McQuillan, Division of Health and Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 4204, Hyattsville, MD 20782, *Phone:* 301–458–4371; *Fax:* 301–458–4028, *e-mail: gmm2@cdc.gov*.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–17267 Filed 7–20–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0309]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL45); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#198) entitled ''Draft Guidance for Industry on Bracketing and Matrixing Designs For Stability Testing of New Veterinary Drug Substances and Medicinal Products,'' VICH GL45. This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance is an annex to a VICH guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision),'' VICH GL3(R), that published in the **Federal Register** of November 23, 2007 (72 FR 65751). This draft VICH guidance document is intended to provide guidance on the application of reduced designs (i.e., bracketing and matrixing) for stability studies conducted in accordance with the principles outlined in VICH GL3(R).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance submit written or electronic comments on the draft guidance by August 20, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–8268, *e-mail: dennis.bensley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (#198) entitled ''Draft Guidance for Industry on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products,'' VICH GL45. 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. Draft Guidance on Bracketing and Matrixing Designs for Stability Testing

The VICH Steering Committee held a meeting on February 11, 2008, and agreed that the draft guidance document entitled ''Draft Guidance for Industry on Bracketing and Matrixing Designs for Stability Testing of New Veterinary Drug Substances and Medicinal Products,'' VICH GL45 should be made available for public comment. This draft VICH guidance document provides guidance on bracketing and matrixing study designs. Specific principles are defined in this guidance for situations in which bracketing or matrixing can be applied. This document is intended to address recommendations on the application of bracketing and matrixing to stability studies conducted in accordance with principles outlined in the VICH GL3(R), ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision).'' FDA and the VICH Expert Quality 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 sections 1–2 of this guidance have been approved under OMB Control No. 0910–0032.

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. 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.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: July 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17251 Filed 7–20–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 13, 2009, from 8 a.m. to 5 p.m. and August 14, 2009, from 8 a.m. to 2 p.m.

Location: National Transportation Safety Board (NTSB) Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594 (at Metro's L'Enfant Plaza station; parking is limited and public transportation is recommended.)

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Policy, Planning and Preparedness, Office of Planning, Food and Drug Administration, 5600 Fishers Lane, rm. 14–90, Rockville, MD 20857, 301–827–2895, FAX: 301–827–4050, e-mail: *RCAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On August 13 and 14, 2009, the Committee will discuss FDA's external research on, and internal assessment of, communications about food safety problems. This discussion will address research on consumer knowledge of food recalls and plans for how to monitor communication effectiveness during the course of a recall. The purpose of the discussion is to advise FDA on developing more effective communication strategies. Also on August 14, 2009, the RCAC will be briefed on the work of the FDA Transparency Task Force.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 7, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on August 13th and 10:30 to 11:30 a.m. on August 14th. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 6, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 7, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lee L. Zwanziger at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Dated: July 10, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–17222 Filed 7–20–09; 8:45 am]

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