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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[30Day-17-16BGH]

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

Canine Leptospirosis Surveillance in Puerto Rico - Existing Collection in use without an OMB Control Number - National Center for Emerging and Zoonotic Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Bacterial Special Pathogens Branch (BSPB) requests a two-year approval of data collection tools used for active surveillance of canine leptospirosis in Puerto Rico. Active surveillance will allow for the collection of prospective data on acute cases to determine the incidence and distribution of leptospirosis in dogs, assess risk factors for infection, characterize circulating *Leptospira* serovars and species, assess applicability of vaccines currently in use based on serovar determination, and assess rodent, livestock, and wildlife reservoirs of leptospirosis based on infecting serovars found in dogs. Findings from this study will aid in the development of evidence-based, targeted interventions for the prevention of canine leptospirosis, be used to focus human leptospirosis surveillance efforts, and guide future investigations on leptospirosis in humans and animals in Puerto Rico.

The information collection for which approval is sought is in accordance with BSPB's mission to prevent illness, disability, or death caused by bacterial zoonotic diseases through surveillance, epidemic investigations, epidemiologic and laboratory research, training and public education. Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). Successful execution of BSPB's public health mission requires data collection activities in

collaboration with the state health department in Puerto Rico and with local veterinary clinics and animal shelters participating in the study.

Researchers will collect information on dogs that meet the study case definition for a suspect case of canine leptospirosis seen at participating veterinary clinics and shelters (sites) throughout Puerto Rico. Examples of information collected about the dog include the dog's signalment, risk factors, clinical signs and symptoms, laboratory results, treatment, and clinical outcome. In addition, basic information about participating clinics and shelters such as site capacity, available resources, vaccination practices, and origin of dogs will also be collected to enhance data analysis and aid in study management.

BSPB will not directly collect the information. Veterinary staff including veterinarians, assistants, and administrative staff will record the information onsite using paper forms by interviewing dog owners, and reviewing medical and administrative records, as necessary. BSPB and Puerto Rico Department of Health study coordinators will maintain the collected information in an electronic database.

BSPB estimates involvement of 26 veterinarians and their staff, and a maximum of 624 responses from owners of enrolled dogs. The enrollment questionnaire is completed once in the beginning of the study while the log sheet and case

questionnaires will be completed for each enrolled suspect case. The number of suspect leptospirosis cases can vary from 0 to 2 cases per month per location based on anecdotal reports from local veterinarians. Taking the highest possible response per month, the number of responses per form for the log sheet and case questionnaire is calculated by multiplying 2 cases/month with 12 months giving a total of 24 responses per form for each veterinarian. The total number of veterinarians is not expected to exceed 26 (the maximum number of participating sites).

A minimum of 385 responses from dog owners is needed based on sample size calculation. However, extra clinics were enrolled to ensure that the sample size is met in the event that some clinics withdraw from the study or if fewer numbers of suspect leptospirosis cases are enrolled at the clinics. Given this, a maximum of 624 responses (26 clinics x 24 responses/clinic) are calculated for the burden to the general public (dog owners). Although it is unlikely the maximum number of responses will be reached, the total number of dog owners will not exceed 624.

This information collection will not impose a cost burden on the respondents beyond that associated with their time to provide the required data.

The total annualized burden for this information collection is estimated to be 168 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
Veterinarian	Enrollment Questionnaire	26	1	5/60
	Log Sheet	26	24	1/60
	Case Questionnaire	26	24	10/60
General Public (Dog owner)	Case Questionnaire	624	1	5/60

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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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