Health Communications (CR14) and insert the following:

Office of Health Communication (CR14). (1) Provides national leadership, in consultation with the NCID divisions and programs and the CDC Office of Communication, on the implementation of a comprehensive and integrated program of public health communications for the prevention an control of new and reemerging infectious diseases; (2) plans, develops, coordinates, and evaluates NCID-wide networks, partnerships, systems, and standards for public and professional health communications; (3) advises the Director and other NCID leadership staff on health communication strategies; (4) provides expert technical assistance, consultation, and training to NCID staff on theory-based health education, behavioral science, distance education, community organization, and electronic, print, and oral communications; (5) develops infectious disease prevention and control messages and promotes their dissemination to lay and professional audiences through various marketing techniques; (6) investigates, plans, develops, evaluates, and promotes the use of electronic technology to expand NCID's health communications capacity and impact in collaboration with CDC communication and information offices, state and local health departments, and other prevention partners; (7) provides services, coordination, identification, guidance, and training for, and promotes usage of, state-of-the-art electronic communication technologies; (8) provides editorial and clearance assistance in the preparation of scientific articles and other documents and products for electronic and hard copy publication or presentation; (9) produces NCID-wide publications, including a newsletter, anthologies and compilations, and cross-cutting background documents; and manages NCID's technical information resources, including document databases.

Office of Surveillance (CR16). (1) Provides leadership, guidance, and coordination on NCID surveillance activities and systems; (2) provides NCID leadership on issues related to internal and external integration of CDC surveillance; (3) advises the Director on surveillance priorities for determining the burden of infectious diseases; (4) provides direction and oversight for the Emerging Infections Programs (EIPs) and sentinel surveillance networks through cooperative agreements with state/local health departments and other organizations; (5) provides technical assistance and direction for surveillance activities in the Epidemiology and Laboratory capacity cooperative agreements and other emerging infections activities/programs with a surveillance emphasis; (6) provides leadership for enhancing surveillance of infectious diseases through collaboration with managed care organizations; (7) provides technical leadership for and consultation on international infectious diseases surveillance activities; (8) provides NCID leadership on economic analysis and prevention effectiveness evaluation of infectious disease control and prevention activities; (9) in carrying out the above functions, collaborates, as appropriate, with other Centers, Institute, and Offices (CIOs) of the CDC.

Dated: June 1, 1998.

Clarie V. Broome,

Acting Director.

[FR Doc. 98–15442 Filed 6–9–98; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Publication of Biennial Report to the Congress on the Status of Children in Head Start Programs; Fiscal Year 1997

AGENCY: Head Start Bureau, Administration on Children Youth and Families, ACF, DHHS.

ACTION: Notice of publication and availability of FY 1997 Biennial Report to Congress on the Status of Children in Head Start Programs.

SUMMARY: The Head Start Bureau announces publication of the Biennial Report to Congress on the Status of Children in Head Start Programs. This report is mandated under Section 650 of the Head Start Act, as amended, which requires the Secretary of Health and Human Services to submit a report to the Congress, at least once during every two-year period, on the status of children in Head Start programs. The sources of data for this report were the Program Information Report (PIR), the Head Start Cost System (HSCOST), the Head Start Monitoring Tracking System (HSMTS) and the 1990 Census.

Head Start is a comprehensive child development program for low-income preschool children and their families. Head Start provides high quality early childhood education which emphasizes cognitive and language development, social and emotional development, physical and mental health, nutrition, social services and parent involvement. The goal of Head Start is to bring about a greater degree of social competence in the children of low-income families by enhancing their effectiveness in dealing with their present environment, and with later responsibilities in school and life.

SUPPLEMENTARY INFORMATION:

Statutory Authority

Section 650 of the Head Start Act, as amended, requires that the Secretary of the Department of Health and Human Services submit a report to the Congress concerning the status of children in Head Start programs.

This notice is submitted to the **Federal Register** in compliance with Section 650 of the Head Start Act, as amended, which states that upon submitting the Biennial Report on the Status of Children in Head Start Programs to Congress, a notification must be placed in the **Federal Register** announcing the report has been submitted to Congress, and noting that the report is available to the general public.

FOR FURTHER INFORMATION CONTACT: A copy of the Head Start Biennial Report may be obtained by contacting: Head Start Publications Management Center, P.O. Box 26417, Alexandria, VA 22313. The fax number is (703) 683–5769. The e-mail address is HSPMC6@idt.net.

Dated: June 3, 1998.

Helen H. Taylor,

Associate Commissioner, Head Start Bureau, Administration on Children, Youth and Families.

[FR Doc. 98–15388 Filed 6–9–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0335]

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 extension of an existing collection of

information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies regulations.

DATES: Submit written comments on the collection of information by August 10, 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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 proposed extension 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.

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 and related statutes 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 (21 U.S.C. 348, 355, 360b, and 360e). 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 (SOP's), 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: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOP's; (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 on-site audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

FDA estimates the burden of 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
58.35(b)(7)	400	60.25	24,100	1	24,100
58.185	400	60.25	24,100	27.65	666,400
Total					690,500

[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
58.29(b)	400	20	8,000	.21	1,700
58.35(b)(1) through (b)(6) and (c)	400	270.76	108,400	3.36	363,900
58.63(b) and (c)	400	60	24,000	.09	2,200
58.81(a) through (c)	400	301.8	120,000	.14	16,800
58.90(c) and (g)	400	62.7	25,000	.13	3,200
58.105(a) and (b)	400	5	2,000	11.8	23,600
58.107(d)	400	1	400	4.25	1,700
58.113(a)	400	15.33	6,132	6.8	41,700
58.120	400	15.38	6,160	32.7	201,200
58.195	400	251.5	100,000	3.9	392,400
Total					1,048,400

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

Dated: June 3, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15409 Filed 6–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0308]

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 obligating holders of approved new animal drug applications (NADA's) and abbreviated new animal drug applications to submit information on adverse drug reactions, lack of effectiveness and product defects.

DATES: Submit written comments on the collection of information by August 10, 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 proposed collection of information, including each proposed reinstatement of an existing collection, 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.

Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510—(OMB Control Number 0910–0012—Reinstatement)

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)), 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved NADA's submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format.

This continuous monitoring of approved new animal drugs, affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Also, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own