DFO by 5 p.m. (e.d.t.), Monday, August 4, 2008, for consideration.

The number of oral presentations may be limited by the time available. Oral presentations should not exceed 5 minutes in length for an individual or an organization.

The Chair may further limit time allowed for presentations due to the number of oral presentations, if necessary.

V. Presenter and Presentation Information

All presenters must submit Form CMS–20017 (revised 01/07). Hardcopies are required for oral presentations; however, electronic submissions of Form CMS–20017 are optional. The DFO must receive the following information from those wishing to make oral presentations:

- Form CMS–20017 completed with all pertinent information identified on the first page of the presentation.
- One hardcopy of presentation.
- Electronic copy of presentation.
- Personal registration information as described in the Meeting Attendance section below.
- Those persons wishing to submit comments only must send hardcopy and electronic versions of their comments, but they are not required to submit Form CMS–20017.

VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

VII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the DFO to register in advance no later than 5 p.m. (e.d.t.), Wednesday, August 13, 2008. A confirmation will be sent to the requester(s) by return e-mail.

The following personal information must be e-mailed to the DFO by the date and time above:

- Name(s) of attendee(s);
- Title(s);
- Organization;
- E-mail address(es); and
- Telephone number(s).

VIII. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on Wednesday, August 13, 2008. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will be held 30 to 45 minutes before the meeting start time each day. You should allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 12:15 p.m. for the 1 p.m. meeting on Wednesday, August 27, 2008. Plan to arrive at the building by 7:15 a.m. on Thursday, August 28, 2008 (and Friday, August 29, 2008—if we have a meeting that day) to ensure that you are able to arrive promptly at the meeting by 8 a.m. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items such as desktops, cell phones, and palm pilots, are subject to physical inspection.

The following are the security, building, and parking guidelines:

- Persons attending the meeting including presenters must be registered and on the attendance list by the prescribed date.
- Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.
- Attendees must present photographic identification to the Federal Protective Service or Guard Service personnel before entering the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.

IX. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must send a request for these services to the DFO by 5 p.m. (e.d.t.), Wednesday, August 13, 2008.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 16, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–13828 Filed 6–26–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0154]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

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 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Good Laboratory Practice (GLP) Regulations for Nonclinical Studies—21 CFR Part 58 (OMB Control Number 0910–0119)—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360(b), 360(e)) and related statues require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include the following information: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies.

In the **Federal Register** of March 12, 2008 (73 FR 13240), 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
58.35(b)(7)	300	60.25	18,075	1	18,075
58.185	300	60.25	18,075	27.65	499,774
Total					517,849

[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 Record	Total Hours
58.29(b)	300	20	6,000	.21	1,260
58.35(b)(1) through (b)(6) and (c)	300	270.76	81,228	3.36	272,926
58.63(b) and (c)	300	60	18,000	.09	1,620
58.81(a) through (c)	300	301.8	90,540	.14	12,676
58.90(c) and (g)	300	62.7	18,810	.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					786,308

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

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