GENERAL SERVICES ADMINISTRATION

[Notice MC–2011–2; Docket No. 2011–0006; Sequence 5]

The President's Management Advisory Board (PMAB); Notification of Upcoming Public Advisory Meeting

AGENCY: Office of Executive Councils, U.S. General Services Administration (GSA).

ACTION: Meeting Notice.

SUMMARY: The President's Management Advisory Board, a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App., and Executive Order 13538, will hold a public meeting on June 17, 2011.

DATES: *Effective date:* May 23, 2011.

Meeting date: The meeting will be held on Friday, June 17, 2011, beginning at 9:30 a.m. eastern time, ending no later than 1 p.m.

Addresses and Meeting Access: The PMAB will convene its meeting in the Eisenhower Executive Office Building, 1650 Pennsylvania Avenue, NW., Washington, DC. Due to security, there will be no public admittance to the Eisenhower Building to attend the meeting. However, public access to the meeting will be available via live webcast at *http://www.whitehouse.gov/live.*

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Brockelman, Designated Federal Officer, President's Management Advisory Board, Office of Executive Councils, General Services Administration, 1776 G Street NW., Washington, DC 20006, at *stephen.brockelman@cxo.gov.*

SUPPLEMENTARY INFORMATION:

Agenda: The main purpose of this meeting is for the two PMAB subcommittees to discuss their work to date and receive feedback from the full PMAB. The subcommittees are examining Information Technology Management in the Federal Government, and Senior Executive Service (SES) Development and Management, for the purpose of identifying leading business practices that have the potential to improve government performance in these areas. On the PMAB Web site, a detailed meeting agenda will be available by June 16; in addition, the meeting transcript will be available after the meeting at: *http://www.whitehouse.gov/administration/advisory-boards/pmab* Information regarding changes to the agenda can be obtained from this Web site or by contacting the identified DFO. In view of the possibility that the starting time scheduled for the PMAB meeting may be adjusted, persons planning to view via webcast should check with the above Web site for time changes if such rescheduling would result in an inconvenience.

Background: The PMAB was established to provide independent advice and recommendations to the President and the President's Management Council on a wide range of issues related to the development of effective strategies for the implementation of best business practices to improve Federal Government management and operation, with a particular focus on productivity and the application of technology.

Availability of Materials for the Meeting: Please see the PMAB Web site for any available materials at *http://www.whitehouse.gov/administration/advisory-boards/pmab.*

Procedures for Providing Public Comments: In general, public statements will be posted on the White House Web site (*http://www.whitehouse.gov/administration/advisory-boards/pmab*), Non-electronic documents will be made available for public inspection and copying in PMAB offices at GSA, 1776 G Street NW., Washington, DC 20006, on official business days between the hours of 10 a.m. and 5 p.m. eastern time. You can make an appointment to inspect statements by telephoning (202) 501–1398. All statements, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. Any statements submitted in connection with the PMAB meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

The public is invited to submit written statements for this meeting to the Advisory Committee prior to the meeting until June 16, 2011, by either of the following methods:

Electronic Statements: Submit written statements to Stephen Brockelman, Designated Federal Officer at *stephen.brockelman@cxo.gov;* or

Paper Statements: Send paper statements in triplicate to Stephen Brockelman at President's Management Advisory Board, Office of Executive Councils, General Services Administration, 1776 G Street, NW., Washington, DC 20006.

Dated: May 16, 2011.

Robert Flaak,

Director, Office of Committee and Regulatory Management, General Services Administration.

[FR Doc. 2011–12647 Filed 5–20–11; 8:45 am]

BILLING CODE 6820–BR–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nomination of In Vitro Test Methods for Detection and Quantification of Botulinum Neurotoxins and Detection of Non-Endotoxin Pyrogens; Data Request for Substances Evaluated by These Test Methods

AGENCY: Division of National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Request for comments and/or data.

SUMMARY: On behalf of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests public comment on nominations received for (1) Three *in vitro* test methods proposed for detecting and quantifying botulinum neurotoxin (BoNT), and (2) an *in vitro* test method proposed for detecting non-endotoxin pyrogens. NICEATM seeks data generated using alternative test methods for detecting and quantifying BoNT, including but not limited to three test methods nominated by BioSentinel Pharmaceuticals, Inc. (BioSentinel). Data from the standardized mouse LD_{50} assay currently used for these endpoints are requested for comparison. In addition, NICEATM seeks data generated using alternative test methods for identifying non-endotoxin pyrogens, including but not limited to the monocyte activation test (MAT), which was nominated by Biotest AG. Data on non-endotoxin pyrogens tested in the rabbit pyrogen test (RPT) are requested for comparison. NICEATM received nominations for validation studies on each of the above test methods, which have the potential to reduce or replace animal use for regulatory testing. At this time, ICCVAM requests public comments on the appropriateness and relative priority of these activities.

DATES: For consideration by the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) at its annual meeting (67 FR 23323), comments and data are

requested by June 2, 2011. NICEATM and ICCVAM will accept comments and data for these nominations until July 7, 2011.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Deputy Director, NICEATM, NIEHS, P.O. Box 12233, *Mail Stop:* K2–16, Research Triangle Park, NC, 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov*. *Courier address:* NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Nomination for the Detection and Quantification of BoNTs

In 2006, NICEATM and ICCVAM convened a workshop, *Alternative Methods to Refine, Reduce, or Replace the Mouse LD_{50} Assay for Botulinum Toxin Testing,* in response to a nomination from the Humane Society of the United States requesting that ICCVAM assess the availability of alternative methods to replace the mouse LD_{50} assay for BoNT potency testing. Workshop participants concluded that some of the methods considered could be used, in specific circumstances or in a tiered-testing strategy, to reduce or refine the use of mice in current *in vivo* BoNT testing protocols (ICCVAM, 2008a). However, none of the reviewed methods was considered suitable to serve as a complete replacement for the mouse LD_{50} assay, either for detection of BoNT or for potency determination. The workshop participants noted that some of the methods considered might be useful as replacements for the mouse LD_{50} assay in the future given additional development and validation efforts.

BioSentinel has developed tests for the detection and quantification of BoNTs. These tests include the *in vitro* BoTest™ and BoTest™ Matrix assays and the cell-based assay BoCell™. Following appropriate validation and demonstration of adequate performance, these methods may have the potential to meet regulatory requirements for detection and quantification of BoNTs in a range of applications.

BioSentinel has forwarded a nomination for these methods to (1) Facilitate collaboration to develop a validation strategy which could lead to the regulatory acceptance of the test methods for the detection and quantification of BoNT contained in suspect substances, the determination of drug product potency, and/or the clinical diagnosis of botulism and (2) coordinate and conduct necessary validation studies.

Nomination for the Detection of Non-Endotoxin Pyrogens

ICCVAM previously evaluated the validation status of five *in vitro* test methods proposed for assessing the potential pyrogenicity (*i.e.,* ability to induce fever) of pharmaceuticals and other products, as potential replacements for the RPT. Subsequent to this evaluation, ICCVAM recommended that, although none of the test methods should be considered as a complete replacement for the RPT for the detection of Gram-negative endotoxin, they can be considered for use to detect Gram-negative endotoxin in human parenteral drugs on a case-by-case basis, subject to product-specific validation to demonstrate equivalence to the RPT, in accordance with applicable U.S. Federal regulations (ICCVAM, 2008b). ICCVAM recognized that these test methods could be applicable for detection of a wider range of pyrogens, including non-endotoxin pyrogens, and made recommendations for future studies that could expand their applicability. In response to these recommendations, Biotest AG recently nominated a commercialized version of one of these tests (*i.e.,* MAT), which uses cryopreserved human blood and quantitates the induction of interleukin (IL)-1β, for additional validation studies to evaluate its usefulness for identifying non-endotoxin pyrogens.

Draft ICCVAM Conclusions and Recommendations

Based on the information provided by the test method sponsors, ICCVAM concludes that the nominated activities are of sufficient interest and applicability to warrant further evaluation. ICCVAM's preliminary recommendation is that both nominations should have a high priority for further discussion to assess what information is needed to adequately characterize the usefulness and limitations of the proposed test methods, and any other similar *in vitro* test methods, for these endpoints. These assessments will identify what data are needed and what studies are required to fill any data gaps that are identified. Studies identified as necessary to adequately characterize the validation status for regulatory testing purposes are proposed to have a high priority.

As part of the nomination review process, NICEATM invites public comments on these nominations and the appropriateness and relative priority assigned by ICCVAM to the nominated activities. ICCVAM will finalize its recommendations on the priority of these nominations after considering comments received from the public and SACATM, which will comment on the ICCVAM draft recommendations at its meeting on June 16–17, 2011.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (decrease or eliminate pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.vnih.gov).*

SACATM was established in response to the ICCVAM Authorization Act (Section 285l–3(d)) and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167.*

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