DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

Proposed Project: Evaluation of the Marriage and Family Strengthening Grants for Incarcerated and Reentering Fathers and their Partners—OMB No. 0990–NEW–Assistant Secretary for Planning and Evaluation (ASPE).

Abstract: The Office of Family Assistance within the Administration for Children and Families (ACF) is conducting a demonstration program called Marriage and Family Strengthening Grants for Incarcerated and Re-entering Fathers and their Partners (MFS–IP). These demonstration programs are funded to support activities in the areas of marriage strengthening and responsible fatherhood among incarcerated and recently released fathers, their partners, and children. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting an evaluation of these demonstration projects. The objective of the evaluation is to help to determine what types of marriage and family strengthening programs work best, what does not work, and what effects these programs may have on fostering healthy marriages, families and children for those involved in the criminal justice system. Information from the evaluation will assist federal, state, and community policymakers and patrons in deciding whether to replicate or redesign identified marriage and family strengthening program models.

The MFS–IP evaluation will assess the effects of marriage and family strengthening activities with incarcerated populations by comparing relationship quality and stability, positive family interactions, family financial well-being, recidivism, and community connectedness between intervention and control groups. Primary data for the evaluation will come from three waves of in-person data collection, including a baseline survey and follow-up surveys at approximately 6 and 12 months post-baseline. Data collection is expected to last 4 years, from the time the first participant is enrolled until the last 12-month follow-up survey is administered.

ESTIMATED ANNUALIZED BURDEN TABLE

Instruments	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
MFS–IP Baseline Survey—Fathers	500	1	1.5	750
MFS–IP Baseline Survey—Partners	500	1	1.5	750
MFS–IP Follow-up Survey—Fathers	500	2	1.5	1,500
MFS–IP Follow-up Survey—Partners	500	2	1.5	1,500
Total				4,500

Alice Bettencourt,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–06BD]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Economic Analysis of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)—New—National Center for Chronic Disease Prevention and Health Promotion (NCDDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC-funded National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is the largest organized cancer screening program in the United States. The NBCCEDP provides critical breast and cervical cancer screening services to underserved women through grants to 50 states, the District of Columbia, 4 U.S. territories, and 13 American Indian/Alaska Native organizations. In the past decade, the NBCCEDP has provided over 7.2 million breast and cervical cancer screening and diagnostic exams to over 3 million low-income women. Women diagnosed with cancer through the program are eligible for Medicaid coverage through the Breast and Cervical Cancer Prevention

and Treatment Act passed by Congress in 2000.

CDC proposes to collect one year of cost data from all 68 NBCCEDP grantees in order to conduct the first systematic, activity-based analysis of the costs and cost-effectiveness of the NBCCEDP. The information required to perform an activity-based cost analysis includes: Staff and consultant salaries, screening costs, contracts and material costs, provider payments, in-kind contributions, administrative costs, allocation of funds, and staff time devoted to specific program activities. Data will be collected electronically via a Web-based Cost Assessment Tool (CAT).

CDC will use information collected through the CAT to assess the costs of various program components, identify factors that impact average cost, perform cost-effectiveness analysis, and to develop a resource allocation tool for ensuring the most appropriate use of limited program resources.

NBCCEDP grantees currently report information on screening and diagnosis volumes (the effectiveness measures for the program) as part of the Minimum Data Elements (MDE)/System for Technical Assistance Reporting (STAR) (OMB 0920–0571, exp. 1/31/2010). Information to be collected through the CAT will complement information currently collected through the MDE/STAR.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,496.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
NBCCEDP Grantees	68	1	22

Dated: November 26, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–23336 Filed 11–30–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0306]

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

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 January 2, 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 0910–0154. 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.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226 (OMB Control Number 0910–0154)–Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), 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 cGMPs for Type A medicated articles have been codified under 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 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 under 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 article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

In the **Federal Register** of August 16, 2007 (72 FR 46087), FDA published a 60-day notice soliciting public comment on the proposed collection of information provisions. 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: