## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005D–0199]**

### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Final Guidance for Industry on ''Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances;'' Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#176) entitled ''Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances'' (VICH GL–39). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to assist to the extent possible, in the establishment of a single set of recommended global specifications for new veterinary drug substances and medicinal products. It provides guidance through recommendations on the setting and justification of acceptance criteria and the selection of test procedures for new veterinary drug substances of synthetic chemical origin, and new medicinal products produced from them, which have not been registered previously in the United States, the European Union, or Japan.

**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:** Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@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 Harmonization 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 Chemical Substance

In the **Federal Register** of May 27, 2005 (70 FR 30761), FDA published the notice of availability of the VICH draft guidance, giving interested persons until June 27, 2005, to submit comments. No comments were received. At a meeting held on November 2005, the VICH Steering Committee endorsed the final guidance for industry, (VICH GL–39). This VICH guidance addresses specifications, i.e., those tests, procedures, and acceptance criteria which play a major role in assuring the quality of the new veterinary drug substance and medicinal product at release and during shelf life.

#### III. Paperwork Reduction Act of 1995

This guidance document 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 21 CFR 514.1 have been approved under OMB Control No. 0910–0032 (expiration date 12/31/2007).

#### IV. 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.'' 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 VICH guidance (#176) is consistent with the agency's current thinking on the new veterinary drug substances and medicinal products. 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**

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

**VI. Electronic Access**

Copies of the guidance document entitled ''Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances (VICH GL–39) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: June 6, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### Privacy Act System of Records—Medical Staff Credentials and Privileges Records

**AGENCY:** Indian Health Service (IHS), HHS.

**ACTION:** Amendment of one altered Privacy Act system of records.

**SUMMARY:** Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), the IHS has amended and is publishing the proposed alteration of a system of records, System No. 09–17–0003, ''Medical Staff Credentials and Privileges Records.'' The amended and altered system of records makes only one administrative revision as necessary.

**DATES:** The amended and altered system, which incorporates no public comments received following the initial publication, shall become effective June 15, 2006.

**FOR FURTHER INFORMATION:** Contact Stephen Heath, MD, IHS Risk Management Consultant, Albuquerque Indian Health Center, 801 Vassar Drive, NE., Albuquerque, New Mexico 87106 or via the Internet at *Stephen.Heath@ihs.qov.*

**SUPPLEMENTARY INFORMATION:** As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), this document sets forth the amendment of the proposed alteration of a system of records maintained by the IHS, following the initial publication in the **Federal Register** at 71 FR 16320 on March 31, 2006. The purpose of altering System No. 09–17–0003, ''Medical Staff Credentials and Privileges Records,'' is to enable IHS to reflect current program changes, technology changes, statutory and implementation changes. During the comment period, IHS received no comments from the public. The revision or modification of the IHS addresses in Appendix 1 is necessary to this system of records as administrative changes. In Appendix 1, the address for the Elko Service Unit, Newe Medical Clinic under the Phoenix Area IHS was removed as this facility is no longer under the control of the IHS.

This Notice meets the requirement to notify the public that the IHS is amending the proposed changes in the IHS system of records by incorporating the administratie change following the initial publication at 71 FR 16320, March 31, 2006. With this notification, this system of records is effective June 15, 2006.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**09–17–0003**

**SYSTEM NAME:**

Indian Health Service Medical Staff Credentials and Privileges Records, HHS/IHS/OCPS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Each Indian Health Service (IHS) Area Office and each IHS Service Unit (Appendix 1). Records may also be located at hospitals and offices of health care providers who are under contract with IHS. A current list of contractor sites is available by writing to the appropriate System Manager (Area or Service Unit Director) at the address shown in Appendix I.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Prospective, current and former IHS medical staff members. The term IHS medical staff includes fully licensed individuals permitted by law to provide patient care services independently and without concurrent professional direction or supervision, within the scope of his/her license and in accordance with individually granted clinical privileges. The IHS medical staff includes physicians (M.D. and D.O.) and dentists and may include other health care practitioners such as psychologists, optometrists, podiatrists, audiologists, and, in some states, certified nurse midwives. Types of assignment categories of current and former IHS medical staff members include the following:

Provisional—Those new members of the medical staff who are serving a required initial probationary period, as specified in the local medical staff bylaws. During this time, their qualifications for membership on the active or courtesy IHS medical staff are assessed.

Active—Those members who are Federal employees and/or spend at least fifty percent of their professional time providing patient care related services in the facility.

Temporary—Those members who provide services on a short-term basis or have applied for active medical staff membership and are awaiting a full credential review.

Courtesy or Associate—Those members who generally provide services on a periodic or episodic basis (*e.g.,* consultants for specialty clinics).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Contains name, Social Security number, IHS medical staff membership and privileges applications and associated forms, employment data, liability insurance coverage, credentialing history of licensed health professionals, personal, educational, and demographic background information, professional performance information consisting of continuing education, performance awards, and adverse or disciplinary actions, and evaluations and approvals completed by IHS medical staff reviewers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Federal Records Act (44 U.S.C. 2901), Privacy Act of 1974, as amended (5 U.S.C. 552a), Indian Self Determination and Education and Assistance Act (25 U.S.C. 450), Snyder Act (25 U.S.C. 13), Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), Indian Health