Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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 505(o)(4) of the FD&C Act within 60 days. (See section 505–1(h)(2)(A)(iii) 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

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: July 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14663 Filed 7–9–19; 8:45 am]

BILLING CODE 4164–01–P

[1] Section 505–1 of the FD&C Act applies to applications for prescription drugs submitted under subsection 505(b) (*i.e.,* new drug applications) or (j) (*i.e.,* abbreviated new drug applications) of the FD&C Act (21 U.S.C. 355(b) or (j), respectively) and applications under section 351 of the Public Health Service Act (*i.e.,* biologics license applications).

[2] See section 505–1(h)(2)(A)(ii) of the FD&C Act. Section 1132(c) of the Food and Drug Administration Safety and Innovation Act also provides that FDA will issue guidance that, for purposes of section 505–1(h)(2)(A) of the FD&C Act, describes the types of modifications to approved risk evaluation and mitigation strategies that are considered to be minor modifications of such strategies.

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, *huangz@mail.nih.gov.*

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

Dated: July 3, 2019.

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