DATE: July 2, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer Centers for Disease Control and Prevention.

[FR Doc. E7–13197 Filed 7–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–07–05CH]

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

An assessment of the determinants of HIV risk factors for African-American and Hispanic women in the southeastern United States—New—the National Center for HIV/AIDS, STD and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, an estimated 1 million people are living with HIV. About 40,000 new HIV infections occur each year. Women account for about 27% of all new HIV/AIDS diagnoses, with women of color in the South being most affected. Women of color represent 80% of all women estimated to be living with HIV/AIDS. In 2004, the rate HIV/AIDS cases per 100,000 for non-Hispanic African-American adult and adolescent females (67.0) was 21 times higher than that for non-Hispanic white females (3.2). Similarly, the rate of HIV/AIDS cases reported in 2004 for Hispanic women (16.3) was 5 times higher than the rate for non-Hispanic white women.

Limited research data suggest that the character and dynamics of women's sexual relationships, gender relationships, sex roles, and experiences related to race and ethnicity may be important determinants of risk, both for engaging in risk behaviors and for doing so with high-risk partners. In addition, women's vulnerability is connected to a variety of socioeconomic factors, including delayed access to care and support for HIV/AIDS. Accordingly, the specific aims of the study are to:

- Enroll 850 African-American and 500 Hispanic women at risk for HIV infection in a one-time survey.
- Conduct rapid oral HIV testing of all women and facilitate linkage to medical care among those identified as HIV-positive.
- Characterize African-American and Hispanic women on demographic, psychological, behavioral, sociocultural, and environmental/contextual dimensions.
- Assess and compare the prevalence of sexual and drug behaviors of African American and Hispanic women.
- Identify characteristics of African-American and Hispanic women associated with sexual behaviors that place them at risk for contracting HIV. Similarly, identify characteristics that protect against becoming infected with HIV.
- Recruit a sub-sample of survey respondents to take in a qualitative interview.
- Use our findings to provide recommendations on the design of behavioral interventions for African American and Hispanic women.

Women will complete a 10-minute eligibility screening interview. The survey interview will take approximately 45 minutes each to complete for those who agree to participate in the study and 10 minutes to complete for those who refuse to enroll. Women completing the survey will take part in a 45 minute HIV counseling and testing session, which will be followed by a 10-minute training for how to refer other women to the project. The qualitative interview will take approximately one hour to complete. The total response burden for the three-year period is estimated to be 2712.39 hours (904.13 annualized burden hours). There is no cost to respondents except for their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Activity with women volunteers	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Venue intercept interview	125	1	3/60
Eligibility screening interview	675	1	10/60
Refusal questionnaire	90	1	10/60
ACASI survey interview	450	1	45/60
HIV Testing & Counseling	450	1	45/60
RDS Training	450	1	10/60
Qualitative interview	20	1	1

Dated: June 29, 2007.

Maryam I. Daneshvar, PhD,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Grant to Forty-Nine Community Services State Associations; Office of Community Services

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Notice to award grant awards.

CFDA Number: 93.570.

SUMMARY: Notice is hereby given that awards will be made to forty-nine Community Services State Associations (CAA), in the amount of $65,000 each for ongoing capacity-building within the Community Services Network of Federal, State and local organizations to continue their work of addressing CSBG program needs. State CAA Associations

have developed a shared vision for addressing the causes and effects of poverty; established a framework to convene fragmented programs across State and local governments; and utilized technological advances to better serve communities and track program successes. The period of this funding will extend from September 30, 2007 through September 29, 2008.

FOR FURTHER INFORMATION CONTACT: Peter Thompson, Office of Community Services, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone: 202–401–4608, E-mail: *peter.thompson@acf.hhs.gov.*

Dated: July 2, 2007.

Yolanda J. Butler,

Deputy Director, Office of Community Services.

[FR Doc. E7–13151 Filed 7–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0229]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices: Current Good Manufacturing Practice Quality System Regulations

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Submit written or electronic comments on the collection of information by September 7, 2007.

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, Jr., Office of the Chief Information Officer (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 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.

Medical Devices: Current Good Manufacturing Practice Quality System Regulations--21 CFR Part 820 (OMB Control Number 0910–0073)—Extension

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services (the Secretary) has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the act.

The CGMP/QS regulation implementing authority provided by this statutory provision is found under part 820 (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The authority for this regulation is covered under sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, and 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, and 383). The CGMP/QS regulation includes requirements for purchasing and service controls, clarifies recordkeeping requirements for device failure and complaint investigations, clarifies requirements for verifying/validating production processes and process or product changes, and clarifies requirements for product acceptance activities quality data evaluations and corrections of nonconforming product/quality problems.

Requirements are compatible with specifications in the international standards ''ISO 9001: Quality Systems Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.'' The CGMP/QS information collections will assist FDA inspections of manufacturers for compliance with quality system requirements encompassing design, production, installation, and servicing processes.

Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review the following topics: (1) The quality policy; (2) the organizational structure; (3) the quality plan; and (4) the quality system procedures of the organization.

Section 820.22 requires the conduct and documentation of quality system audits and reaudits.

Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j), requires in respective order, the establishment, maintenance, and/or