

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date	10-18-00
Publication Date	10-19-00
Certifier	SURROCK

[Docket No. 00D-1532]

**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 Equine” (VICH GL15), “Effectiveness of Anthelmintics: Specific Recommendations for Porcine” (VICH GL16), and “Effectiveness of Anthelmintics: Specific Recommendations for Canine” (VICH GL19); 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 three draft guidances for industry (Nos. 109, 110, and 111, respectively) entitled: “Effectiveness of Anthelmintics: Specific Recommendations for Equine” (VICH GL15), “Effectiveness of Anthelmintics: Specific Recommendations for Porcine” (VICH GL16), and “Effectiveness of Anthelmintics: Specific Recommendations for Canine” (VICH GL19). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products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 guidances by [*insert date 60 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 guidances entitled “Effectiveness of Anthelmintics: Specific Recommendations for Equine” (VICH GL15), “Effectiveness of Anthelmintics: Specific Recommendations for Porcine” (VICH GL16), and “Effectiveness of Anthelmintics: Specific Recommendations for Canine” (VICH GL19) 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 Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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 R. Thompson, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1798, e-mail: [sthompso@cvm.fda.gov](mailto:sthompso@cvm.fda.gov), or Carole R. Andres, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6524, e-mail: [candres1@cvm.fda.gov](mailto:candres1@cvm.fda.gov).

*Regarding the draft guidance documents:* 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 requirements 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 (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use 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.

The VICH Steering Committee held a meeting on November 16 through 19, 1999, and agreed that the three draft guidances entitled "Effectiveness of Anthelmintics: Specific Recommendations for Equine" (VICH GL15), "Effectiveness of Anthelmintics: Specific Recommendations for Porcine" (VICH GL16), and "Effectiveness of Anthelmintics: Specific Recommendations for Canine" (VICH GL19) should be made available for public comment.

The three draft guidances: VICH GL15, VICH GL16, and VICH GL19, should be read in conjunction with the “Efficacy of Anthelmintics: General Recommendations (EAGR)” announced in the **Federal Register** of July 16, 1999 (64 FR 38445). The draft guidances for equine, porcine, and canine are part of the EAGR, and the aim of these three 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 recommendations, and (3) give explanations for disparities with the EAGR. Comments about the draft guidances 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 guidances, 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 “requirement” or “acceptable” have been replaced by “recommendation” or “recommended” as appropriate to the context.

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

## II. Comments

These draft guidances are being distributed for comment purposes only, and they are not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance documents by *[insert date 60 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 are to be identified with

the docket number found in brackets in the heading of this document. A copy of the draft guidances and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 6, 2000

*M. Dotzel*  
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Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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*Suzette N. Rose*  
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