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]

BILLING CODE 4140–01–P

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.

[FR Doc. E9–22433 Filed 9–16–09; 8:45 am]

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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

Management (ICH),'' June 2006 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073511.pdf*), and FDA's guidances for industry entitled ''PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance,'' September 2004 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070305.pdf*), and ''Quality Systems Approach to Pharmaceutical CGMP Regulations,'' September 2006 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070337.pdf*). Quality-by-design and risk-based approaches are also described in ''Q10 Pharmaceutical Quality Systems,'' April 2009 (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073517.pdf*).

The agency's Office of New Drug Quality Assessment in OPS, CDER, initiated a pilot program (70 FR 40719, July 14, 2005) to gain experience in assessing CMC sections of new drug applications (NDAs) that demonstrate an applicant's product knowledge and process understanding at the time of submission. This pilot was extremely useful in helping identify appropriate information to be shared regarding quality-by-design for small molecules. Although many of the principles of quality-by-design apply equally to small molecules and more complex pharmaceuticals, the ability to assess relevant attributes is a much greater challenge for complex pharmaceuticals.

Because the pilot program initiated in 2005 proved constructive, on July 2, 2008, FDA announced this pilot program to provide additional information to FDA for use in facilitating quality-by-design, risk-based approaches for complex molecules. Based on experience gained during the pilot program and prior knowledge, FDA will develop procedures to facilitate implementing a quality-by-design, risk-based approach for complex products. In addition, the experience gained by FDA under this pilot is expected to facilitate the development of guidance for industry. The pilot is open to original submissions and postapproval supplements to biologics license applications (BLAs) and NDAs reviewed by the Office of Biotechnology Products (OBP).

The July 2, 2008, notice provided deadlines related to the submission of certain information related to the pilot program. To ensure inclusive and relevant results from the pilot program, this document extends the deadline for requests to participate in this pilot program for products regulated by OBP from September 30, 2009, to September 30, 2010. Because the deadline for requests to participate in the pilot is being extended, FDA is also extending the application submission deadlines. As explained in the July 2, 2008, notice, it is preferable for original applications to enter the pilot as INDs. FDA is extending the deadline for submission of INDs from March 31, 2010, to March 31, 2011. FDA is also extending the deadline for submission of postapproval supplements from March 31, 2010, to March 31, 2011. In addition, the pilot is being expanded from five to eight original applications for products reviewed by OBP (BLA or NDA) in Common Technical Document format, paper or electronic. See the July 2, 2008, notice for instructions on submitting requests to participate in the pilot program and additional information regarding the pilot program.

Dated: September 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22378 Filed 9–16–09; 8:45 am]

BILLING CODE 4160–01–S

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Draft Program Comment for the National Telecommunications and Information Administration and the U.S. Department of Agriculture's Rural Utilities Service Regarding the Effects of Communication Facilities Construction or Modification Subject To Review by the Federal Communications Commission

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of Intent to Issue Program Comments for the National Telecommunications and Information Administration and the U.S. Department of Agriculture's Rural Utilities Service Regarding the Effects of Communication Facilities Construction or Modification Subject to Review by the Federal Communications Commission.

SUMMARY: The Advisory Council on Historic Preservation (ACHP) is considering issuing a Program Comment for the National Telecommunications and Information Administration and the U.S. Department of Agriculture's Rural Utilities Service that would relieve them of the need to conduct a separate Section 106 review regarding the effects of communication facilities construction or modification that will be subject to such review by the Federal Communications Commission. The ACHP seeks public input on the proposed Program Comment.

DATES: Submit comments on or before October 8, 2009.

ADDRESSES: Address all comments concerning this proposed Program Comment to Blythe Semmer, Office of Federal Agency Programs, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Suite 803, Washington, DC 20004. Fax (202) 606–8647. You may submit electronic comments to: *bsemmer@achp.gov*.

FOR FURTHER INFORMATION CONTACT: Blythe Semmer, (202) 606– 8552, *bsemmer@achp.gov*; or Laura Dean, PhD, RUS Federal Preservation Officer, (202) 720–9634, *laura.dean@wdc.usda.gov*.

SUPPLEMENTARY INFORMATION: Section 106 of the National Historic Preservation Act requires federal agencies to consider the effects of their undertakings on historic properties and to provide the Advisory Council on Historic Preservation (ACHP) a reasonable opportunity to comment with regard to such undertakings. The ACHP has issued the regulations that set forth the process through which Federal agencies comply with these duties. Those regulations are codified under 36 CFR part 800 (Section 106 regulations).

Under Section 800.14(e) of those regulations, agencies can request the ACHP to provide a ''Program Comment'' on a particular category of undertakings in lieu of conducting individual reviews of each individual undertaking under such category, as set forth in 36 CFR 800.4 through 800.7.

The ACHP is now considering issuing a Program Comment to the National Telecommunications and Information Administration (NTIA) and the U.S. Department of Agriculture's Rural Utilities Service (RUS) that would relieve them of the need to conduct a separate Section 106 review regarding the effects of communication facilities construction or modification that will be subject to such review by the Federal Communications Commission (FCC).

I. Background

On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act of 2009 (Recovery Act) into law. The Recovery Act provides the NTIA and the RUS with $7.2 billion to expand access to broadband services in the United States. In implementing this responsibility, NTIA, through its Broadband