

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0441]

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Certifier	<u>[Signature]</u>

Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#136) entitled "Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods." This guidance provides our recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method.

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

ADDRESSES: Submit written requests for single copies of the guidance document 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.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance document to <http://>

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[/www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 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

In the **Federal Register** of November 14, 2006 (71 FR 66335), FDA published a notice of availability for a draft guidance entitled "Guidance for Industry: Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods" giving interested persons until January 29, 2007, to comment on the draft guidance. No comments were received. Therefore, the final guidance has not been substantively changed from the draft version.

Section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) establishes the requirements for a new animal drug approval. FDA regulations specify the information you (the sponsor) must submit as part of your new animal drug application (NADA) and the proper format for the NADA submission (§ 514.1 (21 CFR 514.1)). As part of your NADA submission, you must describe analytical procedures capable of determining the active component(s) of the new animal drug within a reasonable degree of accuracy and of assuring the identity of such components (21 CFR 514.1(b)(5)(vii)). This includes a description of practicable methods of analysis (assay methods) that have adequate sensitivity to determine the amount of the new animal drug in

the final dosage form (21 CFR 514.1(b)(5)(vii)(a)). In the case of a Type A medicated article, the Type C medicated feed is a final dosage form used to treat the animal. Thus, as part of the NADA review process, FDA looks at assay methods for determining the amount of a new animal drug in Type C medicated feed.

This guidance provides recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method. Many testing laboratories, including state feed laboratories and contract laboratories, use Type C medicated feed assay methods to determine whether the drug in a medicated feed is within the assay limits. The term “assay limits” refers to the amount of the drug detected when a Type B/C feed is assayed. The limit is a range that is codified at 21 CFR 558.4(d). When feed assay values fall within this range, it indicates that the feed has been prepared with the correct amount of Type A medicated article. Because many different laboratories use medicated feed assays, it is important that the assay methods are reproducible. Sponsors should conduct method transfer studies to evaluate reproducibility. A method transfer study is part of the evaluation process for a Type C medicated feed assay method and demonstrates the transferability of the feed assay method among different laboratories by comparing the results each laboratory obtains when using the method to analyze a specific set of feed samples. Sponsors may expand the method transfer study to include other medicated feed products, such as Top Dress Type C, Free-Choice Type C, and Type B medicated feeds.

II. Paperwork Reduction Act of 1995

This 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 Nos. 0910–0032 and 0910–0154.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance 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

Interested persons may, at any time, 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 should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

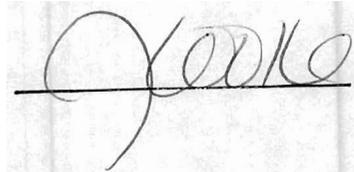
Persons with access to the Internet may obtain the guidance at CVM's Web site (<http://www.fda.gov/cvm>) and from the Division of Dockets Management's Web site <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 4/20/07
April 20, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

**CERTIFIED TO BE A TRUE
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