

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0254]

Draft Guidance for Industry: Analytical Methods Description for Type C Medicated Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry (#137) entitled “Analytical Methods Description for Type C Medicated Feeds.” This draft guidance provides our recommendations for describing methods for analyzing new animal drugs in Type C medicated feeds.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 75 days after publication in the **Federal Register***] to ensure their adequate consideration in preparation of the final document.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.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Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rebecca L. Owen, Center for Veterinary Medicine (HFV-141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9842, e-mail: rebecca.owen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b) establishes the requirements for new animal drug approval. FDA regulations in part 514 (21 CFR part 514) specify the information you must submit as part of your new animal drug application (NADA) and the proper format for the NADA submission. As part of your NADA submission, you must include a “detailed description of the collection of samples and the analytical procedures to which they are subjected” (§ 514.1(b)(5)(vii). This should include a description of practicable methods of analysis which have adequate sensitivity to determine the amount of the new animal drug in the final dosage form (§ 514.1(b)(5)(vii)(a). This draft guidance provides recommendations for describing methods for analyzing new animal drugs in Type C medicated feeds. This draft guidance applies to instrumental methods only (e.g., High Pressure Liquid Chromatography, Gas Chromatography. For guidance on other methods (e.g., microbiological methods) you should contact the center.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 514.1 have been approved under OMB control numbers 0910–0032 and 0910–0154.

III. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does 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.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. 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.

V. Electronic Access

Copies of the draft guidance document entitled “Analytical Methods Description for Type C Medicated Feeds” may be obtained from the CVM Home Page (<http://www.fda.gov/cvm>) and from the Division of Dockets Management Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: June 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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