address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 9, 2003.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–1056 Filed 1–16–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0354]

Agency Information Collection Activities; Proposed Collection; Comment Request; the Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Adminsitration (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 (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 information collection requirements relating to the evaluation of long-term antibiotic drug therapy for persons involved in anthrax remediation activities. In the **Federal Register** of October 8, 2002 (67 FR 62727), FDA published a notice announcing the Office of Management and Budget's (OMB's) approval of this collection of information (OMB control number 0910–0494). Because this was an emergency approval that will expire on March 31, 2003, FDA in this notice is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information by March 18, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* Submit written comments on the collection of information to the Dockets Management Branch (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: Karen Nelson, Officer of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 CRF 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 extension of an existing collection of information, before submitting the collection to the 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: (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.

The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities (OMB Control Number 0910–0494)—Extension

Due to a terrorist event during the fall of 2001, approximately 1,200 decontamination workers were placed on long-term antibiotic therapy to protect them from environmental anthrax spores. Through the services of a contractor, the FDA is currently administering a survey to all 1,200 decontamination workers to collect important health information pertaining to long-term use of antibiotics. This information is critical to the agency's mission in protecting the public health, and failure of the FDA to adequately follow up on these workers will reduce the agency's ability to apply lessons learned from the current situation to provide guidance during future public health emergencies should they occur. This could result, not only, in the loss of time and dollars but also in the loss of life if patients stop taking their medicines because they think the drug therapy is responsible for a health problem when in fact it is not. This type of population is likely to never be available for assessment again until a future terrorist event occurs. It would be unacceptable for the FDA not to obtain drug experience information from this group to assist in any future public health response to a terrorist attack.

FDA is requesting an extension of the OMB approval of a survey to help FDA's Center for Drug Evaluation and Research evaluate the long-term antibiotic drug therapy in persons involved in anthrax remediation activities. The reason for the extension is to allow for more time to complete the survey, which has been delayed for two reasons. The first reason relates to the delays in cleaning up some of the contaminated sites. Primarily, the cleanup of the Brentwood Post Office in Washington, DC was delayed; this post office accounts for approximately 400 of the decontamination workers. The cleanup at Brentwood is almost complete, and it is anticipated that final medical examinations of the Brentwood cleanup workers can begin in earnest in the February/March 2003 timeframe. Once the final medical examination is completed, then Market Facts, the contractor hired to conduct the survey, can begin to administer the questionnaire to these workers. The second reason is the result of having to obtain authorization from approximately 35 subcontractor firms (who employed the decontamination workers) to release contact information on the remediation workers. To date, only contact information for

approximately 300 workers has been released, and further efforts are on going to obtain permission to release the remaining information. The medical service subcontractor is working diligently to obtain the necessary authorizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency /Response	Total Annual Responses	Hours per Response	Total Hours
Telephone	1,200	1	1,200	.25	300
Total					300

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

The estimated annual reporting burden is based on the Centers for Disease Control's administration, in 2001 and 2002, of a similar questionnaire to individuals who were exposed to anthrax spores dispersed during a terrorist event.

Dated: January 15, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–1254 Filed 1–16–03; 3:44 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Evaluation of the CMHS/CSAT Collaborative Program on Homeless Families: Women with Psychiatric, Substance Use, Or Co-Occurring Disorders and Their Dependent Children, Phase II—(OMB No. 0930–0223, Revision)—SAMHSA's Center for Mental Health Services and Center for Substance Abuse Treatment, through a set of cooperative agreements, are conducting a longitudinal, multi-site evaluation study assessing mental health, substance abuse, and trauma interventions received by homeless mothers with psychiatric, substance use, or co-occurring disorders and their dependent children. The study will advance knowledge on appropriate and effective approaches to improving families' residential stability, overall functioning, and decreased risk for violence.

SAMHSA currently has OMB approval for data collection from approximately 1,600 participants recruited from eight sites. At each site, a documented treatment intervention is tested in comparison to an alternative treatment condition. Participants are interviewed at baseline (within two weeks of entering a program) as well as three additional times (3 months after program entry, 9 months after program entry, and 15 months after program entry). Trained interviewers administer the interviews to participating mothers. Information on the children is obtained from the mother.

Key outcomes for the mothers are increased residential stability, decreased substance use, decreased psychological distress, improved mental health functioning, increased trauma recovery, improved health, improved functioning as a parent, and decreased personal violence. Outcomes for the children are reduced emotional/behavioral problems and improved school attendance.

A coordinated set of interviews assessing the key ingredients of each program will supplement the participant data collection during the baseline timeframe. The purpose of the program ingredients interviews, administered in a one-time case study protocol format, is to systematically describe each treatment and comparison intervention with the same set of variables at comparable points in treatment. This case study protocol will examine the intervention and comparison program models, staffing, structure, goals, and services, and will include vignettes describing actual families referred to the programs. In-person interviews of program directors, program line staff, and consumers will be administered in either focus group format or through one-on-one sessions. The case study protocol will be geared towards obtaining a standard set of information from each site. If some of these data are available from other sources or does not apply at a particular site, the protocol will be shortened. The estimated response burden is as follows:

Instrument	Number of respondents	Responses per respondent	Burden response (hrs)	Total burden hours
Currently—Approved Client Instrument (3-yr. annual average)	2,280			3,032
Program Director	35	1	1.0	35
Focus Group: Line Staff	140	1	1.0	140
Interview: Line Staff	140	1	1.0	140
Focus Group: Consumers	350	1	1.5	525