Dated: March 28, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–13PQ]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is 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. Written comments should be received within 60 days of this notice.

Proposed Project

DELTA FOCUS Program Evaluation—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Intimate Partner Violence (IPV) is a serious, preventable public health problem that affects millions of Americans and results in serious consequences for victims, families, and communities. IPV occurs between two people in a close relationship. The term ''intimate partner'' describes physical, sexual, or psychological harm by a current or former partner or spouse. IPV can impact health in many ways, including long-term health problems, emotional impacts, and links to negative health behaviors. IPV exists along a continuum from a single episode of violence to ongoing battering; many victims do not report IPV to police, friends, or family.

Primary prevention means stopping IPV before it occurs. In 2002, authorized by the Family Violence Prevention Services Act (FVPSA), CDC developed the Domestic Violence Prevention Enhancements and Leadership Through Alliances (DELTA) Program, with a focus on the primary prevention of IPV. Since that time, The DELTA Program has funded state domestic violence coalitions (SDVCs) to engage in statewide primary prevention efforts and to provide training, technical assistance, and financial support to local communities for local primary prevention efforts. DELTA FOCUS (Domestic Violence Prevention Enhancement and Leadership through Alliances, Focusing on Outcomes for Communities United with States) builds on that history by providing focused funding to states and communities for intensive implementation and evaluation of IPV primary prevention strategies that address the structural determinants of health at the societal and community levels of the social-ecological model (SEM).

The purpose of the DELTA FOCUS program is to promote the prevention of IPV through the implementation and evaluation of strategies that create a foundation for the development of practice-based evidence. By emphasizing primary prevention, this program will support comprehensive and coordinated approaches to IPV prevention. Each SDVC is required to identify and fund one to two well-organized, broad-based, active local coalitions (referred to as coordinated community responses or CCRs) that are already engaging in, or are at capacity to engage in, IPV primary prevention strategies affecting the structural determinants of health at the societal and/or community levels of the SEM. SDVCs must facilitate and support local-level implementation and hire empowerment evaluators to support the evaluation of IPV prevention strategies by the CCRs. SDVCs must also implement and with their empowerment evaluators, evaluate state-level IPV prevention strategies.

CDC seeks OMB approval to collect information electronically from awardees, their CCRs and their empowerment evaluators. Information will be collected using the DELTA FOCUS Program Evaluation Survey (referred to as DF Survey). The DF survey will collect information about SDVCs satisfaction with CDC efforts to support them; process, program and strategy implementation factors that affect their ability to meet the requirements of the Funding Opportunity Announcement (FOA); prevention knowledge and use of the public health approach; and sustainability of prevention activities and successes.

Information collected through the DF Survey will be used to guide program improvements by CDC in the national DELTA FOCUS program implementation and program improvements by SDVCs in implementation of the program within their state. Specifically the data collection will allow the federal government to assess: a) opportunities and barriers to implementing the DELTA FOCUS program at the state and local levels, b) benefits and challenges of focusing on prevention strategies at the societal and community levels, and c) what data informed program improvements are needed. Not collecting this data could result in inappropriate implementation at the national, state, and local levels. Thus, this data collection is an essential program evaluation activity.

The DF Survey will be completed by 10 SDVC executive directors, 10 SDVC project coordinators, 19 CCR project coordinators, and 10 SDVC empowerment evaluators and take a maximum of 1 hour to complete. We expect for each SDVC there will be four web-based surveys completed in the first year (2013) of awardee activity. CDC will analyze, interpret, translate, and disseminate the survey findings in years two and three of the information collection request. The total estimated annualized burden for the proposed 10 awardees is 44 hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TO RESPONDENTS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Domestic Violence Coalition Executive Director.	DELTA FOCUS Survey	10	1	1	10
State Domestic Violence Coalition Project Coordinator.	DELTA FOCUS Survey	10	1	1	10
Coordinated Community Response Project Coordinator.	DELTA FOCUS Survey	19	1	1	19
State Domestic Violence Coalition Empowerment Evaluator.	DELTA FOCUS Survey	10	1	.50	5
Total	.....	.....	.....	.....	44

Dated: March 28, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1203]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request: Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

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 May 3, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0661. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements (Formerly: Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators and FDA Staff Humanitarian Device Exemption Regulation: Questions and Answers)—(OMB Control Number 0910–0661)—Revision

Under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)), FDA is authorized to exempt a humanitarian use device (HUD) from the effectiveness requirements in sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; (3) the device will not expose patients to an unreasonable or significant risk of illness or injury; and (4) the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit), except in narrow circumstances. Section 613 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), signed into law on July 9, 2012, amended section 520(m) of the FD&C Act. Under section 520(m)(6)(A)(i) of the FD&C Act, as amended by FDASIA, a HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria:

- The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or
- the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, as amended by FDASIA, provides that the Secretary of Health and Human Services (the Secretary) will assign an ADN for devices that meet the eligibility criteria to be permitted to be sold for profit. The ADN is defined as the number of devices ''reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States,'' and therefore shall be based on the following information in a HDE application: The number of devices reasonably necessary to treat such individuals.

Section 520(m)(6)(A)(iii) of the FD&C Act (*http://www.fda.gov/*