

**FOR FURTHER INFORMATION CONTACT:**

Louis T. Mulligan, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6984, e-mail: lmulliga@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 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and 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. Final Guidance on Genotoxicity Studies**

In the **Federal Register** of December 18, 2000 (65 FR 79106), FDA published the notice of availability of the VICH draft guidance, giving interested persons until January 17, 2001, to submit comments. After consideration of comments received, the final draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the final guidance for industry, VICH GL23. Following the endorsement of the final guidance document by the VICH Steering Committee, a change was made to the document in which the reference for each genotoxicity test in the basic battery of tests was moved and used as the heading for the paragraph describing that test. The change was of an editorial nature and did not change the scientific content or intent of the guidance document.

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. This guidance was developed after consideration of the existing ICH guidances for pharmaceuticals for human use entitled "Genotoxicity: A Standard Battery of Genotoxicity Testing of Pharmaceuticals" and "Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals." Account was also taken of the Organization for Economic Cooperation and Development methodological guidances and of the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the U.S.A., Australia, and New Zealand.

This level 1 final guidance document is developed under the VICH process and is consistent with FDA's good guidance practices regulation (21 CFR 10.115). This document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

(Information collection is covered under OMB control number 0910-0117.)

**III. Comments**

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. 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 document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cvm>.

Dated: December 28, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-193 Filed 1-3-02; 8:45 am]

BILLING CODE 4160-02-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 00D-1630]

**International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing" (VICH GL22); Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#115) entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing" (VICH GL22). This final guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding

pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This final VICH guidance document recommends a basic battery of tests that can be used to evaluate the reproduction safety of veterinary drug residues in human food.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the final guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), 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 final guidance document.

Submit written comments on the final 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 final guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Louis T. Mulligan, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6984, e-mail: [lmulliga@cvm.fda.gov](mailto:lmulliga@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 the 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and 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. Guidance on Reproduction Studies

In the **Federal Register** of December 19, 2000 (65 FR 79373), FDA published the notice of availability of VICH draft guidance entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" giving interested persons until February 20, 2001, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the final guidance for industry entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Reproductive Toxicity Testing" (VICH GL22).

In order to establish the safety of veterinary drug residues in human food, a number of toxicological evaluations are recommended, including the assessment of any risks to reproduction. The objective of this guidance is to ensure international harmonization of reproduction toxicity testing, which is appropriate for the evaluation of risks to reproduction from long-term, low-dose exposures, such as may be encountered from the presence of veterinary drug residues in food.

The current final guidance is one of a series of guidances developed to facilitate the mutual acceptance of

safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the safety evaluation of veterinary residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. VICH GL22 was developed after consideration of the existing ICH guidance for pharmaceuticals for human use on "Detection of Toxicity to Reproduction for Medicinal Products" and its addendum, "Toxicity to Male Fertility," in conjunction with the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

This final level 1 guidance document was developed under the VICH process and is consistent with FDA's good guidance practices regulation (21 CFR 10.115). 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations. (Information collection is covered under OMB Control Nos. 0910-0117 and 0910-0032.)

### III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. 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 document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

Comments may also be submitted electronically on the Internet site at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select 00D-1630 "Safety Studies for Veterinary Drug Residues in Human

Food: Reproduction Toxicity Testing" (VICH GL22) and follow the directions.

Copies of the final guidance document entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing" (VICH GL22) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: December 28, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-194 Filed 1-3-02; 8:45 am]

BILLING CODE 4160-02-S

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4730-N-01]

### Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

**EFFECTIVE DATE:** January 4, 2002.

**FOR FURTHER INFORMATION CONTACT:**

Mark Johnston, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-1234; TTY number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or

call the toll-free Title V information line at 1-800-927-7588.

