to *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*.

4. Communications Concerning the Planned Submission

Applicants participating in the pilot program should contact the appropriate center point-of-contact by e-mail (see **FOR FURTHER INFORMATION CONTACT**) 120 days prior to the intended date of the proposed proprietary name submission to discuss specific details of the planned submission. If applicants plan to use alternative or additional methods to evaluate the safety of their proposed proprietary name(s), they should inform the appropriate center 120 days prior to their planned submission date. FDA does not have the resources to review the proposed alternative methodologies with the intent of coming to agreement with an applicant on the appropriateness of these alternative methodologies prior to submission. In such cases, FDA will review the alternative methodologies during the review of the actual submission.

If applicants have questions concerning the planned submission under the pilot program, they should contact the appropriate center point-of-contact by e-mail (see **FOR FURTHER INFORMATION CONTACT**) to discuss their questions. If necessary, applicants will be asked to submit their questions in writing; in some cases, a teleconference or face-to-face meeting to discuss the planned submission may be appropriate.

E. Process To Request FDA Review of an Alternate Proposed Proprietary Name

If, after parallel reviews of the proprietary name submission, FDA informs the applicant that the primary proposed proprietary name is unacceptable, the applicant should confirm in writing that it would like its previously identified alternate proposed proprietary name to be reviewed or submit a different alternate proprietary name. At this time, the applicant can request to have the alternate proprietary name evaluated by FDA under the pilot program or by the traditional review method. If the request is to have the alternate proprietary name reviewed under the pilot program, the applicant should submit the comprehensive evaluation of the alternate proposed proprietary name, including the information and data described in section II.D.2 of this document. If the request is to have the alternate proprietary name evaluated by the traditional method, the applicant may reference the information previously submitted for parallel review of the proposed primary proprietary name (*Section I* of the pilot program submission labeled ''TRADITIONAL REVIEW'').

A new proprietary name review clock for an alternate proposed proprietary name will not start until:

(1) The applicant has confirmed to the appropriate center, in writing, that it would like its alternate proprietary name evaluated by traditional review method or

(2) FDA receives the applicant's submission of an alternate proposed proprietary name along with the comprehensive information for section II ''PILOT REVIEW'' described in section II.D.2 of this document.

For either review method requested (traditional or pilot), the same PDUFA IV review performance goal timeframes apply to the review of the submission of an alternate proposed proprietary name (i.e., IND—180 days from receipt of complete submission; NDA or BLA—90 days from receipt of complete submission).

If the applicant requests that its alternate proprietary name be evaluated under the pilot program, the agency will take into account the date of the alternate proprietary name submission as it relates to the PDUFA IV goal for the application. The responsible center will use discretion to determine whether the agency will conduct a parallel review of the applicant's analysis or only a proprietary name evaluation using FDA's traditional approach. Although FDA would ideally also review the applicant's completed proprietary name analysis for the alternate name under the pilot program, resources may not permit such a review. Factors such as staffing will be used in making this determination.

F. Duration and Evaluation of the Pilot Program

At the end of fiscal year 2011, or after accruing 2 years of experience with pilot program submissions, FDA intends to evaluate the pilot program to determine whether to have applicants perform their own proprietary name analysis and submit resulting data to FDA for review. The results of this pilot program and recommended additions and/or changes to methods based on the reported results will be discussed in a future public meeting. Following that meeting, FDA will publish a draft guidance describing the best test methods for proprietary name evaluation.

III. Paperwork Reduction Act of 1995

The information collection provisions of this pilot program, excluding the submission of information that is part of the agency's traditional review of proprietary names, have been submitted to the Office of Management and Budget (OMB) for review, as required by section 3507 of the Paperwork Reduction Act of 1995. The provisions were approved and assigned OMB control number 0910–0648. This approval expires September 30, 2012. The proprietary name information submitted as part of the traditional review of proprietary names is approved under OMB control numbers 0910–0001 and 0910–0338. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IV. Electronic Access

Persons with access to the Internet may obtain the concept paper at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf*.

Dated: September 25, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23620 Filed 9–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services, Program Expansion Supplement Grant Award

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Notice to award a Program Expansion Supplement Grant.

CFDA Number: 93.710.

Legislative Authority: The legislative authority is provided in the American Recovery and Reinvestment Act of 2009 (ARRA) [Pub. L. 111–5]. Additional legislative authority and requirements are provided in Section 674(b)(2)(B) of the Community Services Block Grant Act (CSBG), as amended, by the Community Opportunity Accountability, and Training and Educational Services (Coats Human Services Reauthorization Act of 1998) [Pub. L. 105–285].

Amount of Award: $500,000.

Project Period: July 1, 2009–June 30, 2010.

Summary: The Office of Community Services (OCS) announces the award of a $500,000 single source program

expansion supplement to the National Association for State Community Services Programs (NASCSP), located in Washington, DC, to support performance training and technical assistance on data collection, analysis and dissemination issues faced by state community services programs within the Community Services Block Grant (CSBG) Network; develop performance based reporting tools for ARRA CSBG funded activities; develop and maintain a catalog of innovative programs and practices related to the American Recovery and Reinvestment Act of 2009 (ARRA). The project activities are designed to support and strengthen the ability of the CSBG Network to comply with and carry out CSBG activities funded by ARRA. The training projects and resources developed under the award will include analysis and explanation of the practical impact of ARRA for States and CSBG-eligible entities so that they can work more effectively to reach the ARRA goals and document how they have in fact reached those goals and used the ARRA funds.

Contact for Further Information: Danielle Williams, U.S. Department of Health and Human Services, Office of Community Services, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20047, Telephone: (202) 205–4717, E-mail: *Danielle.Williams@acf.hhs.gov*.

Dated: September 25, 2009.

Yolanda J. Butler,

Acting Director, Office of Community Services.

[FR Doc. E9–23726 Filed 9–30–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0294]

Regulation of Tobacco Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 28, 2009, the comment period for the notice that appeared in the **Federal Register** of July 1, 2009 (74 FR 31457). In the notice, FDA requested comments on the implementation of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Act). The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit electronic and written comments by December 28, 2009.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850–3229, 301–796–4830, *Erik.Mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 1, 2009 (74 FR 31457), FDA published a notice with a 90-day comment period to request comments on the implementation of the Tobacco Act. Comments from the public will inform FDA's actions implementing the Tobacco Act.

The agency has received a request for an extension of the comment period for the notice. This request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

FDA has considered the request and is extending the comment period for the notice for 90 days, until December 28, 2009. The agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 25, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23607 Filed 9–28–09; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form N–600; Extension of an Existing Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form N–600, Application for Certificate of Citizenship; OMB Control Number 1615–0057.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 25, 2009, at 74 FR 30315, allowing for a 60-day public comment period. USCIS did not receive any comments.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until November 2, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 111 Massachusetts Avenue, Washington, DC 20529–2210. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at rfs.regs@dhs.gov, and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via e-mail at *oira_submission@omb.eop.gov*.

When submitting comments by e-mail, please make sure to add OMB Control No. 1615–0057 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;