additional tests recommended based on specific toxicological concerns associated with the structure, class, mode of action, etc., of the drug; and (3) special tests that might be useful in the evaluation of the relevance or the interpretation of data obtained in the basic or additional tests.

III. Significance of Guidance

This document, 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.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall,'' and ''will'' in the original VICH documents have been substituted with ''should.''

This guidance document represents the agency's current thinking to establish the safety of veterinary drug residues in human food in a variety of toxicological evaluations. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

V. Electronic Access

Copies of the guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing'' (VICH GL33) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: May 13, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–11254 Filed 5–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; NIH Customer/Partner Satisfaction Survey of Modification in Procedures for Applications and Awards of Research Project Grants

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. The proposed information collection was previously published in the **Federal Register** on May 23, 2002, page 36202. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, any information that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: NIH Customer/Partner Satisfaction Survey of Modification in procedures for Applications and Awards of Research Project Grants.

Type of Information Collection Request: New request.

Need and Use of Information Collection: The information collected in these surveys will be used by the Office of Extramural Research to evaluate the re-engineering initiative, including the Modular Grant Application Process and initiatives under the NIH Roadmap Initiative, intended to facilitate application and award of Federal assistance programs administered by the NIH Modular Applicant/Grant process has been in effect for two years. At the outset of its implementation, the community was advised that the process would reduce administrative burden by focusing the efforts of investigators, institutional officials, and National Institutes of Health (NIH) staff on the science of the application. The NIH now believes it is an appropriate time to determine if these objectives have been met.

Frequency of Response: On occasion.

Affected Public: Institutional Officials, Principal Investigators (PI's), Peer Reviewers, Program and Grants Management Staff, Institute Budget Officers.

The annual reporting burden is as follows:

Estimated Number of Respondents: 1,000.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: .334.

Estimated Total Burden Hours Requested: 334. Each year we will repeat the same survey with different respondents. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Anthony Demsey, OD, NIH, Building 1, Room 152, Bethesda, MD 20892–7974, or call non-toll-free number (301) 496–0232, or e-mail your request, including your address to: *Demseya@od.nih.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 30-days of the date of this publication.

Charles Mackay,

Chief, Project Clearance Branch, OPERA, OER, National Institutes of Health.

[FR Doc. 04–11358 Filed 5–18–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council for Complementary and Alternative Medicine.

The meeting will be open to the public as indicated below, 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.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: June 4, 2004.

Closed: 9:30 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Open: 1 p.m. to adjournment.

Agenda: The agenda includes opening remarks by the Director, NCCAM, report from the Cancer Working Group, overview of National Center for Health Statistics, summary of CDC Advanced Date Report: CAM Module, update on co-sponsorship of Program Announcements, and other business of the Council.

Place: Natcher Conference Center, 9000 Rockville Pike, 45 Center Drive, Conference Rooms E1 and E2, Bethesda, MD 20892.

Contact Person: Jane F. Kinsel, PhD, M.B.A., Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 496–6701.

The public comments session is scheduled from 3:40 p.m.–4 p.m. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations are requested to notify Dr. Jane Kinsel, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301–496–6701, fax: 301–480–0087. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later that 5 p.m. on May 25, 2004. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Jane Kinsel at the address listed above up to 10 calendar days (June 14, 2004) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Jane Kinsel, Executive Secretary, NACCAM, National Institues of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301–496–6701, fax: 301–480–0087, or via e-mail at *naccames@mail.nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Dated: May 12, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–11357 Filed 5–18–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 of 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 04–52, Review of R13s.

Date: June 7, 2004.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: H. George Hausch, PhD, Acting Director, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2904, *george hauschnih.gov.*

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 04–53, Review applications in response to RFA DE04–009, Exploratory & Develop Grants in Clinical Research.

Date: June 22, 2004.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Key Bridge Marriott Hotel, 1401 Lee Highway, Arlington, VA 22209.

Contact Person: Rebecca Roper, MS, MPH, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, National Inst of Dental and Craniofacial Research, National Institutes of Health, 45 Center Dr., Rm. 4AN32E, Bethesda, MD 20892, (301) 451–5096.

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

Dated: May 12, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–11354 Filed 5–18–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Recombinant DNA 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 inform the contact person listed below in advance of the meeting.

Name of Committee: NIH Recombinant DNA Advisory Committee (RAC).

Dates: June 8–9, 2004.