injection equivalent to 500 mg allopurinol to Canada. This product is primarily indicated for its prophylactic usage in patients with leukemia, lymphomas, or other malignancies, receiving antineoplastic treatment (radiation or cytotoxic drugs) which might induce increased uric acid levels. The firm does have new drug application approval for Zyluprim (allopurinol) Tablets in two dosage strengths. The application was received and filed in the Center for Drug Evaluation and Research on January 25, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by March 13, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate

consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: February 8, 1995.

Edward Miracco,

Acting Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95-5062 Filed 2-28-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM-070-5101-G014; NMNM93652]

Notice of intent, and Notice of Scoping Meetings and Comment Period; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent, and notice of scoping meetings with a public comment period.

SUMMARY: In accordance with the National Environmental Policy Act, the Bureau of Land Management is directing the preparation of an environmental document for the construction, operation, and maintenance of a pipeline that would be 12 or 16 inches in diameter and approximately 400 miles in length. The proposed project is known as the Mid-American Pipeline Company Four Corners Loop Project. The environmental document is being prepared as an environmental assessment, but will be advanced to the environmental impact statement level if this is indicated by scoping or by a determination of significant impacts in the environmental assessment. Public meetings will be held for the proposed pipeline project with a public comment period.

DATES: Public scoping meetings are planned in Albuquerque, New Mexico at the Albuquerque Convention Center, San Miguel Room, 401 Second Street, NW., on March 15, 1995 at 3:00 p.m. to 9:00 p.m. and in Roswell, New Mexico at the Roswell Inn, Berrendo Room, 1815 North Main at 3:00 p.m. to 9:00 p.m. on March 16, 1995, respectively. The meeting agenda will be to conduct an open-house to receive interested parties from 3:00 p.m. to 5:30 p.m. with a formal presentation starting at 7:00 p.m., followed by a workshop to receive comments, and ending at 9:00 p.m.