

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0224]

DMB

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Certifier D. Hawkins

**Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance (#118) entitled "Guidance For Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues." This guidance describes the basic principles the agency recommends for development, evaluation, or application of qualitative mass spectrometric methods for confirming the identity of new animal drug residues. This guidance document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the guidance defines key terms used throughout the document.

**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, 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 document to the Dockets

Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers  
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Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Once on this site, select "Docket No. 01D-0224 Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues" and follow the directions. Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** David N. Heller, Center for Veterinary Medicine (HFV-510), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301-827-8156, e-mail: [dheller@cvm.fda.gov](mailto:dheller@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 13, 2001 (66 FR 31938), FDA published a notice of availability for a draft guidance entitled "Draft Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues" giving interested persons until September 11, 2001, to submit comments. FDA considered all comments received and, where appropriate, incorporated them into the guidance. The guidance differs from the draft guidance in the following ways:

- There is further clarification of interference testing, control samples, system suitability, minimum signal strength in full scan analysis, recommended rate of false negatives, and number of residue-incurred samples for validation. (The recommendation in the 1994 revision of CVM Guidance #3 for a smaller number of incurred samples for interlaboratory method trials

has not been CVM's practice for some years. CVM is currently revising Guidance #3.)

- Additional definitions were provided for comparison standard, control sample exact mass measurement, false positive rate, false negative rate, limit of confirmation, and validation. Other revisions in the glossary definitions were made to make the definitions consistent with definitions in existing regulations.

- Use of the terms "acceptability range" and "precursor ion" is now consistent.

- General recommendations on the subject of exact mass measurements have been added. Until specific standards for exact mass measurements in animal drug residue analysis are generally accepted, their use will be evaluated on a case-by-case basis. The Center for Veterinary Medicine (CVM) of FDA may modify this document if a more generally accepted standard for confirmation of animal drug residues using exact mass measurements is developed in the future.

The purpose of this guidance document is to facilitate and expedite coordination between CVM and sponsors so the development, evaluation, and application of qualitative mass spectrometric methods will be completed in a consistent and timely manner. This guidance document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the guidance defines key terms used throughout the document.

This guidance should be used: (1) In the development of new methods, (2) the review of methods submitted to CVM, and (3) in the laboratory trial of methods submitted to CVM. The document should also help in making

decisions about appropriate methodology in various regulatory situations and ensuring consistency in work done for CVM's purposes.

Information collection provisions described in this guidance have been approved under OMB control numbers 0910-0032 and 0910-0325.

## II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on mass spectrometry for confirmation of the identity of animal drug residues. The document does not create or confer any rights for or on any person and does 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 guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of 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. The 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.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cvm>.

Dated: 5/5/03  
May 5, 2003.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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*Dawn P. Hawkins*