## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99F–2535]**

### Ciba Specialty Chemicals Corp; Withdrawal of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 9B4680) proposing that the food additive regulations be amended to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer in olefin polymers, adhesives, pressure-sensitive adhesives, and ethylene-vinyl acetate copolymers intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Anna P. Shanklin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3093.

(After December 14, 2001, the Center for Food Safety and Applied Nutrition's address will be: 5100 Paint Branch Pkwy., College Park, MD 20740.)

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of August 6, 1999 (64 FR 42950), FDA announced that a food additive petition (FAP 9B4680) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer for olefin polymers complying with 21 CFR 177.1520, adhesives complying with 21 CFR 175.105, pressure-sensitive adhesives complying with 21 CFR 175.125, and ethylene-vinyl acetate copolymers complying with 21 CFR 177.1350 intended for use in contact with food. Ciba Specialty Chemicals Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: November 16, 2001.

**L. Robert Lake,**

*Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.*

[FR Doc. 01–30765 Filed 12–12–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01D–0501]**

### International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)'' (VICH GL29); Request for Comments;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 (#142) entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)'' (VICH GL29). 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 is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products submitted to the European Union, Japan, and the United States.

**DATES:** Submit written or electronic comments on the draft guidance by January 14, 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 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; 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.

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 Management of Periodic Summary Update Reports

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)'' should be made available for public comment.

This draft guidance should be read in conjunction with the VICH guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs)'' (VICH GL24) that defines the PSU.

The draft guidance describes harmonized submission timing and submission content for PSU reports. 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 guidance presents the terms and definitions intended to harmonize other previously used terms referring to similar pharmacovigilance concepts. The draft guidance describes the various components of information flow within the pharmacovigilance system. Finally, the draft guidance defines data elements that are sufficiently comprehensive to cover complex reports from most sources for the purpose of electronic transmission.

FDA and the VICH Safety Working Group 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. (Information collection is covered under OMB control number 0910– 0012.)

### III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to be consistent with 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, 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 management of PSUs of approved new animal drugs. 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 January 14, 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 electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select [Docket No. 01D–0501] ''Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)'' (VICH GL29) and follow the directions.

Copies of the draft guidance entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)'' (VICH GL29) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: December 3, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## Notice of Availability of a Draft Addendum to the Recovery Plan for the Multi-Island Plants for Public Review and Comment

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of document availability.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, announce the availability for public review of a draft Addendum to the Recovery Plan for the Multi-Island Plants. There are 10 plant taxa included in this plan, all of which are listed as endangered. All 10 taxa are endemic to the Maui Nui group of islands in the Hawaiian Islands.

**DATE:** We will consider comments on the draft addendum received by February 11, 2002.

**ADDRESSES:** Copies of the draft recovery plan addendum are available for inspection, by appointment, during normal business hours at the following locations: U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Box 50088, Honolulu, Hawaii 96850 (phone 808/541–3441) and Hawaii State Library 478 S. King Street, Honolulu, Hawaii 96813. Requests for copies of the draft addendum and written comments and materials regarding this plan should be addressed to Paul Henson, Field Supervisor, Ecological Services, at the above U.S. Fish and Wildlife Service Honolulu address.

**FOR FURTHER INFORMATION CONTACT:** Christa Russell, Plant Conservation Program Coordinator, at the above U.S. Fish and Wildlife Service Honolulu address.

**SUPPLEMENTARY INFORMATION:**

### Background

Restoring endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, we are working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for the conservation of the species, establish criteria for downlisting or delisting listed species, and estimate time and cost for implementing the recovery measures needed.