

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0470]

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Certifier	N. Hawkins

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs For Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B-41, Rockville, MD 20857, 301-827-1472.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for approval of new animal drugs. Section 512(j) of the act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). A sponsor must submit to FDA a Notice of Claimed Investigational Exemption (INAD), before shipping the new animal drug for clinical tests in animals. The INAD 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, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. 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, and that distribution is controlled to prevent potential abuse. The agency utilizes these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used 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 the persons who use new animal drugs investigationaly.

In the **Federal Register** of November 10, 2004 (69 FR 65198), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	190	4.09	778	8	6,224
511.1(b)(5)	190	0.58	110	140	15,400
511.1(b)(6)	190	.01	20	1	20
511.1(b)(8)(ii)	190	.005	1	20	20
511.1(b)(9)	190	.10	20	8	160
Total					21,824

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

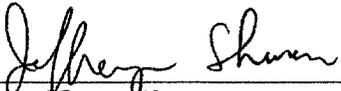
21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	190	2.11	400	9	3,600
511.1(b)(3)	190	4.20	798	1	798
511.1(b)(7)(ii)	400	3.00	1,200	3.5	4,200
511.1(b)(8)(i)	190	6.38	1,200	3.5	4,200
Total					12,798

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: 4-13-05
April 13, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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