

memo #K91-1)" and for the document entitled "FDA Policy for The Regulation of Computer Products; Draft." These two guidance documents were listed in error as both current and withdrawn. These guidances have been withdrawn by the agency.

2. On page 894, in the list, under the heading "Guidance Documents Issued by CFSAN," the entire entry is removed for the document entitled "Investigations Operations Manual" and for the document entitled "Regulatory Procedures Manual." These two guidance documents were listed as being issued by the Center for Food Safety and Applied Nutrition in error. They can be found in the list of guidance documents issued by the Office of Regulatory Affairs.

Dated: February 3, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-2642 Filed 2-10-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0474]

#### **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (VICH GL-36); Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#159) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL36). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Louis T. Mulligan, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6984, e-mail: [lmulliga@cvm.fda.gov](mailto:lmulliga@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

#### **I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United

States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/ New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

#### **II. Guidance on Microbiological Acceptable Daily Intake**

In the **Federal Register** of November 13, 2003 (68 FR 64354), FDA published the notice of availability of the VICH draft guidance, giving interested persons until December 15, 2003, to submit comments. After consideration of comments received, the draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on May 3, 2004, the VICH Steering Committee endorsed the final guidance for industry (VICH GL-36). This VICH guidance provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora. The objectives of this guidance are: (1) To outline the recommended steps in determining the need for establishing a microbiological acceptable daily intake (ADI); (2) to recommend test systems and methods for determining no-observable adverse effect concentrations (NOAECs) and no-observable adverse effect levels (NOAELs) for the endpoints of health concern; and (3) to recommend a procedure to derive a microbiological ADI. It is recognized that different tests may be useful. The experience gained with the recommended tests may result in future modifications to this guidance and its recommendations. Information collection is covered under Office of

Management and Budget (OMB) control number 0910-0032.

### 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, mandatory words such as "must," "shall," and "will" in the original VICH document have been substituted with "should." Similarly, words such as "require" or "requirement" have been replaced by "recommend" or "recommendation" as appropriate to the context.

The VICH guidance (#159) is consistent with the agency's current thinking on the subject matter. 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 Establish a Microbiological ADI" (VICH GL-36) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: February 3, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-2643 Filed 2-10-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 Board of Scientific Counselors, National Cancer Institute.

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 as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Cancer Institute, Subcommittee 1—Clinical Sciences and Epidemiology.

*Date:* March 7-8, 2005.

*Open:* March 7, 2005, 8:30 a.m. to 10:45 a.m.

*Agenda:* Joint Session of NCI, Board of Scientific Advisors and BSC Subcommittees.

*Place:* National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

*Closed:* March 7, 2005, 10:45 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

*Closed:* March 8, 2005, 8 a.m. to 12:45 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* Holiday Inn Bethesda, Versailles IV, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Brian E. Wojcik, PhD, Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, 6116 Executive Boulevard, Room 2114, Bethesda, MD 20892, (301) 496-7628, [wojcikb@mail.nih.gov](mailto:wojcikb@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2005.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-2645 Filed 2-10-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed 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 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/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 Cancer Institute Special Emphasis Panel; CA05-018: CISNET.

*Date:* March 4, 2005.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Bethesda North, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch,