

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.

[FR Doc. 03-11773 Filed 5-12-03; 8:45 am]

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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

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 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: May 5, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-11771 Filed 5-12-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Submission for OMB Emergency Review; Comment Request

AGENCY: Office of the Under Secretary for Management, Homeland Security.

DATES: May 7, 2003.

SUMMARY: The Department of Homeland Security (DHS) has submitted the following (*see below*) information collection request (ICR), utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35), as amended by the Clinger-Cohen Act (Pub. L. 104-106). OMB approval has been requested by May 13, 2003. A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Homeland Security, Theresa M. O'Mally ((202) 722-9686).

Comments: Comments and questions about the ICR listed below should be forwarded to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for Homeland Security, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395-7316). The Office of Management and Budget is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, Under Secretary of Management, Office of the Chief Information Officer.

Title: Vendor Information Site.

OMB Number: 1600—new collection.

Frequency: On occasion.

Affected Public: Individuals or households; businesses or other for-profit; not-for-profit institutions; farms; State, local or tribal government.

Number of Respondents: 20,000.

Estimated Time Per Respondent: 30 minutes for startup; 30 minutes for maintaining.

Total Burden Hours: 20,000.

Total Burden Cost (capital/startup): \$25.00 per respondent; \$500,000 annually.

total Burden Cost (operating/maintaining): \$25.00 per respondent, \$500,000 annually.

Description: This web-based Vendor Information Site information collection will provide a uniform voluntary way companies can provide descriptions of their product-and-service ideas to DHS for enhancing homeland security.

Steve I. Cooper,

Chief Information Officer.

[FR Doc. 03-11855 Filed 5-8-03; 12:16 pm]

BILLING CODE 4410-10-M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1459-DR]

Mississippi; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Mississippi (FEMA-1459-DR), dated April 24, 2003, and related determinations.

EFFECTIVE DATE: April 24, 2003.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 24, 2003, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Mississippi, resulting from severe storms, tornadoes, and flooding on April 6-14, 2003, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (the