information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

OMB Control Number 0910–0797—Extension

FDA has agreed to specific program enhancements and performance goals specified in the Generic Drug User Fee Act Reauthorization (GDUFA II) Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain timeframes. To support these program goals, we have developed the guidance entitled ''Controlled Correspondence Related to Generic Drug Development.'' The guidance is intended to facilitate FDA's prompt consideration of controlled correspondence and to assist in meeting the prescribed timeframes by providing procedural recommendations to include the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs and the ANDA number, if applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain timeframes. To facilitate FDA's prompt consideration of the request and to assist in meeting the prescribed timeframes, the guidance recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification. This information collection supports this Agency guidance.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of controlled correspondence	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic drug manufacturers, related industry, and representatives	390	3.8	1,496	5	7,480

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

This is the first extension of the information collection and we base our estimate on a review of Agency data of fiscal year submissions for 2014, 2015, and 2016 which reflects an increase in submissions that we attribute to an increase in generic drug development. Accordingly, we estimate 390 generic drug manufacturers and related industry (*e.g.,* contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives will each submit an average of 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 and 10 burden hours.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 7,480 total hours annually for industry to prepare and submit inquiries considered controlled correspondence.

Dated: May 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10856 Filed 5–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Drug

Repositioning and Combination Therapy for AD.

Date: June 5, 2018.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Ave., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 17, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10933 Filed 5–21–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Eye Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL EYE INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Eye Institute.

Date: June 11–13, 2018.

Time: 6:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate programmatic concerns and personnel qualifications.

Place: National Institutes of Health, Building 31, Conference Room 6C10, Bethesda, MD 20892.

Contact Person: Sheldon S. Miller, Ph.D., Scientific Director, National Institutes of Health, National Eye Institute, Bethesda, MD 20892, (301) 451–6763, *millerss@nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10837 Filed 5–21–18; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NHLBI. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Heart, Lung, and Blood Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NHLBI.

Date: June 15, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, 6th Floor, Room 6S233, Bethesda, MD 20892.

Contact Person: Robert S. Balaban, Ph.D., Scientific Director, Division of Intramural Research, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 10, 10 Center Drive, 4th Floor, Room 1587, Bethesda, MD 20892, 301–496–2116, *balabanr@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 16, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10836 Filed 5–21–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Pragmatic Trials for Dementia Care in Long Term Services and Support.

Date: June 21, 2018.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carmen, Ph.D. Moten, MPH, Scientific Review Officer, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *cmoten@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 17, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–10935 Filed 5–21–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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