DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2002–D–0268 (formerly Docket No. 2002D–0005)]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH GL30); Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI #143) entitled ''Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The purpose of this VICH guidance document is to describe the controlled lists of terms critical to completing the controlled data fields as identified in the guidance entitled ''Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine'' (GFI #188), available on the FDA Web site at: *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm.*

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* 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.

FOR FURTHER INFORMATION CONTACT: Margarita Brown, Center for Veterinary Medicine (HFV–240), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9048, *CVMAESupport@fda.hhs.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 Registration 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, 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.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the governments of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. 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 Controlled Lists of Terms

In the **Federal Register** of June 21, 2007 (72 FR 34261), FDA published a notice of availability for a revised draft guidance entitled ''Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30). Interested persons were given until July 23, 2007, to comment on the revised draft guidance. FDA received a few comments on the draft revised guidance, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this document finalizes the draft revised guidance dated June 20, 2007. The final guidance is a product of the Pharmacovigilance Expert Working Group of the VICH.

This VICH guidance document describes the controlled lists of terms critical to completing the controlled data fields as indicated in FDA's ''Guidance for Industry, Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine'' (GFI #188). To assess the safety and efficacy of veterinary medicinal products, the use of controlled lists of terms is important in order to assure consistency, as well as to provide for comparison between products and across product classes. This guidance also includes an appropriate maintenance procedure to keep the lists of terms up to date.

III. Significance of Guidance

This 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 guidance represents 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.

IV. Paperwork Reduction Act of 1995

This 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 numbers 0910–0284 and 0910–0645.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

VI. Electronic Access

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

Dated: October 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Science Advisory Board to the National Center for Toxicological Research 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

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 November 6, 2014, from 8:15 a.m. to 4:15 p.m. and on November 7, 2014, from 8 a.m. to 2 p.m.

Location: NCTR SAB, 3900 NCTR Rd., Conference Room B–12, Jefferson, AR 72079.

Contact Person: Donna Mendrick, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 6, 2014, the NCTR Director will welcome the participants and provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the Division of Microbiology Subcommittee and the Subcommittee Site Visit Report. Following the public session, the SAB will hear an update from each of NCTR's research Divisions, the Office of Science Coordination, followed by an update on NCTR's Global Interactions.

On November 7, 2014, the Office of the Chief Scientist will update the SAB on their research needs, and discuss opportunities for collaboration to help address these needs, followed by a report from the National Toxicology Program of the National Institutes of Environmental Health Sciences on current and future collaboration.

The Center for Biological Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, the Center for Tobacco Products, the Office of Regulatory Affairs, and the Center for Food Safety and Applied Nutrition will each briefly discuss their Center-specific research strategic needs.

Following an open discussion of all the information presented, the open session of the meeting will close so that SAB members can discuss personnel issues at NCTR.

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.* Scroll down to the appropriate advisory committee meeting 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 October 30, 2014. Oral presentations from the public will be scheduled between approximately 12 noon to 1 p.m. on November 6, 2014. Those individuals interested in making 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 October 22, 2014. 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 October 23, 2014.

Closed Committee Deliberations: On November 7, 2014, from 12 noon to 2 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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 Donna