/www.cfsan.fda.gov/dms/guidance/html or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 18, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2753 Filed 2–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0005]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30); Request for Comments; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#143) entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30). This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance addresses the process for developing a controlled list of terms in order to assure that terms are used consistently in adverse event reports, and to allow comparison between products and across product classes. This draft guidance is limited to developing a controlled list of terms describing veterinary medicinal products (VMPs), animals, clinical signs, and associated body systems and organs for reporting an adverse event associated with the use of a VMP.

DATES: Submit written or electronic comments on the draft guidance by March 8, 2002, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William C. Keller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6642, e-mail: *wkeller@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 VMPs. 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Controlled List of Terms

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30) should be made available for public comment.

A controlled list of terminology is essential to ensure consistent evaluation of adverse event reports and electronic submission of these reports on a national and international basis. This draft guidance provides recommendations for adopting and managing a controlled list of terminology used to describe veterinary medicinal products, animals, clinical signs, and associated body systems and organs in adverse event reports. Components of the recommendations are directed at regulatory authorities and should be implemented by these agencies as well as by regulated industry.

The VICH closely followed the progress of its human counterpart, ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), in implementing a standardized controlled terminology and believes that with appropriate modification the same approach will be viable for the VICH. Thus, the approach outlined in the guidance document is based on identification of similar technical terminology needs and an approach for meeting those needs used by ICH to develop MedDRA (Medical Dictionary for Drug Regulatory Activities), the international terminology for reports to regulatory authorities describing human adverse events.

These recommendations include that government and industry partner together in development,

implementation, and ongoing maintenance necessary to keep an adverse event terminology updated and distributed to users. It recommends adopting VEDDRA (Veterinary Medicinal Dictionary for Drug Regulatory Authorities) as the controlled list of terminology for adverse event reports. Specific recommendations include an independent joint industry and government oversight board as well as a funding model that will allow use by all regulatory agencies and even the smallest companies in industry. The two background paragraphs provide insight into the deliberations, recommendations, and comments from the Expert Working Group charged by VICH to the VICH Steering Committee on this issue.

FDA and the VICH will consider comments about the draft guidance document. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as a final guidance.

III. Significance of Guidance

This draft 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.'' Similarly, words such as ''require'' or ''requirement'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

The draft guidance represents the agency's current thinking on developing a controlled list of terms for reporting an adverse event associated with the use of an approved new animal drug. 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

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document. Written or electronic comments should be submitted to the Dockets Management Branch (address above). Submit written or electronic comments by March 8, 2002, to ensure adequate consideration in preparation of the final guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select ''02D–0005 Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30)'' and follow the directions.

Copies of the draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*. The draft guidance is also available at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Children's Hospitals Graduate Medical Education Payment Program (CHGME) (OMB No. 0915–0247): Revision

The CHGME Payment Program was enacted by Public Law 106–129 to provide Federal support for graduate medical education (GME) to ''freestanding'' children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

Technical assistance workshops and consultation with applicant hospitals resulted in an opportunity for hospital representatives to raise issues and provide suggestions resulting in proposed revisions in the CHGME application forms and instructions.

Eligible children's teaching hospitals submit relevant data such as weighted and unweighted full-time equivalent (FTE) resident counts, inpatient discharges and case mix index information by which direct and indirect payments are made to the participating hospitals. Data are submitted by children's hospitals in an annual CHGME application in order to receive funding. Through a reconciliation process, participating hospitals are required to correct and furnish final FTE resident count numbers reflecting changes in counts reported in the annual application form. The reconciliation process begins with fiscal year (FY)2002 and occurs before the end of the fiscal year.

The estimated burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
HRSA 99–1	60	1	24	1,440
HRSA 99–1 (Reconciliation)	60	1	8	480