

Food and Drug Administration**Illini Feeds; Swine Mix Tylan 10 Premix; Withdrawal of Approval of NADA**

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration withdraws approval of a new animal application (NADA) providing for use of Swine Mix Tylan (Tylosin phosphate) 10 Premix in making finished feeds. The feeds are indicated for increased rate of weight gain and improved feed efficiency. The sponsor, Illini Feeds, requested the withdrawal of approval.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT:

David N. Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1846.

SUPPLEMENTARY INFORMATION: Illini Feeds, Box T, Oneida, IL 61467, is the sponsor of NADA 110-202, which provided for use of a 10-gram-per-pound tylosin premix in making complete swine feeds containing 10 to 100 grams of tylosin per ton. The feeds are indicated for increased rate of weight gain and improved feed efficiency. The NADA was originally approved July 28, 1978. By letter of July 21, 1980, the sponsor requested withdrawal of approval of the NADA because the product has never been manufactured or marketed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e); 82 Stat. 345-347 (21 U.S.C. 360b(e))), under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 110-202 and all supplements for Illini Feeds' Swine Mix Tylan 10 Premix is hereby withdrawn, effective - December 29, 1980.

In a separate document published elsewhere in this issue of the Federal Register, § 558.625 *Tylosin* is amended by revoking paragraph (b)(55), which provides for approval of this NADA.

Dated: December 3, 1980.

Terence Harvey,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 80-39120 Filed 12-18-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 76N-0052]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter (OTC) Human Use; Decision on Dosage of Pseudoephedrine Preparations

AGENCY: Food and Drug Administration, HHS.

ACTION: Extension of effective date.

SUMMARY: The Food and Drug Administration is extending until May 1, 1981, the date by which manufacturers of OTC oral nasal decongestant drug products containing pseudoephedrine are required to comply with FDA's revised dosage limit. The revised labeling would reflect the agency's decision to reduce the maximum daily dosage of pseudoephedrine preparations in the proposed monograph for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products. The effective date is being changed in response to petitions from two manufacturers who believed that the agency deadline did not allow enough time to reformulate fixed combination products.

DATE: Effective date for required relabeling is May 1, 1981.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 30, 1980 (45 FR 64709), the Commissioner of Food and Drugs announced the decision that the available data did not support the 360-milligram (mg) maximum daily dosage for drug products containing pseudoephedrine for OTC use as an oral nasal decongestant that had been recommended by the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products. The notice explained that data submitted to the agency after the publication of the Panel's proposed monograph suggest that significant side effects could result from the 360-mg daily dosage and that a 240-mg maximum adult daily dosage is more appropriate. The agency concluded that, under the procedures established in 21 CFR 330.13(b)(2), pseudoephedrine products labeled with the higher dosage limitations would be required to be relabeled with specified lower dosage limitations by January 30, 1981.

On October 30, 1980, the Commissioner received two petitions, one from McNeil Consumer Products Co. and the other from Marion Laboratories, Inc., requesting a reconsideration of the

January 30, 1981, effective date for the required relabeling. (Copies of the petitions are on file in the Dockets Management Branch (HFA-305), Rm. 4-62, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.) They based their requests on their belief that the deadline did not allow enough time for changes in fixed combination products, which must be reformulated as well as relabeled to conform to the new reduced dosage limitation. The petitions pointed out that reformulation entails a variety of technical procedures and business transactions that take longer than 4 months to complete. Accordingly, they stated that it would be impossible to reformulate before the announced deadline. Both manufacturers also stressed that there would be increased production costs if current inventories could not be used. The petitions requested that the effective date be extended until either April 1 or May 1, 1981.

The Commissioner has considered these requests and has concluded that good and sufficient reason has been provided for extending the effective date. Therefore, FDA is granting both petitions by extending until May 1, 1981, the effective date for compliance with the revised dosage limitations set forth in the September 30, 1980 notice.

