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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 03D–0051]

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals With Respect to Antimicrobial Resistance" (VICH GL27); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#144) entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance" (VICH GL27). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is an initial step in developing harmonized technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. The draft guidance outlines the types of studies and data which are recommended for assessing the potential for resistance to

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develop in association with the use of antimicrobial drugs in food-producing animals.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 30 days after publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–2), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail: wflynn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA announced the availability of a related draft guidance for industry (#152)

entitled "Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern." Draft guidance #152 represents FDA's current thinking on an approach for using data, such as that outlined in the VICH draft guidance, for completing an assessment on the safety of antimicrobial drugs that focuses on antimicrobial resistance concerns. The publication of the draft VICH guidance (#144) in the United States was delayed until FDA developed an understanding of how the outlined data could be incorporated into an assessment process such as that described in the FDA draft guidance #152.

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 International Conference on Harmonization of Technical Requirements for Approval 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, 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.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/ New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. 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. Draft Guidance on Antimicrobial Resistance

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food Producing Animals with Respect to Antimicrobial Resistance" (VICH GL27) should be made available for public comment. However, subsequent to the June 2001 Steering Committee meeting, the FDA decided to delay the publication of the draft VICH guidance in the United States until the FDA draft guidance (#152) related to antimicrobial resistance was published. FDA believed that it was important to first develop its thinking on how data, such as that described

in the draft VICH guidance, could be used for completing an assessment on antimicrobial resistance.

The draft VICH guidance is an initial step in developing harmonized technical guidance in the European Union, Japan, and the United States for approval of therapeutic antimicrobial veterinary medicinal products intended for use in food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern.

This draft guidance outlines the types of studies and data that may be used to characterize the potential for resistance to develop in the target animal when an antimicrobial drug product is used under the proposed conditions. This includes information which describes the drug substance, drug product, nature of the resistance, and potential exposure of gut flora in the target animal species.

FDA and the VICH Expert Working Group on Antimicrobial Resistance will consider comments about the draft guidance document. Information collection is covered under the Office of Management and Budget control number 0910–0032.

III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." Because guidance documents are not binding, mandatory words such as "must," "shall," and "will" in the original VICH document have been substituted with "should." Similarly, words such as "require" or "requirement" have been replaced by "recommend" or "recommendation" as appropriate to the context.

The draft VICH guidance (#144) is consistent with the agency's current thinking, described in draft guidance #152, on the type of preapproval information that should be considered for new veterinary medicinal products for food-producing animals with regard to characterization of antimicrobial resistance selection in bacteria of human health concern. 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 alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments regarding this draft guidance document to the Dockets Management Branch (see **ADDRESSES**). Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Two copies of any mailed 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 guidance 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

Electronic comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select Docket No. 03D–0051 "Pre-Approval Information for Registration of New

Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance" and follow the directions.

Copies of the draft guidance document entitled "Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing

Animals with Respect to Antimicrobial Resistance'' (VICH GL27) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: 6/4/03
June 4, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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