Name of Committee: Center for Scientific Review Special Emphasis Panel, Skeletal Biology.

Date: December 16, 2009.

Time: 5:30 p.m. to 7:30 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: Daniel F. McDonald, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892. (301) 435–1215. *mcdonald@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, Urology Business Applications.

Date: December 21, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Ryan G. Morris, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892. 301–435–1501. *morrisr@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 4, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–29473 Filed 12–9–09; 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 (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: Muscle and Skeletal Biology.

Date: January 8, 2010.

Time: 9 a.m. to 1 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: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–451–1327, *liuyh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RM09–009 and RM009–008: Development of New Technologies Needed for Studying Human Microbiome.

Date: January 25, 2010.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692, (301) 435–1149, *elzaataf@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 4, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–29487 Filed 12–9–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0561]

Electronic Margin of Safety and NonClinical Toxicology Study Data Submission; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Veterinary Medicine (CVM) is seeking sponsors interested in participating in a pilot project to test the electronic submission of margin of safety and nonclinical toxicology study data using the Standard for Exchange of Nonclinical Data (SEND), a new electronic data standard format which is used to support review activity. FDA anticipates that a successful pilot will enable CVM to accept margin of safety and nonclinical toxicology study data related to investigational new animal drug (INAD) files and new animal drug applications (NADA's) electronically in SEND format.

DATES: Submit electronic or written requests to participate in the pilot project by March 10, 2010. General comments on the pilot project are welcome at any time.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding the project to *http://www.regulations.gov.* Submit written requests and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV–135), 7500 Standish Pl., Rockville, MD 20855, 240–276–8348, e-mail: *Janis.messenheimer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing an opportunity to participate in a 3-year CVM pilot project. This pilot involves FDA's ongoing testing of SEND, a data model initially developed for non-clinical data from animal toxicology studies submitted in support of applications for approval of human drugs. This pilot is designed to test the ability of SEND to support the review of margin of safety and nonclinical toxicology study data submitted to INAD files and as part of NADA's at CVM. CVM considers this pilot to be the beginning of a phased implementation of SEND that will enable CVM to receive and evaluate data from toxicology studies as part of the human food safety evaluation and margin of safety studies.