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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0905]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) 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; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 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 (OMB No. 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 is 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 estimated annual burden is 268 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Patients	Case questionnaire	161	1	25/60
Controls	Control questionnaire	483	1	25/60

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Office of Scientific Integrity,
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Office of the Director,
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