

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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Certifier	<u>Monnie Oliver</u>

[Docket No. 99D-2248]

**International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidances Entitled “Effectiveness of Anthelmintics: General Recommendations” (VICH GL7), “Effectiveness of Anthelmintics: Specific Recommendations for Bovine” (VICH GL12), “Effectiveness of Anthelmintics: Specific Recommendations for Ovine” (VICH GL13), and “Effectiveness of Anthelmintics: Specific Recommendations for Caprine” (VICH GL14); Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of four final guidances for industry (Nos. 90, 95, 96, and 97) entitled “Effectiveness of Anthelmintics: General Recommendations” (EAGR) (VICH GL7), “Effectiveness of Anthelmintics: Specific Recommendations for Bovine” (VICH GL12), “Effectiveness of Anthelmintics: Specific Recommendations for Ovine” (VICH GL13), and “Effectiveness of Anthelmintics: Specific Recommendations for Caprine” (VICH GL14). These guidances have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Approval 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.

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**DATES:** You may submit written comments at anytime.

**ADDRESSES:** Copies of the final guidances entitled “Effectiveness of Anthelmintics: General Recommendations” (VICH GL7), “Effectiveness of Anthelmintics: Specific Recommendations for Bovine” (VICH GL12), “Effectiveness of Anthelmintics: Specific Recommendations for Ovine” (VICH GL13), and “Effectiveness of Anthelmintics: Specific Recommendations for Caprine” (VICH GL14) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/guidance/guidance.html>. Persons without Internet access may 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.

You may submit written comments any time on the final guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Thomas Letonja (HFV-135), Center for Veterinary Medicine, 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 recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical recommendations 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; 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 Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

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

These four guidances are entitled "Effectiveness of Anthelmintics: General Recommendations" (VICH GL7), "Effectiveness of Anthelmintics: Specific Recommendations for Bovine" (VICH GL12), "Effectiveness of Anthelmintics: Specific Recommendations for Ovine" (VICH GL13), and "Effectiveness of Anthelmintics: Specific Recommendations for Caprine" (VICH GL14).

In the **Federal Register** of July 16, 1999 (64 FR 38445), FDA published these VICH guidances in draft form, giving interested persons until August 16, 1999, to submit comments. FDA shared the comments with the appropriate VICH Expert Working Group and after considering the comments, the work group submitted the final guidance to the VICH Steering Committee. At a meeting held from November 16 to 19, 1999, the VICH Steering Committee endorsed the four final guidances for industry, VICH GL7, VICH GL12, VICH GL13, and VICH GL14.

VICH GL7 is intended to standardize and simplify the methods used for the effectiveness evaluation of new anthelmintics and generic copies for use in domesticated animals. Animal welfare will benefit by the elimination of duplicate studies that will reduce the number of animals required for necessary studies. Likewise this will benefit the industry by reducing research and development costs. VICH GL12, VICH GL13, and VICH GL14 should be read in conjunction with the EAGR, VICH GL7. The guidances for bovine, ovine, and caprine are part of the EAGR, and the aim of these three 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.

This final level 1 guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). These final guidances represent the agency's current thinking on effectiveness recommendations for anthelmintic medicinal products. These guidances do not create or confer any rights for or on any person, and do 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.

### III. Comments

As with all of FDA's guidances, the public is encouraged to submit written 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, at any time, submit written comments to the Dockets Management Branch (address above) regarding these guidances. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of 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.

Dated: March 29, 2001  
March 29, 2001.

*Ann M. Witt*

Ann M. Witt,  
Acting Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

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*Romone Oliver*

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