DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0005 (formerly 02D–0005)]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30); Request for Comments; Availability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; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a revised draft guidance for industry (#143) entitled ''Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30). This revised draft guidance, which updates a draft guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 6, 2002 (the 2002 guidance), has been developed for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 VICH guidance document describes the specific data elements to be used for the submission and exchange of spontaneous adverse event reports (AERs) between marketing authorization holders (MAHs) and regulatory authorities (RAs).

DATES: Submit written or electronic comments on the revised draft guidance by July 23, 2007, to ensure their adequate consideration in preparation of the final document.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ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

Submit written comments on the revised draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Comments should be identified with the full title of the revised draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Post, Center for Veterinary Medicine, (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9062, e-mail: *lynn.post@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 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. VICH is a parallel initiative for veterinary medicinal products. 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.

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. Revised Draft Guidance on Controlled Lists of Terms

In June 2006, the VICH steering committee agreed that a revised draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30), should be made available for public comment. The draft guidance is a revision of a guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 6, 2002 (67 FR 5605). This revised draft guidance clarifies the 2002 guidance, adding information, and providing consistency with more recently published VICH guidances.

This draft VICH guidance document describes the specific data elements to be used for the submission and exchange of spontaneous AERs between MAHs and RAs. Although the revised draft guidance includes, as Appendix A, a proposed list of terms, FDA prefers the list of terms maintained by the National Cancer Institute's *NCI Thesaurus* and would like to refer to the *NCI Thesaurus* in the final guidance. FDA invites comments regarding which list of terms (Appendix A or the *NCI Thesaurus*) would be the best choice to further the goals set forth in this revised draft guidance. Since Appendix A was included in the revised draft guidance for discussion purposes only, it has not yet been formally considered within the VICH process. FDA expects that the list of terms included in Appendix A will be discussed by a task force chosen from the members of the VICH pharmacovigilance expert working group.

III. Paperwork Reduction Act of 1995

This revised 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 section III of the revised draft guidance have been

approved under OMB Control No. 0910–0284.

IV. 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.'' 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 VICH guidance (#143) is consistent with the agency's current thinking on this topic. 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.

V. 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 to the Division of Dockets Management (see **ADDRESSES**). 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. A copy of the draft guidance and 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

Electronic comments may also be submitted electronically on the Web site *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 2002D–0005 entitled ''Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30), and follow the directions.

Copies of the draft guidance document entitled ''Revised Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30) may be obtained on the Internet from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: June 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11996 Filed 6–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Geographic Composition of the Contract Health Service Delivery Areas (CHSDA) and Service Delivery Areas (SDA) of the Indian Health Service

AGENCY: Indian Health Service (IHS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The purpose of this notice is to revise and update the list of Contract Health Service Delivery Areas (CHSDA) as defined in 42 CFR part 136, Subparts A–C and Service Delivery Areas (SDA) as established by the Director, Indian Health Service (IHS) administratively to effectuate the intent of Congress. This list replaces and supplements the FR notice dated January 10, 1984 (49 FR 1291) establishing CHSDAs and FR notice dated August 25, 1988 (53 FR 32460) establishing Health Service Delivery Areas (HSDAs).

EFFECTIVE DATE: June 21, 2007.

FOR FURTHER INFORMATION CONTACT: Hankie Ortiz, Director, Division of Regulatory Affairs, 801 Thompson Avenue, Rockville, Maryland 20852, telephone: (301) 443–1116. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On September 16, 1987, the Department of Health and Human Services (HHS) published new final regulations governing eligibility for the Indian Health Service (IHS) services at 52 FR 35044. In the Fiscal Year 1988 Appropriations Act, Section 315, Public Law 100–202, Congress delayed implementation of the new regulations for one year and imposed a moratorium on the use of appropriated funds for implementation of the new regulations in subsequent fiscal years. In Section 719(a) ofthe Indian Health Care Amendments of 1988, Public Law 100–713, Congress directed that during the moratorium that IHS should provide services pursuant to the criteria for eligibility for such services that were in effect on September 15, 1987. Because the moratorium continues in effect, for the convenience of the public, the HHS republished the eligibility regulations in effect on September 15, 1987. These regulations appear re-designated in the Code of Federal Regulations at Title 42, Part 136, Subparts A–C.

The regulations of September 16, 1987, that are under moratorium, provided that the IHS would designate and publish as a notice in the **Federal Register** specific geographic areas within the United States including Indian reservations and areas surrounding those reservations as Health Service Delivery Areas (HSDAs). The HSDAs are the geographic areas within which *direct* and *contract health services* may be made available by the IHS to eligible individuals who reside within the areas. In anticipation of the Congressional moratorium being lifted, the IHS on August 25, 1988 published at 53 FR 32460 a list of HSDAs. If the Congressional moratorium were lifted, the list was to be effective September 16, 1988 or such later date as may be estblished by Congress. Because the Congressional moratorium continues in effect, the HSDA list never became effective.

As noted above, the IHS currently provides services under regulations in effect on September 15, 1987 and republished at 42 CFR Part 136, Subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA) as the geographic area within which contract health services will be made available by the IHS to members of an identified Indian community who reside in the area. It should be clearly understood that residence within a CHSDA or Service Delivery Area (SDA) by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to contract health services but only potential eligibility for services. Services needed but not available at an IHS/tribal facility are provided under the Contract Health Services (CHS) program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The purpose of this FR notice is to revise and update the list of CHSDAs and SDAs as last published in 1984. The current eligibility regulations at 42 CFR 136.22(a)(1)–(5) defines certain CHSDAs by designating some States as CHSDAs and certain counties within a state as a CHSDA. In addition, Section 136.22(a)(6) provides that:

With respect to all other reservations (*i.e.*, other than those not specifically listed in 42 CFR 136.22(a)(1)–(5)) within the scope of the Indian health program, the CHSDA shall consist of a county which includes all or part of a reservation, and any county or counties