Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Animal Drugs for Investigational Use (21 CFR Part 511) (OMB Control Number 0910–0117—Reinstatement)

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for approval of new animal drugs for investigational use. Section 512(j) of the act (21 U.S.C. 360b(j)), requires that a sponsor submit to FDA a ''Notice of Claimed Investigational Exemption'' INAD, prior to shipment of the new animal drug for clinical tests in animals. The regulations implementing statutory requirements for INAD approval have been codified under part 511 (21 CFR part 511). The INAD application must contain, among other things, the following specific information: (1) Identity of the new animal drug; (2) labeling; (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices; and (4) name and address of each clinical investigator and the approximate number of animals to be treated or amount of new animal drug(s) to be shipped. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, that distribution is controlled to prevent potential abuse, and that edible products of treated animals will not be distributed for food without proper authorization from FDA. The agency utilizes these required records under its ''Bio-Research Monitoring Program'' to monitor the validity of the studies and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are sponsored primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are both sponsors and investigators.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	190	6	1,147	8	9,176
511.1(b)(5)	190	1.5	287	140	40,180
511.1(b)(6)	190	.005	1	250	250
511.1(b)(8)(ii)	190	.005	1	20	20
511.1 (b)(9)	190	.16	30	8	240
Total Burden Hours					49,866

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	190	7.5	1,434	9	12,906
511.1(b)(3)	190	10	1,912	1	1,912
511.1(b)(7)(ii)	190	2	956	3.5	3,346
511.1(b)(8)(i)	190	4	956	3.5	3,346
Total Burden Hours					21,510

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on agency communication with industry. Additional information needed to make a final calculation of the total burden hours (i.e., the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

Dated: June 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18145 Filed 7–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0308]

Determination of Regulatory Review Period for Purposes of Patent Extension; IVOMEC® EPRINEX™ Pour-On for Beef and Dairy Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IVOMEC® 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 IVOMEC® EPRINEX™ Pour-On for Beef and Dairy Cattle (eprinomectin). IVOMEC® EPRINEX™ Pour-On for Beef and Dairy Cattle is indicated for treatment and control of gastrointestinal nematodes (adults and fourth stage larvae, L_4), lungworms (adults and L_4), 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 IVOMEC® 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 IVOMEC® 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 IVOMEC® 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 IVOMEC® 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]

BILLING CODE 4160–01–F

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