

an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571—OMB control number 0910–0014, and FDA Form 356h—OMB control number 0910–0338.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the Agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency’s tracking databases enables the appropriate Agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the Center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (*i.e.*, scientific, procedural, or both), possible solutions based on information in the administrative file,

whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last Agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the Agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA’s experience with dispute resolution, the Agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biological product regulated by the Agency under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

In the **Federal Register** of June 2, 2015 (80 FR 31386), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Burden Estimate: Provided in this document is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately eight sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits requests for formal dispute resolution to CBER annually. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 31 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the Agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 8 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Requests for formal dispute resolution	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER	8	2	31	8	248
CBER	1	1	1	8	8
Total					256

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

Dated: October 2, 2015.
Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015–25623 Filed 10–7–15; 8:45 am]
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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 (5 U.S.C. App.), 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Lung Imaging Phase 2.

Date: November 2, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street NW., Washington, DC 20037.

Contact Person: Stephanie L. Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301-443-8784, constantsl@nhlbi.nih.gov

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; SBIR Phase IIB Small Market Awards.

Date: November 4, 2015.

Time: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact Person: Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892-7924, 301-435-0725, creazzotl@mail.nih.gov

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI SBIR Phase IIB Bridge Awards (R44).

Date: November 4, 2015.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, sunnarborgsw@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: October 2, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-25582 Filed 10-7-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Environmental Health Sciences Special Emphasis Panel; Training for Career Independence in Environmental Health Sciences.

Date: November 2, 2015.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, Room 1003A, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 2, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

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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 (5 U.S.C. App.), 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Therapeutic Strategies for Lysosomal Storage and Amino; Acid Metabolism Disorders.

Date: November 3, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alessandra C Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205 MSC7846, Bethesda, MD 20892, (301) 435-1021, rovescaa@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Laboratory for Fluorescence Dynamics.

Date: November 8–10, 2015.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Atrium Hotel, 18700 MacArthur Blvd., Irvine, CA 92612.

Contact Person: Mike Radtke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301-435-1728, rادتک@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Informatics.

Date: November 9, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Claire E Gutkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3106, MSC 7808, Bethesda, MD 20892, 301-594-3139, gutkincl@csr.nih.gov.