Devices Panel (did not include a closed session); Dental Products Panel; Ear, Nose, and Throat Devices Panel; Gastroenterology and Urology Devices Panel; General and Plastic Surgery Devices Panel; General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Immunology Devices Panel; Microbiology Devices Panel; Neurological Devices Panel; Obstetrics and Gynecology Devices Panel; Ophthalmic Devices Panel; Orthopedic and Rehabilitation Devices Panel; and the Radiological Devices Panel).
National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

FDA is also announcing the availability of annual reports for the following advisory committees during the period October 1, 1995, through September 30, 1996:
Center for Biologics Evaluation and Research:

Allergenic Products Advisory Committee,

Blood Products Advisory Committee,

Vaccines and Related Biological Products Advisory Committee.
Center for Drug Evaluation and Research:

Anesthetic and Life Support Drugs Advisory Committee,

Antiviral Drugs Advisory Committee,

Endocrinologic and Metabolic Drugs Advisory Committee,

Medical Imaging Drugs Advisory Committee,

Oncologic Drugs Advisory Committee,

Pulmonary-Allergy Drugs Advisory Committee.
Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of reports for the Anesthesiology and Respiratory Therapy Devices Panel; Circulatory System Devices Panel; Clinical Chemistry and Clinical Toxicology Devices Panel; Dental Products Panel; Ear, Nose, and Throat Devices Panel; Gastroenterology and Urology Devices Panel; General and Plastic Surgery Devices Panel; General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Immunology Devices Panel; Microbiology Devices Panel; Neurological Devices Panel; Obstetrics and Gynecology Devices Panel; Ophthalmic Devices Panel; Orthopedic and Rehabilitation Devices Panel; and the Radiological Devices Panel).
National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

FDA is also announcing the availability of annual reports for the following advisory committees during the period October 1, 1996, through September 30, 1997:
Center for Biologics Evaluation and Research:

Allergenic Products Advisory Committee,

Biological Response Modifiers Advisory Committee,

Blood Products Advisory Committee,

Vaccines and Related Biological Products Advisory Committee.
Center for Drug Evaluation and Research:

Anesthetic and Life Support Drugs Advisory Committee,

Anti-Infective Drugs Advisory Committee,

Antiviral Drugs Advisory Committee,

Arthritis Advisory Committee,

Cardiovascular and Renal Drugs Advisory Committee,

Drug Abuse Advisory Committee,

Dermatologic and Ophthalmic Drugs Advisory Committee,

Endocrinologic and Metabolic Drugs Advisory Committee,

Nonprescription Drugs Advisory Committee.
Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of reports for the Anesthesiology and Respiratory Therapy Devices Panel; Circulatory System Devices Panel; Clinical Chemistry and Clinical Toxicology Devices Panel; Ear, Nose and Throat Devices Panel; Gastroenterology and Urology Devices Panel; General and Plastic Surgery Devices Panel; General Hospital and Personal Use Devices Panel; Hematology and Pathology Devices Panel; Immunology Devices Panel; Neurological Devices Panel; Obstetrics and Gynecology Devices Panel; Ophthalmic Devices Panel; Orthopedic and Rehabilitation Devices Panel; and Radiological Devices Panel).
National Center for Toxicological Research:

Science Advisory Board to the National Center for Toxicological Research.

Annual reports are available for public inspection at: (1) The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and (2) the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 29, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–18143 Filed 7–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0363]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for new animal drugs for investigational use.

DATES: Submit written comments on the collection of information by September 8, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

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]

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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.