Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Dear Health Care Provider Letters: Improving Communication of Important Safety Information

OMB Control Number 0910–0754—Extension

This information collection supports recommendations found in the Agency guidance document entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' The guidance provides instruction to industry and FDA staff on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. The guidance is available from our website at: *https://www.fda.gov/media/79793/download.*

The guidance document gives specific instruction on what should and should not be included in DHCP letters. Some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on how to develop a DHCP letter, when to send a letter, what type of letter to send, and how to assess the letter's impact. Based on a review of FDA's Document Archiving, Reporting, and Regulatory Tracking System for 2016—2018, we identified 38 DHCP letters that were sent by 24 distinct sponsors during the 3-year timeframe. We estimate that we will receive approximately 13 DHCP letters annually from approximately 8 application holders. FDA professionals familiar with DHCP letters, and with the recommendations in the guidance, estimate that it should take an application holder approximately 100 hours to prepare and send DHCP letters in accordance with the guidance.

In the **Federal Register** of August 19, 2019 (84 FR 42929), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received expressing the importance of communicating safety information, for which we are appreciative. No other comments were received.

We estimate the annual reporting burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Dear Health Care Provider Letters	8	1.625	13	100	1,300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we have reduced our burden estimate by 17 respondents with a corresponding decrease in annual hours by 1,200. We attribute the decrease to the effectiveness of the guidance.

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25333 Filed 11–21–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

The meeting 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 material, 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for AIDS Research (P30) and Developmental Centers for AIDS Research (P30).

Date: December 16–17, 2019.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Chelsea D. Boyd, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC–9823, Rockville, MD 20852–9834, 240–669–2081, *chelsea.boyd@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 15, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–25306 Filed 11–21–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, November 25, 2019, 11:00 a.m. to November 25, 2019, 4:00 p.m., National Institutes of Health Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852, which was published in the **Federal Register** on November 14, 2019, 84 FR 61920.

This notice is to amend the date of the NIMH HIV/AIDS Review meeting from November 25, 2019, from 11:00 a.m.–4:00 p.m. to December 17, 2019, from 1:00 p.m.–5:00 p.m. The meeting is closed to the public.