SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Risk Evaluation and Mitigation Strategies: Modifications and Revisions.” This guidance provides information on what types of changes to approved REMS will be considered modifications of the REMS and what types of changes will be considered revisions. (See section 505–1(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1(h))). This guidance also provides information on how REMS modifications and revisions should be submitted to FDA and how FDA intends to review and act on these submissions.

If FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks, FDA is authorized to require a REMS for such drugs under section 505–1 of the FD&C Act.1 Section 505–1(g) and (h) of the FD&C Act include provisions for the assessment and modification of an approved REMS. Section 505–1(h) of the FD&C Act requires FDA to review and act on proposed minor modifications, as defined in guidance, within 60 days.2 It also requires FDA to establish, through guidance, that “certain modifications” can be implemented following notification to FDA. (See section 505–1(h)2(A)(iv) of the FD&C Act.) In addition, FDA is required to review and act on REMS modifications to conform the REMS to approved safety labeling changes, or to a safety labeling change that FDA has directed the application holder to make pursuant to section 3505(o)(4) of the FD&C Act within 60 days. (See section 505–1(h)2(A)(vi) of the FD&C Act.) Finally, section 505–1(g)(4)(A) of the FD&C Act specifies that proposed REMS modifications no longer require submission of a REMS assessment; instead, proposed modifications must include an adequate rationale for the proposed changes.

This guidance updates the guidance of the same name, issued April 7, 2015 (80 FR 18629), and finalizes the portion that sets forth the submission procedures for REMS revisions. FDA carefully considered all comments received, including comments on the submission procedures portion, and revised the guidance as appropriate.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Risk Evaluation and Mitigation Strategies: Modifications and Revisions.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This final guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). REMS modifications are submitted to FDA as supplements to approved new drug applications (NDAs) under 21 CFR 314.70 and for abbreviated new drug applications (ANDAs) under 21 CFR 314.97, and for approved biologics license applications (BLAs) under 21 CFR 601.12. Burden hours for NDAs and ANDAs are approved by OMB under control number 0910–0001, and for BLAs under control number 0910–0338. REMS revisions are submitted to FDA as application correspondence and are also approved by OMB under control numbers 0910–0001 and 0910–0338.

III. Electronic Access


DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Informatics, Library and Data Sciences Review Committee.

Date: November 14–15, 2019.

Time: November 14, 2019, 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Hyatt, 1 Metro Center, Bethesda, MD 20814.

Time: November 15, 2019, 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–594–4937, huangze@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)


Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–14645 Filed 7–9–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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DEPARTMENT OF HOMELAND SECURITY

Cybersecurity and Infrastructure Security Agency Vulnerability Assessments

AGENCY: Infrastructure Security Division (ISD), Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; Revision, 1670–0035.

SUMMARY: DHS CISA ISD will submit the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are due by September 9, 2019.

ADDRESSES: You may submit comments, identified by docket number CISA–2019–0007, by one of the following methods:

- Email: IPGatewayHelpDesk@hq.dhs.gov. Please include docket number CISA–2019–0007 in the subject line of the message.
- Mail: Written comments and questions about this Information Collection Request should be forwarded to DHS/CISA/ISD, ATTN: 1670–0035, 245 Murray Lane SW, Mail Stop 0602, Washington, DC 20598–0602.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at http://www.regulations.gov, including any personal information provided.

Docket: For access to the docket and comments received, please go to www.regulations.gov and enter docket number CISA–2019–0007.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT:
Ricky Morgan, 866–844–8163, IPGatewayHelpDesk@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: The Homeland Security Presidential Directive-7, the Presidential Policy Directive-21, and the National Infrastructure Protection Plan highlight the need for a centrally managed repository of infrastructure attributes capable of assessing risks and facilitating data sharing. To support this mission need, the DHS CISA ISD has developed a data collection system that contains several capabilities which support the homeland security mission in the area of critical infrastructure (CI) protection.

Protective Security Advisors (PSAs) and Cyber Security Advisors (CSAs) conduct voluntary assessments on CI facilities. These assessments are web-based and are used to collect an organization’s basic, high-level information, and its dependencies. This data is then used to determine a Protective Measures Index (PMI) and a Resilience Measures Index (RMI) for the assessed organization. This information allows an organization to see how it compares to other organizations within the same sector as well as allows them to see how adjusting certain aspects...