• Press release announcing the effective date of the cigarette flavor ban,

• Flavored tobacco products fact sheet, and

• Flavored tobacco products parental advisory.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Activity and Form FDA 3734	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Minutes per Response	Total Hours
Reporting violations of section 907(a)(1)(A) of the FDCA	1,700	1	1,700	10	283

Dated: October 15, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25604 Filed 10–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Community Services Block Grant (CSBG) Program Model Plan Application.

OMB No.: New collection.

Description: Sections 676 and 677 of the Community Services Block Grant Act require States, including the District of Columbia and the Commonwealth of Puerto Rico, Tribes, Tribal organizations and U.S. territories applying for Community Services Block Grant (CSBG) funds to submit an application and plan (Model Application Plan). The application plan must meet statutory requirements prior to being funded with CSBG funds. Applicants have the option to submit a detailed application annually or biannually. Entities that submit a biannual application must provide an abbreviated application the following year if substantial changes to the initial application will occur. OMB approval is being sought.

Respondents: State Governments, including the District of Columbia and the Commonwealth of Puerto Rico, Tribal Governments, Tribal Organizations, and U.S. territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Model State CSBG Application	56	1	10	560
Model Indian Tribes & Tribal Organizations CSBG Application	30	1	10	300

Estimated Total Annual Burden Hours: 860

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 21, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–25650 Filed 10–23–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Cross-Site Evaluation of the Children's Bureau Grantee Cluster: Supporting Evidence-Based Home Visiting Programs to Prevent Child Maltreatment (EBHV).

OMB No.: New collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing this cross-site evaluation data collection activity to identify successful strategies for adopting, implementing, and sustaining high-quality home visitation programs to prevent child maltreatment. An evaluation study will address four domains: (1) Systems change to develop infrastructure, (2) fidelity to evidence-

based models, (3) costs of home visiting programs, and (4) family and child outcomes (via a review of grantee analysis reports). A process study will focus on the broader grant initiative to understand how programs plan and develop the infrastructure needed to support home visitation services and how they ensure service quality.

Information will be collected through biennial site visits, web-based data entry, a data quality progress table, a relationship questionnaire completed by participants and home visitors, and a grantee-partner network survey. In particular, site visits will include interviews with key grantee staff and stakeholders involved in the execution of the grant and in the efforts to make system changes. Grantees will complete systems web-based data entry on goals and operations every six months while agencies implementing home visiting programs associated with the grantee will utilize the fidelity/cost web-based data entry to provide EBHV program, provider, and participant characteristics along with yearly data on costs of home visiting programs.

Respondents: EBHV grantee and key staff (evaluators, home visitors and supervisors), partners, implementing agencies, home visiting participants, and home visitors.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
EBHV grantee and key staff-partner interview guide	249	2	1.60	797
EBHV grantee systems web-based data entry	17	2	1.00	34
EBHV agency fidelity/cost web-based data entry	50	12	9.00	5,400
EBHV grantee data quality progress table	17	4	4.25	289
Participant-home visitor relationship questionnaire	4,716	2	0.25	2,358
Home visitor-participant relationship questionnaire	4,716	2	0.25	2,358
EBHV grantee-partner network survey	142	2	0.42	119
Estimated Total Burden Hours				11,355

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: October 14, 2009.

Seth F. Chamberlain,

OPRE Reports Clearance Officer.

[FR Doc. E9–25259 Filed 10–23–09; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0307 (formerly Docket No. 2007–D–0173)]

Guidance for Industry on Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects.'' This guidance is intended to assist investigators in meeting their responsibilities with respect to protecting human subjects and ensuring the integrity of data in the conduct of clinical investigations. The guidance also clarifies FDA's expectations concerning the investigator's responsibility for supervising a clinical study in which some study tasks are delegated to employees of the investigator or to outside parties.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993, 301–796–2270, *Joseph.Griffin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects.'' Under the regulations in part 312 (21 CFR part 312) (Investigational New Drug Application) and part 812 (21 CFR part 812) (Investigational Device Exemptions), an investigator is responsible for ensuring that a clinical investigation is conducted according to the signed investigator statement, the