Dated: June 20, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14535 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0172]

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.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0117. Also include the FDA docket number found in brackets in the heading of this document.

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

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 (OMB Control Number 0910–0117)—Extension

FDA has authority under the Federal Food, Drug, and Cosmetic Act (the act) to approve new animal drugs. Section 512(j) of the act (21 U.S.C.360b(j)), authorized FDA to issue regulations for the investigational use of new animal drugs. The regulations which set forth conditions for investigational use of new animal drugs are codified under part 511 (21 CFR part 511). If a new animal drug is only for tests in vitro, or testing in laboratory research animals, the person distributing the new animal drug must maintain records showing: (1) The name and post office address of the expert or expert organization to whom the drug is shipped; and (2) the date, quantity, batch or code mark for each shipment for a period of 2 years after such shipment or delivery. Prior to shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) The identity of the new animal drug, (2) labeling, (3) a statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) the 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 the distribution is controlled to prevent potential abuse. The agency uses 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 the pharmaceutical industry, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical professional. Respondents to this collection of information are investigators who use new animal drugs for investigational purposes.

In the **Federal Register** of April 8, 2008 (73 FR 19073), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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)	134	7.66	1027	8	8,216
511.1(b)(5)	134	.19	25	140	3,500
511.1(b)(6)	134	.01	2	1	2
511.1(b)(8) (ii)	134	.11	15	20	300
511.1(b)(9)	134	6.7	20	8	160
Total					12,178

[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)	134	2.96	400	9	3,600
511.1(b)(3)	134	7.66	1,027	1	1,027

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(b)(7)(ii)	134	7.46	1,000	3.5	3,500
511.1(b)(8)(i)	134	7.46	1,000	3.5	3,500
Total					11,627

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

The burden estimates for reporting requirements, record preparation, and maintenance for this collection of information are based on agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 134 respondents. We use this estimate consistently throughout the table and calculated the ''annual frequency per respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make final calculations of the total burden hours i.e., the number of respondents, the number of record keepers, the number of NCIEs received, etc., was derived from agency records.

Dated: June 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14653 Filed 6–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0227]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

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.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0485. Also include the FDA docket number found in brackets in the heading of this document.

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

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.

Medical Device Labeling Regulations—(OMB Control Number 0910–0485)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a regulatory action. Certain provisions under section 502 of the act require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices, on the labels or labeling for the devices. Section 502(b) of the act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the act requires that the labeling for a device must contain adequate directions for use. FDA may however, grant an exemption, if the agency determines that the adequate directions for use labeling requirements are not necessary for the particular case, as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves or the devices, on the label or labeling for the devices to health professionals and consumers. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations under parts 800, 801, and 809 are derived from requirements of section 502 of the act, which provides in part, that a device shall be misbranded if among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

Reporting Burden

Sections 800.10(a)(3) and 800.12(c) require that the label for contact lens cleaning solutions bear a prominent statement alerting consumers of the tamper-resistant feature. Further, § 800.12 requires that packaged contact lens cleaning solutions contain a tamper-resistant feature, to prevent malicious adulteration.

Section 800.10(b)(2) requires that the labeling for liquid ophthalmic preparations packed in multiple-dose containers provide information on the duration of use and the necessary warning information to afford adequate protection from contamination during use.

Section 801.1 requires that the label for a device in package form, contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that labeling for a device include information on intended use as defined under § 801.4 and provide adequate directions to assure safe use by the lay consumers.

Section 801.61 requires that the principal display panel of an over-the-counter (OTC) device in package form must bear a statement of the identity of the device. The statement of identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label for an OTC device in package form, must bear a statement of declaration of the net quantity of contents. The label