

Data.” This report summarizes findings and recommendations from eight FDA working groups established to enhance the transparency and public accessibility of the Agency’s compliance and enforcement data.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a report entitled “FDA Transparency Initiative: Increasing Public Access to FDA’s Compliance and Enforcement Data.” FDA is responsible for a broad range of compliance and enforcement activities. Increasing the transparency of these activities enhances the public’s understanding of the Agency’s decisions and promotes accountability of the Agency and the regulated industry.

On October 3, 2011, FDA issued a report entitled, “Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency’s Compliance and Enforcement Data.” The report advanced eight draft proposals for making FDA’s publicly available compliance and enforcement data more accessible and user-friendly (available at: <http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf>). Following extensive public comment on the report and internal FDA deliberation, the FDA Commissioner adopted all eight draft proposals, committing FDA to exploring numerous avenues for increasing the transparency and public accessibility of its compliance and enforcement data (see 77 FR 5027, February 1, 2012, and <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm289638.htm>).

To develop plans for addressing the eight initiatives, FDA established eight working groups with representatives from all of FDA’s centers and several of its offices. Each group was asked to draft a report on its initiative and to include recommendations for moving forward. These efforts culminated in the preparation of this report, which summarizes the eight initiatives and the recommendations from the relevant working groups for enhancing the transparency and public accessibility of FDA’s compliance and enforcement data.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 a meeting of the Board of Scientific Counselors, National Institute of Biomedical Imaging and Bioengineering.

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 Institute of Biomedical Imaging and Bioengineering, including consideration of personal 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 Institute of Biomedical Imaging and Bioengineering.

Date: June 1, 2014.

Time: 7:30 p.m. to 9:00 p.m.

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

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

Date: June 2, 2014.

Time: 8:30 a.m. to 3:00 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, Bethesda, MD 20892.

Date: June 3, 2014.

Time: 8:30 a.m. to 12:00 p.m.

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

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

Contact Person: Richard D. Leapman, Intramural Scientific Director, National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD 20892, 301-496-2599, leapmanr@mail.nih.gov.

Dated: April 17, 2014.

David Clary,

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 Special Topic: R21 Re-review.

Date: April 24, 2014.

Time: 3:00 p.m. to 3:30 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: David B Winter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301-435-1152, dwinter@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS and AIDS Related Research.

Date: April 28, 2014.

Time: 11:00 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, (Telephone Conference Call).

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435-1165, walkermc@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.