''Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act.'' This guidance is part of FDA's implementation of FALCPA (Public Law 108–282). If a food is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains a major food allergen, the food must comply with section 403(w) of the act (21 U.S.C. 343(w)). Section 403(w)(1) requires that the food's label declare the name of the food source from which the major food allergen is derived in a manner specified by that section. This source declaration requirement is extended by section 403(w)(4) to any incidental additive that is, or that bears or contains, a major food allergen, notwithstanding the regulatory exemption for incidental additives in 21 CFR 101.100(a)(3). The requirements of section 403(w) of the act apply to foods labeled on or after January 1, 2006.

II. Discussion

The purpose of the guidance document is to provide guidance to the industry on the labeling, under section 403(w) of the act, of certain uses of lecithin derived from soy in packaged foods. In particular, as discussed in the guidance, FDA intends to consider the exercise of enforcement discretion for a packaged food labeled on or after January 1, 2006, in which lecithin derived from soy is used solely as a component of a release agent and the label for such food does not declare the presence of the lecithin consistent with the requirements of section 403(w). FDA intends to consider exercising such discretion when all of the factors discussed in the guidance are present.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, foods labeled on or after January 1, 2006, must comply with section 403(w) of the act's labeling requirements.

This guidance represents the agency's current thinking on the labeling of certain uses of lecithin derived from soy under section 403(w) of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments ortwo 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: April 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–6551 Filed 5–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0170]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports (VICH GL42); 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 draft guidance document for industry (#182) entitled ''Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports'' (VICH GL42). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The objective of this draft guidance document is to standardize the data for submission of adverse events relating to veterinary medicinal products.

DATES: Submit written or electronic comments on the draft guidance by June 1, 2006, 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, 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 guidance document.

Submit written comments on the 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 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 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. 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

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