Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 30, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–07628 Filed 4–2–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–15–0576; Docket No. CDC–2015–0013]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the information collection entitled *Possession, Use, and Transfer of Select Agents and Toxins* (OMB Control No. 0920–0576). CDC is requesting Office of Management and Budget (OMB) approval to continue to collect information under the select agent regulations through the use of five forms: (1) Application for Registration for Possession. Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); (2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); (3) Incident Form to Report Potential Theft, Loss, Release, or Occupational Exposure (APHIS/CDC Form 3); (4) Report of Identification of Select Agent or Toxin from Clinical/Diagnostic Specimen, Proficiency Testing, or Seizure by Federal Law Enforcement (APHIS/CDC Form 4); and (5) Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

DATES: Written comments must be received on or before June 2, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0013 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576, Expiration—11/30/2015)—Revision—Office of Public Health Preparedness and Response (OPHPR), 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 through the use of five forms: (1) Application for Registration for Possession. Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); (2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); (3) Incident Form to Report Potential Theft, Loss, Release, or Occupational Exposure (APHIS/CDC Form 3); (4) Report of Identification of Select Agent or Toxin from Clinical/Diagnostic Specimen, Proficiency Testing, or Seizure by Federal Law Enforcement (APHIS/CDC Form 4); and (5) Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

An entity may amend its registration (42 CFR 73.7(h)(1)) if any changes occur to the information previously submitted to CDC. When applying for an amendment to a certificate of registration, an entity would complete the relevant portion of the application package (APHIS/CDC Form 1).

Besides the forms listed above, there is no standard form for the following information:

1. An individual or entity may request an exclusion from the requirements of the select agent regulations of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. (42 CFR 73.3(e) and 73.4(e)).

2. Annual inspections that are conducted by the entity must be documented. (42 CFR 73.9(a)(6)).

3. An individual's security risk assessment may be expedited upon written request by a Responsible Official and a showing of good cause. (42 CFR 73.10(f)).

4. An individual or entity may request approval to perform a ''restricted experiment'' (42 CFR 73.13).

5. An individual or entity must develop and implement a written security plan, biosafety plan, and incident response plan (42 CFR 73.11(a), 42 CFR 73.12(a), and 42 CFR 73.14(a)).

6. The Responsible Official at the must ensure a record of the training for each individual with access to select agents and toxins and each escorted individual is maintained (42 CFR 73.15(d)).

7. An individual or entity may appeal a denial, revocation, or suspension of registration. (42 CFR 73.20(a)).

8. An individual may appeal a denial, limitation, or revocation of access approval. (42 CFR 73.20(b)).

The total estimated annualized burden for all data collection was calculated using data obtained from the FSAP database and is estimated as 8,528 hours. Information will be collected via fax, email and hard copy mail from respondents. Upon OMB approval, CDC will begin use of the revised forms in November 2015 through November 2018. There is no cost to the respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
73.3 & 73.4	Request for Exclusions	3	1	1	3
73.5 & 6	Report of Identification of a Select Agent or Toxin	303	3	1	909
73.5 & 73.6	Request of Exemption	1	1	1	1
73.7	Application for Registration	5	1	5	25
73.7	Amendment to a Certificate of Registration	277	7	1	1,939
73.9	Documentation of self-inspection	277	1	1	277
73.10	Request for Expedited Review	1	1	30/60	1
73.11	Security Plan	277	1	5	1,385
73.12	Biosafety Plan	277	1	5	1,385
73.13	Request Regarding a Restricted Experiment	20	2	1	40
73.14	Incident Response Plan	277	1	5	1,385
73.15	Training	277	1	1	277
73.16	Request to Transfer Select Agents and Toxins	156	2	1	312
73.17	Records	277	1	30/60	139
73.19	Notification of Theft, Loss, or Release	215	2	1	430
73.20	Administrative Review	5	4	1	20
Total					8,528

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.

[FR Doc. 2015–07606 Filed 4–2–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2187]

Identifying Potential Biomarkers for Qualification and Describing Contexts of Use To Address Areas Important to Drug Development; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice entitled ''Identifying Potential Biomarkers for Qualification and Describing Contexts of Use to Address Areas Important to Drug Development; Request for Comments'' that appeared in the **Federal Register** of February 13, 2015 (80 FR 8089). In the notice, FDA requested comments on identifying potential biomarkers for qualification and describing contexts of use to address areas important to drug development. The Agency is taking this action for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by May 15, 2015

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–7495.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 13, 2015 (80 FR 8089), FDA published a notice with a 60-day comment period to request comments on identifying potential biomarkers for qualification and describing contexts of use to address areas important to drug development. FDA is encouraging interested groups and individuals to submit information on specific medical and biological areas where novel biomarkers can be identified that would meaningfully advance drug development.

The current 60-day comment period does not allow sufficient time to obtain the broad public response that will inform FDA's Biomarker Qualification Program going forward. FDA is extending the comment period for an additional 30 days, thus extending the comment period to May 15, 2015. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying progress on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: March 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–07631 Filed 4–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

Correction: This notice was published in the **Federal Register** on March 24, 2015, Volume 80, Number 56, Pages 15621–15622. The times and dates should read as follows:

Times and Dates: 12:30 p.m.—5:00 p.m., April 15, 2015; 8:30 a.m.—12:00 p.m., April 16, 2015.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Programs, Standards, and Services, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, CDC, 1600 Clifton Road NE., Mailstop F–11, Atlanta, Georgia 30329–4018; telephone (404) 498–2741; or via email at *NAnderson@cdc.gov*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–07639 Filed 4–2–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Extension, With Change, of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information collection for review; I–312/I–312A; Designation of Attorney in Fact/ Revocation of Attorney In Fact; OMB Control No. 1653–0041.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 2, 2015.

Written comments and suggestions regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Scott Elmore, Forms Management Office, U.S. Immigration and Customs Enforcement, 801 I Street NW., Mailstop 5800, Washington, DC 20536–5800.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the