been set forth within the draft guidances entitled, ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24), ''Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms'' (VICH GL30) and ''Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports'' (VICH GL42), this draft guidance defines recommended electronic standards for transfer of data.

In order to allow for electronic exchange of this information between stakeholders, further specification of the field descriptors and their relationships, including agreement on format of the electronic message is essential.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB Control No. 0910–0284.

IV. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: September 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23605 Filed 9–14–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel, Review Conference Grant Application (R13).

Date: October 12, 2011.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications,

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mary Kelly, Scientific Review Officer, Scientific Review Branch, National Inst of Dental & Craniofacial Research, NIH 6701 Democracy Blvd, room 672, MSC 4878, Bethesda, MD 20892–4878, 301–594–4809, *mary_kelly@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 9, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–23650 Filed 9–14–11; 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 Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: October 3, 2011.

Time: 8:30 a.m. to 4 p.m.

Agenda: Discussion of Programs and Issues.

Place: National Institutes of Health, 6701 Rockledge Drive, Conference Rooms 9100/9104, Bethesda, MD 20892.

Contact Person: W. Keith Hoots, MD, Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 9030, Bethesda, MD 20892, 301–435–0080, *hootswk@nhlbi.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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 9, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–23654 Filed 9–14–11; 8:45 am]

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