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.

SEND was developed by the Clinical Data Interchange Standards Consortium's (CDISC's) SEND Team. CDISC is an open, multidisciplinary, nonprofit organization that has established worldwide industry standards to support the electronic acquisition and submission of clinical trial data and metadata for medical and biopharmaceutical product development (*http://www.cdisc.org*[1]). CDISC is currently facilitating and testing the extension of the same SEND standard for nonclinical toxicology data. Where possible, the standards developed for clinical datasets and metadata, as described in the overall Study Data Tabulation Model (SDTM), are being used to develop a standardized dataset format for nonclinical studies.

Recently, the Center for Drug Evaluation and Research (CDER) completed a pilot project (phase 1) using the SEND format in sample toxicology datasets, that is, outside of a regulatory setting (68 FR 3885, January 27, 2003). The phase 1 CDER pilot also evaluated data validation and analysis tools specifically designed to validate datasets according to the current SEND standard and to enable a reviewer to display and evaluate data efficiently from animal toxicity studies submitted in the SEND format. The phase 1 pilot resulted in the development of a SEND Implementation Guide (SENDIG) describing the process for formatting data from single- and repeat-dose animal toxicity and carcinogenicity studies for submission purposes. Following the phase 1 pilot, CDER announced a second pilot (phase 2) to test SEND formatted datasets in a regulatory setting (72 FR 56363, October 3, 2007). To support the new CDER pilot, the SENDIG has been updated to ensure the harmonized implementation of the CDISC SDTM and SEND models. The updated guide can be found at *http://www.cdisc.org*.

CVM currently receives margin of safety and nonclinical toxicology study data in paper, portable document format (PDF), and other electronic formats. The lack of uniformity in the formats used by sponsors to submit data, in addition to the inconsistent use of terminology across submissions, complicates the agency's efforts to validate, display, and evaluate the data using modern, computer-based review and analysis tools. As part of FDA's effort to modernize its information technology systems and improve efficiency, CVM is planning to transition to a true electronic data format for submission of study data for regulatory review.

[1] FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site address after this document publishes in the **Federal Register**.

II. Pilot Project Description

This pilot is intended to help CVM evaluate the adequacy of the current SEND format (SAS transport files, XPT version 5) in accommodating margin of safety and nonclinical toxicology study data submitted to the Center. As part of this evaluation and in anticipation of FDA receiving datasets for regulatory review, the CDISC SEND Team, in collaboration with FDA and available pilot participants, will first update the SENDIG as needed to include veterinary-specific data elements and terms.

As experience from the ongoing pilot is gained with various types of margin of safety and nonclinical toxicology study data, CVM expects to recommend new technical specifications for margin of safety and toxicology studies as part of a continuing process of transitioning from paper-based submissions to the submission of study data by electronic means.

III. Participation

CVM is seeking a limited number of sponsors (approximately five to eight, but no more than eight) to participate in this pilot. Because a limited group of voluntary participants is needed, CVM will use its discretion in choosing volunteers, based on their experience with datasets previously submitted to CVM. The duration of the pilot is expected to be approximately 3 years, but it may be extended as needed. A familiarity with SEND (e.g., from involvement in the CDER pilot) would benefit participants but is not necessary for participation in the project. A participant should be willing to provide the same study data in both paper format and SEND electronic format using SAS transport files (XPT version 5). The pilot provides the best opportunity to compare and evaluate the same data available in paper and SEND formats in order to test the accuracy and reliability of the SEND format.

For the purposes of this pilot, study reports from margin of safety and nonclinical toxicology study data will be requested for submission. We anticipate that a successful pilot, including the implementation of any needed changes to the SENDIG and/or the data validation, viewing, and analysis tools, will allow CVM to accept specific types of margin of safety and nonclinical toxicology study data electronically based on the SEND format.

Requests to participate in the pilot project should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

Under current FDA regulations, applicants must provide evidence to establish safety and effectiveness as part of their NADA (21 CFR 514.1(b)(8)). Participation in this pilot program will not exempt participants from compliance with applicable requirements for the submission of evidence to establish safety and effectiveness.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to 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.

Dated: December 4, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–29419 Filed 12–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2009–0001]

Agency Information Collection Activities: Proposed Collection; Comment Request, 1660–0105; Community Preparedness and Participation Survey

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0105; 088–0–2, Household Preparedness Telephone Survey.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the