

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 and Territorial Health Departments or Sexual Assault Coalition Designee. | RPE-MIS: Initial population | 55 | 1 | 15 | 825 |
| | RPE-MIS: Annual reporting | 55 | 1 | 3 | 165 |
| Total | | | | | 990 |

Leroy A. Richardson,
Chief, Information Collection Review Office, 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-14-0905]

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 Leroy Richardson 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

FoodNet Non-O157 Shiga Toxin-Producing *E. coli* Study: Assessment of Risk Factors for Laboratory-Confirmed Infections and Characterization of Illnesses by Microbiological Characteristics (0920-0905 expires 11/30/14)—Extension—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year many Shiga toxin-producing *E. coli* (STEC) infections occur in the United States, ranging in severity from mild diarrhea, to hemorrhagic colitis and in some cases, life-threatening hemolytic uremic syndrome (HUS). HUS occurs most frequently following infection with serogroup O157; 6% of patients with this type of STEC infection develop HUS, with highest occurrence in children aged < 5 years. HUS has a fatality rate of approximately 5%; up to 25% of HUS survivors are left with chronic kidney damage. STEC are broadly categorized into two groups by their O antigens, STEC O157 and non-O157 STEC. The serogroup O157 is most frequently isolated and most strongly associated with HUS. Risk factors for STEC O157 infections in the United States and internationally have been intensely studied. Non-O157 STEC are a diverse group that includes all Shiga toxin-producing *E. coli* of serogroups other than O157. Over 50 STEC serogroups are known to have caused human illness. Numerous non-O157 outbreaks have been reported from

throughout the world and clinical outcomes in some patients can be as severe as those seen with STEC O157 infections, however, little is known about the specific risk factors for infections due to non-O157 STEC serogroups. More comprehensive understanding of risk factors for sporadic non-O157 STEC infections is needed to inform prevention and control efforts.

The FoodNet case-control study is the first multistate investigation of non-outbreak-associated non-O157 STEC infections in the United States. It investigates risk factors for non-O157 STEC infections, both as a group and individually for the most common non-O157 STEC serogroups. In addition, the study characterizes the major known virulence factors of non-O157 STEC to assess how risk factors and clinical features vary by virulence factor profiles. As the largest, most comprehensive, and most powerful study of its kind, it is making an important contribution towards better understanding of non-O157 STEC infections and will provide science-based recommendations for interventions to prevent these infections. Study enrollment began between July and September 2012 (sites had staggered start dates) and is scheduled to run for 36 months. Since we have not yet enrolled enough cases to meet the study objectives, we are requesting an extension.

Persons with non-O157 STEC infections who are identified as part of routine public health surveillance and randomly selected healthy persons in the patients' communities (to serve as controls) are contacted and offered enrollment into this study. Participation is completely voluntary and there is no cost for enrollment. The total burden is 268 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total |
|----------------|-----------------------------|-----------------------|------------------------------------|--|-------|
| Patients | Case questionnaire | 161 | 1 | 25/60 | 67 |
| Controls | Control questionnaire | 483 | 1 | 25/60 | 201 |
| | | | | | 268 |

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 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

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ACF Program Instruction: Children's Justice Act.
OMB No.: 0970-0425.

Description: The Program Instruction, prepared in response to the enactment of the Childrens Justice Act (CJA), Title II of Public Law 111-320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the States and Territories to accomplish the purposes of assisting States in developing, establishing and operating programs designed to improve: (1) The assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the child's family; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, including child

sexual abuse and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111-320 at Sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.
Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-------------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Application and Annual Report | 52 | 1 | 60 | 3,120 |

Estimated Total Annual Burden Hours: 3,120.

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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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: 202-395-7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0062]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exception From General Requirements for Informed Consent

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