

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 Draft Guidance on Management of Periodic Summary Update Reports

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled "Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)" should be made available for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This draft guidance should be read in conjunction with the VICH guidance document entitled "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports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The draft guidance describes harmonized submission timing and submission content for PSU reports.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 More specifically, the draft guidance presents the terms and definitions intended to harmonize other previously used terms referring to similar pharmacovigilance concepts. The draft guidance describes the various components of information flow within the pharmacovigilance system. Finally, the draft guidance defines data elements that are sufficiently comprehensive to cover complex reports from most sources for the purpose of electronic transmission.

FDA and the VICH Safety Working Group will consider comments about the draft guidance document.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 Similarly, words such as "require" or "requirement" have been replaced by "recommendation" or "recommended" as appropriate to the context.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.

The Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act requires that public notice and an opportunity for public review and comment be provided during recovery plan development. We will consider all information presented during the public comment period prior to approval of each new or revised recovery plan. Substantive technical comments will result in changes to the plans. Substantive comments regarding recovery plan implementation may not necessarily result in changes to the recovery plans, but will be forwarded to appropriate Federal or other entities so that they can take these comments into account during the course of implementing recovery actions.

This draft Addendum to the Recovery Plan for the Multi-Island Plants covers 10 plant taxa, all of which are listed as endangered. These 10 Hawaiian plant taxa are endemic to the Maui Nui group of islands in the Hawaiian Islands. This group includes Maui, Molokai, Lanai, and Kahoolawe. Five taxa are endemic to the island of Maui, three taxa are endemic to the island of Lanai, one taxon is endemic to Molokai, and one taxon is endemic to the island of Kahoolawe. The listed plants are: *Clermontia samuellii* (oha wai), *Cyanea copelandii* ssp. *haleakalaensis* (haha), *Cyanea glabra* (haha), *Cyanea hamatiflora* ssp. *hamatiflora* (haha), *Dubautia plantaginea* ssp. *humilis* (naenae), *Hedyotis schlechtendahlia* var. *remyi* (kopa), *Kanaloa kahoolawensis* (kohe malama malama o Kanaloa), *Labordia tinifolia* var. *lanaiensis* (kamakahala), *Labordia triflora* (kamakahala), and *Melicope munroi* (alani).

The 10 taxa included in this draft addendum grow in a variety of vegetation communities (shrublands and forests), elevational zones (coastal to montane), and moisture regimes (dry to wet). These taxa and their habitats have been variously affected or are currently threatened by one or more of the following: competition for space, light, water, and nutrients by introduced vegetation; habitat degradation by wild, feral or domestic animals (pigs, goats, and deer); predation by animals (deer, pigs, goats, rats, slugs, and insects); substrate loss, and collecting for scientific or horticultural purposes. In addition, due to the small number of existing individuals and their very narrow distributions, these taxa and most of their populations are subject to an increased likelihood of extinction

and/or reduced reproductive vigor from naturally occurring events such as hurricanes.

The objective of the addendum to the recovery plan is to provide a framework for the recovery of these 10 taxa so that their protection by the Endangered Species Act (ESA) is no longer necessary. The interim objective is to stabilize all existing populations of these 10 plants. To be considered stable, each taxon must be managed to control threats (e.g., fenced) and be represented in an *ex situ* (such as a nursery or arboretum) collection. In addition, a minimum total of three populations of each taxon should be documented on islands where they now occur or occurred historically. Each of these populations must be naturally reproducing and increasing in number, with a minimum of 25 mature individuals per population for long-lived perennials (*Kanaloa kahoolawensis* and *Melicope munroi*) and a minimum of 50 mature individuals per population for short-lived perennials (*Clermontia samuellii*, *Cyanea copelandii* ssp. *haleakalaensis*, *Cyanea glabra*, *Cyanea hamatiflora* ssp. *hamatiflora*, *Dubautia plantaginea*, *Hedyotis schlechtendahlia* var. *remyi*, *Labordia tinifolia* var. *lanaiensis*, and *Labordia triflora*).

For downlisting, a total of five to seven populations of each taxon should be documented on islands where they now occur or occurred historically. In certain cases, however, a particular taxon may be eligible for downlisting even if all five to seven of the populations are on only one island, provided all of the other recovery criteria have been met and the populations in question are widely distributed and secure enough that one might reasonably conclude that the taxon is not in danger of extinction throughout all or a significant part of its range.

Each of these populations must be naturally reproducing, stable or increasing in number, and secure from threats, with a minimum of 100 mature individuals per population for long-lived perennials and a minimum of 300 mature individuals per population for short-lived perennials. Each population should persist at this level for a minimum of 5 consecutive years before downlisting is considered. A total of 8 to 10 populations of each taxon should be documented on islands where they now occur or occurred historically. As with downlisting, there may be certain cases in which a particular taxon may be eligible for delisting even if all 8 to 10 of the populations are on only one island, provided all of the other

recovery criteria have been met and the populations in question are widely distributed and secure enough that one might reasonably conclude that the taxon is not in danger of extinction throughout all or a significant part of its range. Each of these populations must be naturally reproducing, stable or increasing in number, and secure from threats, with a minimum of 100 mature individuals per population for long-lived perennials and a minimum of 300 mature individuals per population for short-lived perennials. Each population should persist at this level for a minimum of 5 consecutive years.

Public Comments Solicited

We solicit written comments on the recovery plan addendum described. All comments received by the date specified above will be considered prior to approval of this plan.

Authority: The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533 (f).

Dated: August 22, 2001.

Rowan W. Gould,

Regional Director, Region 1, U.S. Fish and Wildlife Service.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submitted to the Office of Management and Budget for Renewal Under the Paperwork Reduction Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces the Information Collection Request for Adult Education Annual Report Form OMB #1076-0120 requires renewal. The information collection requirement, with no appreciable changes, is submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 14, 2002.

ADDRESSES: Comments are to be mailed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Department of the Interior, 725 17th Street, Washington, DC 20503. Copies of comments should be sent to William Mehojah, Director, Office of Indian Education Programs, Department of the Interior, Bureau of Indian Affairs, 1849