

and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has

taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for

the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
308	3	924	.17	157

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: May 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0224]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 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.

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