**SUPPLEMENTARY INFORMATION:** In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: December 28, 2001.

**John D. Garrity,**

*Director, Office of Special Needs Assistance Programs.*

[FR Doc. 02-81 Filed 1-3-02; 8:45 am]

BILLING CODE 4210-29-M

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice of Issuance of Permits for Incidental Take

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

**ACTION:** Notice of issuance of 111 permits for incidental take of threatened and endangered species: Annual report.

**SUMMARY:** Between October 1, 2000 and September 30, 2001, Region 2 of the Fish and Wildlife Service issued 111 permits for the incidental take of threatened and endangered species,

pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act), as amended. Of the 111 permits issued in the greater Austin, Texas area; one is for the golden-cheeked warbler (GCW) related to the Balcones Canyonlands Preserve, one is for karst invertebrates, and 109 are for the Houston toad (HT). In addition, between October 1, 2000 and September 30, 2001, 2 permits had amendments.

**ADDRESSES:** If you would like copies of any of the above documents, please contact the U.S. Fish and Wildlife Service, Ecological Services, P.O. Box 1306, Albuquerque, New Mexico.

**FOR FURTHER INFORMATION CONTACT:**

Leslie Dierauf, Regional Habitat Conservation Plan Coordinator, at the above address, 505-248-6651. Further details of these permits may also be viewed on the Internet at <http://ecos.fws.gov>.

**SUPPLEMENTARY INFORMATION:** Section 9 of the Act and Federal Regulation prohibit the "take" of wildlife species listed as threatened or endangered species. Under the Act, the term "take" means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed wildlife, or to attempt to engage in any such conduct. The Service may, under limited circumstances, issue permits to authorize incidental take, i.e. that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity. Regulations governing permits for endangered species are at 50 CFR 17.22.

#### 111 Incidental Take Permits Issued

Permittee	(State) species	Permit No.	Date of Issuance
Siefert .....	(TX)HT .....	TE-025997-0-005 .....	10/2/00
Bastrop Seventh Day Adventist Church .....	(TX)HT .....	TE-025997-0-003 .....	10/2/00
Becerra .....	(TX)HT .....	TE-025997-0-004 .....	10/2/00
Kummermehr .....	(TX)HT .....	TE-025997-0-010 .....	10/2/00
Jarrels .....	(TX)HT .....	TE-025997-0-006 .....	10/13/00
Circle B Homes .....	(TX)HT .....	TE-025997-0-011 .....	10/13/00
McClure .....	(TX)HT .....	TE-025997-0-014 .....	10/13/00
McClure .....	(TX)HT .....	TE-025997-0-015 .....	10/13/00
Schena .....	(TX)HT .....	TE-029608-0 .....	10/27/00
MacQueen .....	(TX)HT .....	TE-025997-0-021 .....	10/31/00
Ligon .....	(TX)HT .....	TE-025997-0-012 .....	11/21/00
Smith .....	(TX)HT .....	TE-025997-0-024 .....	11/21/00
Lindenau .....	(TX)HT .....	TE-025997-0-023 .....	11/21/00
Pierson .....	(TX)HT .....	TE-025997-0-025 .....	11/21/00
Kelley .....	(TX)HT .....	TE-025997-0-008 .....	12/1/00
Groves .....	(TX)HT .....	TE-025997-0-026 .....	12/21/00
Johnson .....	(TX)HT .....	TE-025997-0-027 .....	12/21/00
Niehus .....	(TX)HT .....	TE-025997-0-029 .....	12/21/00
Walraven .....	(TX)HT .....	TE-033185-0 .....	1/18/01
Gilfillan .....	(TX)HT .....	TE-033887-0 .....	1/23/01
Holter .....	(TX)HT .....	TE-025997-0-030 .....	1/29/01
Gillespie .....	(TX)HT .....	TE-025997-0-032 .....	1/29/01
Vavricek .....	(TX)HT .....	TE-025997-0-028 .....	1/29/01
Steins .....	(TX)HT .....	TE-025965-0-003 .....	2/20/01
Stobaugh .....	(TX)HT .....	TE-025965-0-002 .....	2/20/01