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 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 Biomedical Imaging and Bioengineering Special Emphasis Panel—NIBIB Training Review.

Date: November 5, 2009.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Quincy Hotel, 1823 L Street, NW., Washington, DC 20036.

Contact Person: Manana Sukhareva, PhD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 959, Bethesda, MD 20892. 301–451–3397. *sukharem@mail.nih.gov*.

Dated: September 11, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–22432 Filed 9–16–09; 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Mentored Clinical Scientist Research Awards.

Date: October 8–9, 2009.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Washington National Airport, 1489 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: Robert Blaine Moore, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7213, Bethesda, MD 20892, 301–594–8394, *mooreb@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: September 11, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0355]

Submission of Quality Information for Biotechnology Products in the Office of Biotechnology Products; Notice of Extension of Deadlines to Request Participation in Pilot Program and to Submit Applications; and Notice of Increase in the Number of Original Applications in Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension of the deadline for submitting requests to participate in a pilot program involving the submission of quality (chemistry, manufacturing, and controls (CMC)) information for biotechnology products in an Expanded Change Protocol consistent with the principles of quality-by-design and risk management in pharmaceutical manufacturing. Because the deadline for requests to participate in the pilot is being extended, FDA is also extending the application submission deadlines. FDA is also announcing an increase in the number of original applications being accepted into the pilot program.

DATES: Submit written and electronic requests to participate in the pilot program by September 30, 2010. Submit investigational new drug (IND) applications and postapproval supplements by March 31, 2011.

ADDRESSES: Submit written requests to participate in the pilot program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to participate in the pilot to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Marilyn Welschenbach, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, rm. 1514, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, e-mail: *Marilyn.Welschenbach@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 2, 2008 (73 FR 37972) (the July 2, 2008, notice), FDA announced that it is seeking volunteers from pharmaceutical companies to participate in a pilot program involving the submission of quality (CMC) information for biotechnology products in an Expanded Change Protocol, consistent with the principles of quality-by-design and risk management in pharmaceutical manufacturing. As explained in the July 2, 2008, notice, the Office of Pharmaceutical Science (OPS), in FDA's Center for Drug Evaluation and Research (CDER), is establishing a quality-by-design, risk-based approach to pharmaceutical quality, which is based on the FDA final report on ''Pharmaceutical cGMPs for the 21st Century—A Risk-Based Approach'' (*http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm*). The new quality-by-design approach will focus on critical quality attributes related to chemistry, formulation, and process design. Under quality-by-design, manufacturing will depend on a risk-based approach linking attributes and processes to product performance, safety, and efficacy.

The principles underlying this new approach to a quality-by-design, risk-based assessment can be found in the International Conference on Harmonisation guidances, ''Q8(R1) Pharmaceutical Development,'' June 2009 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073507.pdf*), and ''Q9 Quality Risk