

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1629]

DHB

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**International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances for Industry on “Effectiveness of Anthelmintics: Specific Recommendations for Feline” (VICH GL20) and “Effectiveness of Anthelmintics: Specific Recommendations for Poultry” (VICH GL21); Availability; Request for Comments**

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

**ACTION:** Notice; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comment of two draft 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” (VICH GL21). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products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**DATES:** Submit written comments on the draft guidance documents by [*insert date 30 days after date of publication in the Federal Register*], to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of the draft guidance documents entitled “Effectiveness of Anthelmintics: Specific Recommendations Feline” (VICH GL20) and “Effectiveness of Anthelmintics: Specific

Recommendations for Poultry'' (VICH GL21) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/fda/TOCs/guideline.html>. Persons without Internet access may submit written requests for single copies of the draft 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 to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the VICH:* Sharon Thompson, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4514, e-mail: [sthompso@cvm.fda.gov](mailto:sthompso@cvm.fda.gov), or Carole R. Andres, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-2977, e-mail: [candres1@cvm.fda.gov](mailto:candres1@cvm.fda.gov).

*Regarding the guidance documents:* 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 differences in technical recommendations for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) 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; 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 Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

## **II. Guidance on Anthelmintics**

The VICH Steering Committee held a meeting from June 14 through 16, 2000, and agreed that the two draft guidance documents entitled "Effectiveness of Anthelmintics: Specific Recommendations for Feline" (VICH GL20) and "Effectiveness of Anthelmintics: Specific Recommendations for Poultry" (VICH GL21) should be made available for public comment.

The two draft guidances, VICH GL20 and VICH GL21, should be read in conjunction with the “Effectiveness of Anthelmintics: General Recommendations (EAGR)” (64 FR 38445, July 16, 1999). The guidances for feline and poultry are part of the EAGR, and the aim of these two draft 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 recommendation, and (3) give explanations for disparities with the EAGR. Comments about the draft guidance documents will be considered by the FDA and the VICH Anthelmintic Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee’s final guidances and publish them as future guidances.

These draft documents, developed under the VICH process, have been revised to conform to FDA’s good guidance practices (65 FR 56468, September 19, 2000). For example, the documents have 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.

These draft documents represent current FDA thinking on effectiveness recommendations for certain veterinary anthelmintic medicinal products. 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.

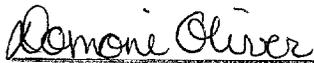
### **III. Comments**

These draft guidance documents are being distributed for comment purposes only and are not intended for implementation at this time. Interested persons should submit to the Dockets Management Branch (address above) written comments regarding the draft guidance documents by [*insert date 30 days after date of publication in the Federal Register*]. 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 brackets in the heading of this document. A copy of the draft guidance documents 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: 12/8/00  
December 8, 2000.

  
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Margaret M. Dotzel,  
Associate Commissioner for Policy.

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