

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For animal drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the animal drug product IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle (eprinomectin). IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle is indicated for treatment and control of gastrointestinal nematodes (adults and fourth stage larvae, L₄), lungworms (adults and L₄), cattle grubs (all parasitic stages), lice, mange mites, and flies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle (U.S. Patent No. 4,427,663) from Merck & Co., Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated November 7, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle is 2,492 days. Of this time, 2,475 days occurred during the testing phase of the regulatory review period, while 17 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective:* June 22, 1990. FDA has verified the applicant's claim that the date the investigational new animal drug application became effective was on June 22, 1990.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act:* March 31, 1997. The applicant claims March 27, 1997, as the date the new animal drug application (NADA) for IVOMECE® EPRINEX™ Pour-On for Beef and Dairy Cattle (NADA 141-079) was initially submitted. However, FDA records indicate that the date of FDA's official acknowledgement letter assigning a number to NADA 141-079 was March 31, 1997, which is considered to be the initially submitted date for NADA 141-079.

3. *The date the application was approved:* April 16, 1997. FDA has verified the applicant's claim that

NADA 141-079 was approved on April 16, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,255 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 8, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 4, 1999 publication in the **Federal Register**, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 1998.

Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98-18141 Filed 7-7-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 78N-0070; DESI 1626]

Combination Drugs Containing Theophylline, Ephedrine Sulfate, and Hydroxyzine Hydrochloride; Withdrawal of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug applications (NDA's) for Marax Tablets and Marax

Syrup. FDA is also declaring all identical, similar, and related drug products, not otherwise subject to an approved drug application, unlawful, including Brofed Tablets and Hydroxyzine Compound Syrup. Each of these products contains theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. The basis of the withdrawals is that there is a lack of substantial evidence that these combination drugs are effective for the treatment of bronchial asthma.

EFFECTIVE DATE: August 7, 1998.

ADDRESSES: Requests for applicability of this notice to a specific product should be identified with the Docket and DESI numbers found in brackets in the heading of this document and directed to the Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: As part of the agency's drug efficacy program, in a notice published in the **Federal Register** of September 17, 1984 (49 FR 36443), the Commissioner of Food and Drugs granted an evidentiary hearing before an administrative law judge on the proposal to withdraw approval of NDA 11-768 for Marax Tablets and NDA 12-879 for Marax Syrup, each containing theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. The NDA's are held by J. B. Roerig, Division of Pfizer, Inc. (Pfizer), 235 East 42d St., New York, NY 10017.

Other party participants were:

1. Barre-National, Inc., 4128 Haywood Ave., Baltimore, MD 21215 (Barre); Hydroxyzine Compound Syrup (no NDA).

2. Cord Laboratories, Inc. (now Geneva Pharmaceuticals, Inc.), 2555 West Midway Blvd., Broomfield, CO 80038 (Cord); Brofed Tablets (no NDA).

3. Barrows Research Group, Inc., 99 West Hawthorne Ave., Valley Stream, NY 11580 (Barrows). Unnamed drug product. Barrows later withdrew its hearing request.

Subsequently, in accordance with agreements to resolve, by other means, the issue of their drug products' effectiveness, Pfizer, Barre, and Cord withdrew their hearing requests. Under those agreements, FDA has concluded that Marax Tablets and Marax Syrup have not been shown to be effective, and

FDA is now withdrawing approval of the NDA's for these products.

This notice applies to any drug product that is identical, related, or similar to these products and is not the subject of an approved NDA (21 CFR 310.6). Such products include Hydroxyzine Compound Syrup and Brofed Tablets, each of which contains theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and under the authority delegated to her (21 CFR 5.82), finds that on the basis of new information before her with respect to Marax Tablets and Marax Syrup, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approvals and all the amendments and supplements thereto of NDA 11-768 and NDA 12-879 are withdrawn effective August 7, 1998. Shipment in interstate commerce of the products listed above or of any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: June 15, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98-18144 Filed 7-7-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appears in the **Federal Register** of June 25, 1998 (63 FR 34655). The notice announced a meeting of the

Anti-Infective Drugs Advisory Committee, which was scheduled for July 29, 30, and 31, 1998. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

In FR Doc. 98-16934 appearing on page 34655 in the **Federal Register** of Thursday, June 25, 1998, the following correction is made:

On page 34655, under the *Agenda* caption, in the 2d column, beginning in the 1st line, "http://www.fda.gov/cder/guidance.htm" is corrected to read "http://www.fda.gov/cder/guidance/index.htm".

Dated: July 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of New York Title XXI State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on July 29, 1998; 10:00 a.m., Thirty-Eighth floor, 26 Federal Plaza, New York, New York 10278 to reconsider our decision to disapprove New York Title XXI SPA.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by July 23, 1998.

FOR FURTHER INFORMATION CONTACT: Stan Katz, Presiding Officer, HCFA, C1-09-13, 7500 Security Boulevard, Baltimore, Maryland 21244, Telephone: (410)-786-2661.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove the New York Title XXI State Plan Amendment (SPA) submitted March 26, 1998.

Section 1116 of the Social Security Act (the Act) and 42 CFR Part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. These requirements are made applicable under