

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 ICH 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 Draft Guidance on Carcinogenicity Testing

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing" (VICH GL28) should be made available for public comment. This guidance is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food ("VICH Guidance on General Testing

Approach") will be made available at a later time.

VICH developed this draft guidance after consideration of the existing ICH guidances for pharmaceuticals for human use entitled "Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals" and "Testing for Carcinogenicity of Pharmaceuticals," which published in the **Federal Register** of March 1, 1996 (61 FR 8153), and February 23, 1998 (63 FR 8983), respectively. The draft guidance has been adapted for veterinary use by the VICH from the aforementioned guidances regarding pharmaceuticals for human use. VICH also took into account the Organisation for Economic Cooperation and Development methodological guidances and the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

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 future guidance. (Information collection is covered under OMB No. 0910-0117. Information collection also could be covered by OMB No. 0910-0032.)

## III. Significance of Guidance

This draft 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." Because guidance documents are not binding, unless specifically supported by statute or regulation, 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 carcinogenicity testing for veterinary drug residues in human food. 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 September 28, 2001, 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 "01D-0357 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (VICH GL28)" and follow the directions.

Copies of the draft guidance entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing" (VICH GL28) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: August 21, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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BILLING CODE 4160-01-S

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Information Collection Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

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

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** The collection of information listed below has been submitted to the Office of Management and Budget (OMB) for renewal under the provisions of the Paperwork Reduction Act. Copies of the specific information collection requirements, related forms, and explanatory material may be obtained by contacting the Service Information

Collection Clearance Officer at the address listed below.

**DATES:** Consideration will be given to all comments received on or before September 27, 2001. OMB has up to 60 days to approve or disapprove information collection but may respond after 30 days. Therefore, to ensure maximum consideration OMB should receive public comments by September 27, 2001.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the information collection request, explanatory information and related forms, contact Rebecca A. Mullin at (703) 358-2287, or electronically to [rmullin@fws.gov](mailto:rmullin@fws.gov).

**ADDRESSES:** Comments and suggestions on the requirement should be sent directly to the Office of Information and Regulatory Affairs; Office of Management and Budget; Attention: Interior Desk Officer, Washington, DC 20503; and a copy of the comments should be sent to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, ms 224-ARLSQ, 1849 C Street, NW., Washington, DC 20204.

**SUPPLEMENTARY INFORMATION:** The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). The U.S. Fish and Wildlife Service (Service) has submitted a request to OMB to renew its approval of the collection of information for the Migratory Bird Harvest Surveys. The Service is requesting a 3-year term of approval for this information collection activity. A previous 60-day notice on this information collection requirement was published in the April 12, 2001 (66 FR 18973) *Federal Register* inviting public comment. No comments on the previous notice were received as of June 14, 2001. This notice provides an additional 30 days in which to comment on the following information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is listed in 5 CFR 1320.8(d) and 16 U.S.C. 742d, which is 1018-0015.

The Migratory Bird Treaty Act (16 U.S.C. 703-711) and Fish and Wildlife Act of 1956 (16 U.S.C. 742d) designate the Department of the Interior as the key agency responsible for the wise

management of migratory bird populations frequenting the United States and for the setting of hunting regulations that allow appropriate harvests that are within the guidelines that will allow for those populations' well being. These responsibilities dictate the gathering of accurate data on various characteristics of migratory bird harvest of a geographic and temporal nature. Knowledge attained by determining harvests and harvest rates of migratory game birds is used to regulate populations (by promulgating hunting regulations) and to encourage hunting opportunity, especially where crop depredations are chronic and/or lightly harvested populations occur. Based on information from harvest surveys, hunting regulations can be adjusted as needed to optimize harvests at levels that provide a maximum of hunting recreation while keeping populations at desired levels.

This information collection approval request combines three sets of surveys (the Waterfowl Hunter Survey, the Migratory Bird Hunter Survey, and the Parts Collection Survey, OMB Approval Number 1018-0015) and associated forms because they are interrelated and/or dependent upon each other.

The Waterfowl Hunter Survey, which estimates the harvest of ducks and geese, is based on Federal Duck Stamp sales. This survey asks people who purchase Federal Duck Stamps from randomly sampled Post Offices and other stamp vendors to complete and return a postcard (form 3-1823A) with their name and address. Hunters who complete and return the postcard are sent a postcard questionnaire (form 3-2056G) at the end of the hunting season, asking them to report their harvest of ducks and geese. Their responses provide estimates of the average harvest per hunter, which, combined with total Federal Duck Stamp sales, enables the Service to estimate the total harvest of ducks and geese.

The Migratory Bird Hunter Survey is based on the Migratory Bird Harvest Information Program, under which each State annually provides a list of all licensed migratory bird hunters in the State. Randomly selected migratory bird hunters are sent either a waterfowl questionnaire (form 3-2056J), a dove and band-tailed pigeon questionnaire (form 3-2056K), a woodcock questionnaire (form 3-2056L), or a snipe, rail, gallinule, and coot questionnaire (form 3-2056M) and are asked to report their harvest of those species. The resulting estimates of harvest per hunter are combined with the complete list of migratory bird hunters to provide estimates of the total

harvest of those species. This survey will replace the Waterfowl Hunter Survey after it has been fully implemented in all States and comparisons of results with Waterfowl Hunter Survey results have been completed.

The Parts Collection Survey estimates the species, sex, and age composition of the harvest, and the geographic and temporal distribution of the harvest. Randomly selected successful hunters who responded to the Waterfowl Hunter Survey or the Migratory Bird Hunter Survey the previous year are asked to complete and return a postcard (forms 3-165A and C) if they are willing to participate in the Parts Collection Survey. Respondents are provided postage-paid envelopes before the hunting season and asked to send in a wing or the tail feathers from each duck, goose, or coot (form 3-165) they harvest, or a wing from each woodcock, band-tailed pigeon, snipe, rail, or gallinule (form 3-165B) they harvest. The wings and tail feathers are used to identify the species, age, and sex of the harvested sample. Respondents are also asked to report on the envelope the date and location (state and county) of harvest for each bird. Results of this survey are combined with harvest estimates from the Waterfowl Hunter Survey and the Migratory Bird Hunter Survey to provide species-specific national harvest estimates.

The combined results of these surveys enable the Service to evaluate the effects of season length, season dates, and bag limits on the harvest of each species, and thus help determine appropriate hunting regulations.

*Title:* Migratory Bird Harvest Surveys.  
*Approval Number:* 1018-0015.

*Service Form Number(s):* 3-1823A, 3-2056G, 3-165, 3-165A-C, 3-2056J-M.

*Frequency of Collection:* Annually.

*Description of Respondents:* Individuals and households.

*Total Annual Burden Hours:* The reporting burden is estimated to average 2 minutes per respondent for the Migratory Bird Harvest Information Program, 8 minutes per respondent for the Waterfowl Hunter Survey, 4 minutes per respondent for the Migratory Bird Hunter Survey, and 50 minutes per respondent for the Parts Collection Survey. The Total Annual Burden is 138,917 hours.

*Total Annual Responses:* About 3,600,000 individuals are expected to participate in the Migratory Bird Harvest Information Program. Recent Service experience indicates that about 20,500 hunters will respond to the Waterfowl Hunter Survey each year, about 11,400 hunters will respond to the

Parts Collection Survey annually, and about 90,000 hunters will respond to the Migratory Bird Hunter Survey annually.

*Annual Burden Hours: 138,917.*

Pursuant to this renewal, comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and, (4) ways to minimize the burden of the collection of information on respondents. The information collections in this program will be part of a system of a record covered by the Privacy Act 95 U.S.C. 552(a).

Dated: June 27, 2001.

**Rebecca A. Mullin,**

*Information Collection Officer, Fish and Wildlife Service.*

[FR Doc. 01-21656 Filed 8-27-01; 8:45 am]

**BILLING CODE 4310-55-M**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Endangered Species Permit Applications

**AGENCY:** Fish and Wildlife Service.

**ACTION:** Notice of receipt of permit applications.

**SUMMARY:** The following applicants have applied for a scientific research permit to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 USC 1531 *et seq.*).

*Permit No. TE-036499-0.*

*Applicant:* National Park Service, Golden Gate National Recreation Area, San Francisco, California.

