

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0219]

Guidance for Industry: General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled “General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (GFI #3).” This version of the guidance replaces the version that was made available in July 1994. This has been revised to remove outdated information on toxicological testing and to provide references to other available guidance on the topic. In addition, the document has been revised to address minor formatting issues.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (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 guidance document.

FOR FURTHER INFORMATION CONTACT: Mark M. Robinson, Center for Veterinary Medicine (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5282, e-mail: mrobinson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published the guidance for industry entitled “General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (GFI #3)” in July 1994. Since that time, FDA has published a number of guidance documents in its participation with International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) that provide recommendations on toxicological testing of compounds used in food-producing animals. This version of guidance #3 replaces the version that was made available in July 1994. The guidance has been updated to remove outdated information on toxicological testing and refers the reader to the relevant Center for Veterinary Medicine/ VICH guidance documents. In addition, the document was revised to address minor formatting issues including correcting an error in the numbering of the guidance sections.

II. Significance of Guidance

This document is being revised as a level 2 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115.) The guidance represents the agency’s current thinking on the subject matter. The document does not create or confer any rights for or on any person and will not operate

to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Copies of the guidance document entitled “General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (#3)” may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: June 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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