References

ICCVAM. 2008a. ICCVAM–NICEATM/ECVAM Scientific Workshop on Alternative Methods to Refine, Reduce, or Replace the Mouse LD_{50} Assay for Botulinum Toxin Testing. NIH Publication No. 08–6416. Research Triangle Park, NC: NIEHS. *Available: http://iccvam.niehs.nih.gov/docs/biologics-docs/BoNTwkshprept.pdf.*

ICCVAM. 2008b. ICCVAM Test Method Evaluation Report: Validation Status of Five *In Vitro* Test Methods Proposed for Assessing Pyrogenicity of Pharmaceuticals and Other Products. NIH Publication No. 08– 6392. Research Triangle Park, NC: NIEHS. *Available: http://iccvam.niehs.nih.gov/methods/pyrogen/pyr_tmer.htm.*

Dated: May 16, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011–12627 Filed 5–20–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–11–0576]

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 404–639–5960 and send comments to Daniel Holcomb, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail 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

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Revision—Office of Public Health Preparedness and Response (OPHPR), Division of Select Agents and Toxins, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188 (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 (i.e., select agents and toxins) that could pose a severe threat to public health and safety. The *Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107–188 (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 (*i.e.,* select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. In accordance with these Acts, HHS and USDA promulgated regulations requiring entities to register with the CDC or the Animal and Plant Health Inspection Service (APHIS) if they possess, use, or transfer a select agent or toxin (42 CFR part 73, 7 CFR part 331, and 9 CFR part 121).

CDC is requesting continued OMB approval to collect this information through the use of five forms: (1) Application for Registration, (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption. There have been no new select agent program forms added to this information collection request. The current versions of the standard forms have been revised to: (1) Reduce the burden expended by the regulated entities and CDC by removing similar questions, (2) enhance clarification of the transfer process, (3) determine the level of potential exposure, and (4) improve surveillance methods for monitoring the reports of select agents and toxins identified by registered entities. In addition to the standardized forms listed above, requests for expedited reviews, administrative reviews and inspections are also submitted to CDC. There is not a standardized form for the request for expedited review, administrative review and inspections. Therefore, an entity must submit a written request to the Secretary of Health and Human Services, by way of the Attorney General for expedited reviews (42 CFR 73.10(e)) and exclusions of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)). Inspections take place prior to issuance of a certificate of registration to ensure compliance with regulation 42 CFR 73.18. Following the inspection an entity may be asked to respond to written requests and submits the documentation to CDC.

Entities may also amend their registration (42 CFR, 73.7(h)(1)) if any changes occur to the information previously submitted. When applying for an amendment to a certificate of registration, an entity must obtain and complete the relevant portion of the application package.

The total estimated annualized burden for all data collection is 8,878 hours. Information will be collected via fax, email and mail from respondents of the 320 entities registered with the Select Agent Program. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

CFR	Form name	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
73.3(d)	Application for Registration	5	1	4.5	23
73.7(h)(1)	Amendment to Registration Application.	320	8	1	2,560
73.16	Request to Transfer Select Agents or Toxins.	320	1	1.5	480

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

CFR	Form name	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
73.19(a)(b)	Notification of Theft, Loss or Release.	180	1	1	180
73.5 & 73.6(a)(b)	Report of Identification of Select Agent.	320	9	1	2,880
73.5 & 73.6(d–e)	Request of Exemption	3	1	1	3
73.3 & 73.4(e)(1)	Request for Exclusions/Restricted	71	1	1	71
73.10(e)	Request for Expedited Review	1	1	1	1
73.20	Administrative Review	30	1	4	120
73.18	Inspections	320	1	8	2,560
Total					8,878

Dated: May 17, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–12571 Filed 5–20–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned committee:

Time and Date

8 a.m.–6 p.m., June 22, 2011.
8 a.m.–4 p.m., June 23, 2011.

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent "Oz" Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: The agenda will include discussions on: human papillomavirus vaccines, pertussis, meningococcal vaccine, influenza, febrile seizures related to vaccine administration, herpes zoster vaccine, 13-valent pneumococcal conjugate vaccine (PCV13), new MMR Vaccine Work Group, two dose varicella vaccination and hepatitis B vaccine.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Stephanie B. Thomas, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., (E–05), Atlanta, Georgia 30333, Telephone: (404)639–8836, Fax: (404)639–8905, E-mail: *acip@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.

Dated: May 16, 2011.

Elaine L. Baker,

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

[FR Doc. 2011–12563 Filed 5–20–11; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Ethics Subcommittee (ES)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned subcommittee:

TIMES AND DATES:

1 p.m.–5 p.m., June 16, 2011
8:30 a.m.–12:30 p.m., June 17, 2011

PLACE: CDC, Thomas R. Harkin Global Communications Center, Distance Learning Auditorium, 1600 Clifton Road, NE., Atlanta, Georgia 30333. This meeting is also available by teleconference. Please dial (877) 928–1204 and enter code 4305992.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 60 people. To accommodate public participation in the meeting, a conference telephone line will be available. The public is welcome to participate during the public comment. The public comment periods are tentatively scheduled from 4 p.m.–4:15 p.m. on June 16, 2011 and from 12 p.m.–12:15 p.m. on June 17, 2011.

PURPOSE: The ES will provide counsel to the ACD, CDC, regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.

MATTER TO BE DISCUSSED: Agenda items will include the following: An update on ES presentation during the April 28, 2011, ACD, CDC meeting; discussion of next steps on addressing potential public health ethical issues associated with implementation of effective preventive interventions for noncommunicable disease; and review of workgroup progress on developing practical tools to assist state, tribal, local, and territorial health departments in their efforts to address public health ethics challenges. The agenda is subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: For security reasons, members of the public interested in attending the meeting should contact Drue Barrett, PhD, Designated Federal Officer, ACD, CDC–ES, 1600 Clifton Road, NE., M/S D–50, Atlanta, Georgia 30333. Telephone (404) 639–4690. E-mail: *dbarrett@cdc.gov.* The deadline for