The applicant requests a recovery permit amendment to remove/reduce to possession the Raven's manzanita (*Arctostaphylos hookeri* var. *Ravennii*), Marin dwarf flax (*Hesperolinon congestum*), Presidio clarkia (*Clarkia franciscana*), San Francisco lessingia (*Lessingia germanorum*), and California sea-blite (*Suaeda californica*) in conjunction with native habitat restoration and enhancement, including collection of plants and their propagation, seeding and planting, invasive exotic plant removal and controlled burning, on the Presidio of San Francisco, Golden Gate National Recreation Area, Marin County, CA, for the purpose of enhancing the survival of

these species. This permit was previously issued as subpermit GGNRA-2.

*Permit No. TE-027427.*

*Applicant:* Jeff Alvarez, Sacramento, California.

The applicant requests a permit to take (capture, mark, radio-tag) Alameda whipsnakes (*Masticophis lateralis euryxanthus*) throughout the species range in conjunction with surveys and ecological research for the purpose of enhancing its survival.

*Permit No. TE-045733.*

*Applicant:* Bureau of Land Management, Burns District, Hines, Oregon.

The applicant requests a recovery permit to remove/reduce to possession seeds of the Malheur wire lettuce (*Stephanomeria malheurensis*) throughout the species' range, in conjunction with various recovery activities as outlined in the Recovery Plan, for the purpose of enhancing its survival.

*Permit No. TE-045937.*

*Applicant:* Alan Hastings, Ph.D. et al., Dept. of Environmental Studies, University of California at Davis, Davis, California.

The applicant requests a recovery permit to take (harm, harass) salt marsh harvest mouse (*Reithrodontomys raviventris*) and California Clapper Rail (*Rallus longirostris obsoletus*) within the San Francisco estuary, Alameda and San Mateo Counties, California, in conjunction with an ecological study of invasive cordgrass (*Spartina alterniflora* x *Spartina foliosa* hybrids) in tidal marshes, in order to ascertain how the cordgrass is altering the ecosystem, for the purpose of enhancing their survival.

*Permit No. TE-045994.*

*Applicant:* U. S. Geological Service, Biological Resources Division, Western Ecological Research Center, San Diego Field Station, San Diego, California.

The applicant requests a recovery permit to take (conduct surveys, capture, and collect for voucher specimens) up to 20 each of unarmored threespine stickleback (*Gasterosteus aculeatus*), Santa Ana sucker (*Catostomus santaanae*), and Mojave tui chub (*Gila bicolor mojavensis*) and to take (conduct surveys, capture, take tissue samples, and salvage unlimited numbers of dead, sick, or malformed) desert slender salamander (*Batrachoseps aridus*), California red-legged frog (*Rana aurora*), and the California arroyo toad (*Bufo microscaphus californicus*) on Department of Interior lands in Los Angeles, Riverside, and San Bernardino Counties, California, in conjunction

with population demographic studies, determining parasites present, and genetic studies, for the purpose of enhancing their survival.

**DATES:** Written comments on these permit applications must be received within 30 days of the date of publication of this notice.

**ADDRESSES:** Written data or comments should be submitted to the Chief, Endangered Species, Ecological Services, Fish and Wildlife Service, 911 NE. 11th Avenue, Portland, Oregon 97232-4181; Fax: (503) 231-6243. Please refer to the respective permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

**FOR FURTHER INFORMATION CONTACT:**

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 20 days of the date of publication of this notice to the address above; telephone: (503) 231-2063. Please refer to the respective permit number for each application when requesting copies of documents.

Dated: August 17, 2001.

**Rowan W. Gould,**

*Acting Regional Director, Region 1, Portland, Oregon.*

[FR Doc. 01-21662 Filed 8-27-01; 8:45 am]

**BILLING CODE 4310-55-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Aquatic Nuisance Species Task Force Western Regional Panel

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

**ACTION:** Notice of workshop and meeting.

**SUMMARY:** This notice announces a meeting of the Aquatic Nuisance Species (ANS) Task Force Western Regional Panel and an Invasive Species Screening Process workshop. The meeting topics and workshop agenda are identified in the **SUPPLEMENTARY INFORMATION**.

**DATES:** The Invasive Species Screening Process workshop will be held from 8:30 a.m. to 4:30 p.m., Tuesday, September 25, 2001, and 9 a.m. to noon, Wednesday, September 26, 2001. The