Dated: December 12, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39425 Filed 12-18-80; 8:45 am]

BILLING CODE 4110-03-M

Ayerst Laboratories; Hycholin Injectable; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency withdraws approval of a new animal drug application (NADA) sponsored by Ayerst Laboratories providing for use of Hycholin (pentapiperide methylsulfate injectable) in management of gastrointestinal disturbances in dogs and cats. The sponsor has requested this action.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT:

Howard Meyers, Bureau of Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: Ayerst Laboratories, Division of American Home Products Corp., 685 Third Ave.,

New York, NY 10017, is the sponsor of NADA 13-917 which provides for intravenous or intramuscular use of Hycholin in dogs and cats for treating excessive salivation, gastroenteritis, and diarrhea. The application was originally approved November 7, 1963. By letter of January 9, 1978, the sponsor requested withdrawal of approval of the NADA because the product is no longer being manufactured or marketed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115(d) *Withdrawal of approval of applications* (21 CFR 514.115(d)), notice is given that approval of NADA 13-917 and all supplements for Ayerst Laboratories', Hycholin Injectable is hereby withdrawn, effective December 29, 1980.

Dated: December 10, 1980.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 80-39048 Filed 12-19-80; 8:45 am]

BILLING CODE 4110-03-M

Burns-Biotec Laboratories, Inc.; Pentosol (Pentobarbital Sodium Injection); Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) withdraws approval of a new animal drug application (NADA) providing for use of Pentosol (pentobarbital sodium injection) as an intermediate-acting anesthetic in dogs and cats. The sponsor, Burns-Biotec Laboratories, Inc., requested the action.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT: Leonard D. Krinsky, Bureau of Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: Burns-Biotec Laboratories, Inc., 8530-8536 K St., P.O. Box 3113, Omaha, NE 68103, is the sponsor of NADA 46-588 which provides for use of Pentosol (pentobarbital sodium injection) as an anesthetic in dogs and cats. The application was originally approved October 4, 1974. In a letter dated August 27, 1980, the firm requested that

approval of NADA 46-588 be withdrawn.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))), under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 46-588 and all supplements for Pentosol (pentobarbital sodium injection) is hereby withdrawn, effective December 29, 1980.

In a separate document published elsewhere in this issue of the *Federal Register* § 522.1704(b)(2) is amended to delete that portion of the regulation which reflects approval of this NADA.

Dated: December 3, 1980.

Terence Harvey,

Deputy Director, Bureau of Veterinary Medicine.

[FR Doc. 80-39047 Filed 12-18-80; 8:45 am]

BILLING CODE 4110-03-M

Merck Sharp & Dohme Research Laboratories; Equizole Liquid Horse Wormer; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency withdraws approval of a new animal drug application (NADA) sponsored by Merck Sharp & Dohme Research Laboratories providing for use of Equizole (thiabendazole) Liquid Horse Wormer for controlling certain helminth infections. The sponsor has requested this action.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT: Howard Meyers, Bureau of Veterinary Medicine (HFV-216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: Merck Sharp & Dohme Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065, is the sponsor of NADA 47-714 which provides for use of Equizole Liquid Horse Wormer for controlling infections of large strongyles, small strongyles, pinworms and threadworms. The application was originally approved October 8, 1971. By letter of April 21, 1980, the sponsor requested withdrawal of approval of the application because the product has never been marketed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and

under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115(d) *Withdrawal of approval of applications* (21 CFR 514.115(d)), notice is given that approval of NADA 47-714 and all supplements for Merck's Equizole Liquid Horse Wormer is hereby withdrawn, effective (December 29, 1980).

Dated: December 10, 1980.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 80-39050 Filed 12-18-80; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 80M-0435]

Zimmer-USA; Premarket Approval of Zimmer® Direct Current Bone Growth Stimulator

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the Zimmer® Direct Current Bone Growth Stimulator sponsored by Zimmer-USA, Warsaw, IN. After reviewing the recommendation of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel, FDA notified the sponsor that the application was approved because the device has been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by January 19, 1981.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (formerly the Hearing Clerk's Office) (HFA-305), Food and Drug Administration, Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Henry A. Goldstein, Bureau of Medical Devices (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8162.

SUPPLEMENTARY INFORMATION: The sponsor, Zimmer-USA, Warsaw, IN, submitted an application for premarket approval of the Zimmer® Direct Current Bone Growth Stimulator to FDA on February 26, 1979. The application was reviewed by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel, an FDA advisory committee, which