Technological and administrative changes necessitate that a new toll-free telephone number and a new, more sophisticated routing system be operational by January 1, 2005. This entails collecting administrative information from each of the 144 crisis centers currently participating in the network (*e.g.*, location, hours of operation, call capacity, non-English language capability) and programming the data into a new routing system to ensure that each caller is linked to the nearest and most appropriate crisis center. The form developed to secure this information requests only factual information that is essential to the design of the routing system.

The following table is the estimated hour burden:

Number of respondents	Responses/ respondent	Burden/ response (hrs.)	Total burden hours
144	1	.17	24.50

Emergency approval is being requested because SAMHSA does not want to risk the possibility of disrupting the functioning of the national suicide prevention hotline network, and the subsequent possibility that even one individual who tries calling a non-working hotline might ultimately take his/her own life.

Written comments and recommendations concerning the proposed information collection should be sent within two weeks of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: November 4, 2004.

Patricia S. Bransford,

Acting Executive Officer, SAMHSA.

[FR Doc. 04–25028 Filed 11–9–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application 05017]

Intervention and Evaluation Trials To Prevent Intimate Partner Violence; Notice of Availability of Funds-Amendment

A notice announcing the availability of fiscal year (FY) 2005 funds for a research cooperative agreement program to conduct efficacy and effectiveness trials of intervention strategies to prevent intimate partner violence and/or its negative consequences, particularly studies of strategies that have not been well studied, for at-risk or underserved populations was published in the **Federal Register** on October 27, 2004, Vol. 69, No. 207, pages 62694–62701. The notice is amended as follows: On page 62696, Column 3, Line 2, delete $1,800,000 and replace with the new amount of $2,250,000.

Dated: November 3, 2004.

William Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–25027 Filed 11–9–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Health Service Act; Delegation of Authority

Notice is hereby given that I have delegated to the Director, Centers for Disease Control and Prevention (CDC), the authority vested in the Secretary of Health and Human Services under Section 319F–2 of Title III of the Public Health Service Act, as amended, to enter into agreements with recipients of the Stockpile material will be deployed. The authority to deploy the Stockpile referred to herein is limited to the CHEMPACK Program.

This authority cannot be redelegated. Further, CDC must notify the Office of Public Health Emergency Preparedness before entering into an agreement.

This delegation became effective upon date of signature. In addition, I have affirmed and ratified any actions taken by the Director, CDC, or his/her subordinates which involved the exercise of the authorities delegated therein prior to the effective date of the delegation.

Dated: October 27, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 04–25002 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0470]

Agency Information Collection Activities: Proposed Collection; 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 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 reporting and recordkeeping requirements for ''New Animal Drugs for Investigational Use.''

DATES: Submit written or electronic comments on the collection of information by January 10, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 Management Programs (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 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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)—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 investigationally.

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	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 Burden Hours					21,824

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

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	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 Burden Hours					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: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24991 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0481]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Additive Petitions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of June 4, 2004 (69 FR 31617), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0546. The approval expires on November 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24992 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0244]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request, Current Good Manufacturing Practice Regulations for Type A Medicated Articles

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 December 10, 2004.

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.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR 226 (OMB Control No. 0910–0154) Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) (the act), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including type A medicated articles. A type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A type A medicated article is intended solely for use in the manufacture of another type A medicated article or a type B or type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency. Statutory requirements for cGMP's for type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under 21 CFR part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e. batch and stability testing) and product distribution. This information is needed so that FDA can monitor drug usage and possible misformulation of type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the act as to safety and also meet the articles, claimed identity, strength, quality and purity, as required by section 501(a)(2)(B) of the act as to safety and also meet the articles claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

In the **Federal Register** of June 4, 2004 (69 FR 31615), the FDA published a 60-day notice, soliciting comment on the collection of information requirements. In response to that notice, no comments were received. The respondents for type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs and commercial feed mills.

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