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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0576]

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

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920-0576, Expiration Date 11/30/2015) – Revision - Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or the Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on

persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations for the next three years. Information will be collected via fax, email and hard copy mail from respondents.

The revisions to the data collection are primarily changes to the forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. Changes were made to the following forms: Report of Identification of a Select Agent or Toxin, Request for Exemption, Application for Registration, Request to Transfer Select Agents and Toxins, and Administrative Review.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 8,527.

Estimated Annualized Burden Hours

Regulation Sections	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
73.3 & 73.4	Request for Exclusions	3	1	1
73.5 & 6	Report of Identification of a Select Agent or Toxin	303	3	1
73.5 & 73.6	Request for Exemption	1	1	1
73.7	Application for Registration	5	1	5
73.7	Amendment to a Certificate of Registration	277	7	1
73.9	Documentation of self-inspection	277	1	1
73.10	Request for Expedited Review	1	1	30/60
73.11	Security Plan	277	1	5

73.12	Biosafety Plan	277	1	5
73.13	Request Regarding a Restricted Experiment	20	2	1
73.14	Incident Response Plan	277	1	5
73.15	Training	277	1	1
73.16	Request to Transfer Select Agents and Toxins	156	2	1
73.17	Records	277	1	30/60
73.19	Notification of Potential Theft, Loss, or Release	215	2	1
73.20	Administrative Review	5	4	1

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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