DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services

AGENCY: Office of Community Services, ACF, DHHS.

ACTION: Notice to Award a Program Expansion Supplement for the Community Action Partnership (CAP) in Washington, DC.

CFDA#: 53.570.

Legislative Authority: Section 678A(a)(1)(A) of the Community Services Block Grant (CSBG) Act of 1981, (Pub. L. 97–35) as amended by the Community Opportunities, Accountability, and Training and Educational Services (COATES) Human Services Reauthorization Act of 1998, (Pub. L. 105–285) authorizes the Secretary of Health and Human Services (HHS) to use a percentage of appropriated funds for training, technical assistance, planning, evaluation, performance measurement, monitoring, assistance for States in carrying out corrective actions and the correction of programmatic deficiencies of eligible entities under the CSBG Act.

Amount of Award: $40,000.

Project Period: 9/30/2006–9/29/2009.

SUMMARY: This supplement would enhance the ability for the CAP to find new ways to address training and technical assistance needs. After gathering information from the Community Action Network, the applicant will provide a report to the Office of Community Services (OCS) containing recommendations about creative approaches and strategies for providing technical assistance and training to Community Action Agencies (CAAs). The applicant will compile information gathered thru: Brainstorming sessions with members of the Community Action Network and the Virtual CAP. The report to OCS will include sections on major recommendations and a strategy for implementation. These will be supported by summaries of the ideas presented at the sessions and input compiled by Virtual CAP.

FOR FURTHER INFORMATION CONTACT: Josephine B. Robinson, Director, Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC 20047, Telephone: 202/401–9333.

Dated: September 16, 2008.

Josephine B. Robinson,

Director, OCS.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0240]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

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 October 24, 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 0910–0139. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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 Finished Pharmaceuticals (OMB Control Number 0910–0139)—Extension

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMPs) to ensure that such drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

FDA has the authority under section 701(a) of the act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain over-the-counter (OTC) drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that ''for records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.'' To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced, as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to