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 Draft Guidance on Pharmacovigilance of Veterinary Medicinal Products

In November 2005, the VICH Steering Committee agreed that a draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports'' (VICH GL42) should be made available for public comment. Elements of this draft guidance were previously published in 2000 as part of a draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24). The objective of draft guidance VICH GL42 is to standardize the data for submission of adverse events relating to VMPs. A consistent set of data will contribute to a harmonized approach for the detection and investigation of adverse effects of marketed VMPs and thus help to increase public and animal health. The draft guidance is the product of the Pharmacovigilance Expert Working Group of the VICH. Comments on this draft will be considered by FDA and the Pharmacovigilance Expert Working Group.

## III. Paperwork Reduction Act of 1995

This draft guidance document refers to previously approved collections of information found in FDA regulations. The collections of information have been approved under OMB control number 0910–0284 (expiration date June 30, 2006). Prior to the finalization and implementation of this guidance, FDA intends to add the new collection of information to the related form for submitting adverse event reports entitled ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report'' (Form FDA 1932), and FDA will publish a separate notice in the **Federal Register** requesting comment on any new collection of information in the updated form.

## IV. Significance of Guidance

Under 21 CFR 10.115(i)(3), when issuing draft guidance documents that are the product of international negotiations, FDA need not apply 21 CFR 10.115(i)(2), which states that guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''required,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement. However, any final guidance document issued according to 21 CFR 10.115(i) must contain the elements in 21 CFR 10.115(i)(2). In this draft guidance, any language that is mandatory under U.S. laws and/or regulations is followed by a citation to the appropriate statutory or regulatory provision. In accordance with 21 CFR 10.115(i)(3), any mandatory language in this draft guidance that does not describe a statutory or regulatory requirement will be revised in the final guidance document to comply with 21 CFR 10.115(i)(2).

The draft VICH guidance 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 are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## VI. Electronic Access

Comments may be submitted electronically on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 2006D–0170, entitled draft guidance for industry on ''Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports'' (VICH GL42), and follow the directions.

Copies of the draft guidance document entitled ''Draft Guidance for Industry on ''Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports'' (VICH GL42), may be obtained on the Internet from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: April 26, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–6601 Filed 5–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2000D–1632 (formerly 00D–1632)]**

### International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products; Draft Revised Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports; 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 of draft revised guidance for industry (#117) entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' VICH GL24. This draft revised guidance, which updates a draft guidance on the

same topic for which a notice of availability was published in the **Federal Register** of December 18, 2000 (the 2000 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 revised guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMPs) submitted to the European Union, Japan, and the United States.

**DATES:** Submit written comments on the draft revised guidance by June 1, 2006, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft revised 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 draft revised guidance document.

Submit written comments on the draft revised 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 draft revised 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 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. 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. Draft Guidance on Adverse Event Reports

In November 2005, the VICH steering committee held a meeting and agreed that the draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' VICH GL24, should be revised and made available for a second public comment period. This draft revised guidance updates the draft guidance on the same topic for which a notice of availability was published in the **Federal Register** of December 18, 2000 (65 FR 79111). The draft revised guidance clarifies the 2000 draft guidance, adds information, and provides consistency with more recently published VICH guidances. The draft revised guidance is the product of the Pharmacovigilance Expert Working Group of VICH. Comments on this draft will be considered by FDA and the Pharmacovigilance Expert Working Group.

The draft revised guidance describes the harmonized and common systems, common definitions, and standardized terminology within pharmacovigilance. Harmonization of those elements between the VICH regions facilitates the reporting responsibilities for the marketing authorities or drug sponsors, many with worldwide activities. More specifically, the draft revised guidance presents the terms and definitions intended to harmonize other previously used terms referring to similar pharmacovigilance concepts. This draft revised guidance describes a system for the management of adverse drug event reports following the use of marketed veterinary medicinal products.

This draft revised guidance includes revised text on the definition of a veterinary medicinal product, definition of international birth date, and third country reporting. Data elements for the submission of AERs were removed from this draft revised guidance, but are addressed in a separate VICH draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports'' VICH GL42. The notice of availability for VICH GL42 is published elsewhere in this issue of the **Federal Register**.

## III. Paperwork Reduction Act of 1995

This draft revised 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 21 CFR 514.80 have been approved under OMB control number 0910–0284 (expiration date 06/30/2006).

## IV. Significance of Guidance

Under part 10 (21 CFR part 10), specifically § 10.115(i)(3), when issuing draft guidance documents that are the product of international negotiations, FDA need not apply § 10.115(i)(2), which states that guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''required,'' or ''requirement,'' unless FDA is using these words to describe a statutory or

regulatory requirement. However, any final guidance document issued according to § 10.115(i) must contain the elements in § 10.115(i)(2). In this draft revised guidance, any language that is mandatory under U.S. laws and/or regulations is followed by a citation to the appropriate statutory or regulatory provision. In accordance with § 10.115(i)(3), any mandatory language in this draft revised guidance that does not describe a statutory or regulatory requirement will be revised in the final guidance document to comply with § 10.115(i)(2).

The draft revised VICH guidance represents the agency's current thinking on the management of AERs of approved new animal drugs. This draft revised 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 revised guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft revised guidance 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. A copy of the draft revised 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 Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 2000D–1632, entitled ''Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' VICH GL24 and follow the directions.

Copies of the draft revised guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' VICH GL24 may be obtained on the Internet from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: April 26, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–6602 Filed 5–1–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Environmental Health Sciences; Submission for OMB Review; Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

*Summary:* Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 23, 2006 on pages 9358–9359 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*5 CFR 1320.5: Reporting and Recordkeeping Requirements: Final Rule:* Respondents to this collection of information are not required to respond unless the data collection instruments display a currently valid OMB control number.

*Proposed Collection Title:* The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer.

*Type of Information Collection Request:* Revision of OMB No. 0925–0522 and expiration date July 31, 2006.

*Need and Use of Information Collection:* The purpose of the Sister Study is to study genetic and environmental risk factors for the development of breast cancer in a cohort of sisters of women who have had breast cancer. In the United States, there were approximately 210,000 new cases in 2003, accounting for 30% of all new cancer cases among women. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect about 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters will be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. We are enrolling a cohort of 50,000 women who have not had breast cancer. Initial recruitment of the first 2000 women took place from August 2003–September 2004 before beginning nationwide recruitment in October 2004. The data collected in the initial phase allowed us to evaluate subject recruitment and data collection procedures, and helped us better target our recruitment efforts. We estimate that a cohort of 50,000 sisters aged 35–74 years would provide about 1500 breast cancer cases over five years (approximately 300 new cases per year once the cohort is fully enrolled).

*Frequency of Response:* Burden calculations include eligibility screening for 22,750 more women, and completion of enrollment activities for 25,000 more women (difference due to expected 2,250 women, and completion of enrollment activities for 25,000 more women (difference due to expected 2,250 women whose time lag between initial screening and fully completing enrollment baseline activities is expected to cross OMB expiration/revision date) to reach 50,000. These women will complete one initial 15-minute screening (either on the telephone OR on the Internet), two 1-hour telephone interviews, 4 mailed self-administered questionnaires (90 minutes total), and will collect biological and household specimens. Also in the next 3 years, all 50,000 sisters will complete one annual update (10 minutes) and one biennial follow-up questionnaire (60 minutes); in addition 25,000 will complete a second annual update. Women diagnosed with breast cancer or other health outcomes of interest (~1800 allowing for 300 bc/year over our first 6 years, plus 1800 other outcomes) will be asked to provide