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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0199]

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 and 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: Importation of Etiologic Agents (42 CFR 71.54) (OMB Control No. 0920-0199, exp. 1/31/2014) - Revision - Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F – Importations - contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC.

CDC requests Office of Management and Budget approval to collect information for three years using the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States and Application for a Permit to Import or Transport Live Bats. We are also requesting a title change to read -- *Application for Permit to Import Infectious Biological Agents into the United States (42 CFR 71.54*.

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to request information on where the imported material will be stored at the recipient facility and who would be responsible for this location; verification that the permittee has implemented biosafety measures commensurate with the hazard posed by the

infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use; and a secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC plans to revise this application to request secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours.

Estimates of burden for the survey are based on information obtained from the CDC import permit database on the number of permits issued on annual basis since 2010. The total estimated burden for the one-time data collection is 545 hours.

There are no costs to respondents except their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States	1,625	1	20/60	542
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats	10	1	20/60	3
Total					545

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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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