

**SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document 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>.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS)" dated June 2002. The draft guidance document provides information that would help human cellular and tissue-based product manufacturers minimize the possible risk of transmission of CJD/vCJD by HCT/PS through deferral of donors with possible exposure to the agents causing CJD and vCJD.

The draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

##### **II. Comments**

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by December 23, 2002. Two copies of any written comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number

found in the 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.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 13, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-15898 Filed 6-24-02; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. 02D-0199]

##### **Advertisements for High-Intensity Mercury Vapor Discharge Lamps; Revocation of Compliance Policy Guide 7133.13; Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 21, 2002 (67 FR 35826). The document revokes the Compliance Policy Guide (CPG) entitled "Sec. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13)."

##### **FOR FURTHER INFORMATION CONTACT:**

Doris B. Tucker, Office of Policy, Planning, and Legislation (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 02-12623, appearing on page 35826 in the **Federal Register** of Tuesday, May 21, 2002, the following correction is made:

1. On page 35827, in the first column, the **DATES** section is corrected to read "**DATES:** This revocation is effective June 20, 2002."

Dated: June 18, 2002.

**Deborah D. Ralston,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 02-15955 Filed 6-24-02; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. 00D-1629]

##### **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidances for Industry on "Effectiveness of Anthelmintics: Specific Recommendations for Feline" (VICH GL20), and "Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus gallus" (VICH GL21); Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of two final guidances for industry (Nos. 113 and 114, respectively) entitled "Effectiveness of Anthelmintics: Specific Recommendations for Feline" (VICH GL20), and "Effectiveness of Anthelmintics: Specific Recommendations for Poultry-Gallus gallus" (VICH GL21). These related guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States. **DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the final guidances to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the final guidance documents 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance documents.

##### **FOR FURTHER INFORMATION CONTACT:**

Thomas Letonja, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl.,

Rockville, MD 20855, 301-827-7576, e-mail: [tletonja@cvm.fda.gov](mailto:tletonja@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 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical recommendations 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 recommendations 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.

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 Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

##### II. Final Guidance on Effectiveness of Anthelmintics

In the **Federal Register** of December 18, 2000 (65 FR 79113), FDA published the notice of availability of these VICH draft guidances, giving interested persons until January 17, 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 guidances for industry, VICH GL20 and VICH GL21.

These final guidances, VICH GL20 and VICH GL21 should be read in conjunction with the "Effectiveness of Anthelmintics: General Recommendations (EAGR)" which was published in the **Federal Register** of April 6, 2001 (66 FR 18257). The guidances for feline and poultry are part of the EAGR, and the aim of these final guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on effectiveness data recommendations, and (3) give explanations for disparities with the EAGR.

The final level 1 guidance documents, developed under the VICH process, are consistent with FDA's good guidance practices regulation (21 CFR 10.115). These documents do 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 collected is covered under OMB control number 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 these guidances. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidances. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding these guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. The guidances 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

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

Dated: June 17, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-15896 Filed 6-24-02; 8:45 am]

**BILLING CODE 4160-01-S**

#### DEPARTMENT OF THE INTERIOR

##### Fish and Wildlife Service

##### Receipt of Applications for Permit

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

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

**SUMMARY:** The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

**DATES:** Written data, comments or requests must be received by July 25, 2002.

**ADDRESSES:** 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 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358-2281.

**FOR FURTHER INFORMATION CONTACT:** Division of Management Authority, telephone 703/358-2104.

##### SUPPLEMENTARY INFORMATION:

##### Endangered Species

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

##### PRT-057065

*Applicant:* Perlegen Sciences, Inc., Mountain View, California