

V. Comments and Electronic Access

Interested persons may submit to the Committee on Food Chemicals Codex written comments regarding the monographs, general test procedure, and test solutions identified in this notice by July 30, 2001. Timely submission will allow comments to be considered for the third supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the third supplement, but will be considered for the fifth edition of the Food Chemicals Codex. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs, the general test procedure, or the test solutions listed in this notice are to be submitted to the Committee on Food Chemicals Codex (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this **Federal Register** notice. The committee staff will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of the proposed changes may also be obtained through the Internet at <http://www.iom.edu/fcc>.

Dated: June 4, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01-14864 Filed 6-12-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies (TSE) Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 28, 2001, 8 a.m. to 5 p.m. and on June 29, 2001, 8 a.m. to 11:30 a.m.

Location: Holiday Inn, Versailles Ballroom I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: William Freas, or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 28, 2001, the committee will review and discuss the suitability of blood donors who have lived or traveled in various countries based on recent information concerning new-variant Creutzfeldt-Jakob disease and bovine spongiform encephalopathy in those countries. In the afternoon, the committee will discuss the safety of FDA-regulated plasma derivatives prepared in establishments proposing to use on the same manufacturing line, plasma which does and plasma which does not comply with current U.S. standards, with regard to donor deferral for vCJD risk factors. On June 29, 2001, the committee will discuss the interim results of a new study on the inactivation of TSE agent by the manufacturing process for gelatin.

Procedure: On June 28, 2001, from 8 a.m. to 4:30 p.m. and June 29, 2001, from 8 a.m. to 11:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 15, 2001. Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:30 a.m., and between approximately 2:30 p.m. and 3:10 p.m. on June 28, 2001, and between approximately 10 a.m. and 10:30 a.m. on June 29, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 15, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 28, 2001, from 4:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 5, 2001.

Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-14812 Filed 6-12-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0224]

Draft 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 draft guidance entitled "Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues." This draft 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 draft document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the draft guidance defines key terms used throughout the document.

DATES: Submit written comments by September 11, 2001.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail:

fdadockets@oc.fda.gov. 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.

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

Section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) requires FDA to determine whether each new animal drug proposed for use in food-producing animals is safe and effective. In some cases, the new animal drugs used in food-producing animals have the potential to adversely affect the health of the humans who consume food derived from these animals. The sponsor of the new animal drug is responsible for establishing the safety of each new animal drug through appropriate tests.

To determine human food safety of new animal drugs, FDA evaluates the information/data, identifies and characterizes potential hazards, assesses exposure levels and characterizes the overall risk. Through this process, FDA establishes an allowable daily intake and tolerances (the amount of drug residue allowed in tissues) for each drug. Drug sponsors submit to FDA analytical methods that are designed to measure the concentration of the proposed drug in the edible tissues at the drug's tolerances. Analytical methods are used to monitor the tolerances set by FDA. FDA reviews the analytical methods during its review of new animal drug applications (21 CFR 514.1(b)(7)).

Analytical methods may also be used to monitor safe levels as established by the agency. Under section 512(a)(4)(B) of the act and 21 CFR 530.22, the agency may establish a safe level for extra-label use of a drug when the agency finds that there is a reasonable probability that an extra-label use may result in drug residues in edible tissue of the treated animals at a level that may present a risk to the public health if it was above the safe level. Under the same provisions, FDA may require the development of an acceptable analytical method for the quantification of residues above any safe level.

FDA issues guidance recommending methods of analysis to potential sponsors to foster timely and objective review of proposed new animal drugs,

including the review of analytical methods. In the **Federal Register** of December 31, 1987 (52 FR 49589), FDA announced the availability of a set of eight guidance documents entitled "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals" (52 FR 49589); revisions to one of the guidances were announced in the **Federal Register** of July 22, 1994 (59 FR 37499). These guidances were designed to inform sponsors of the scientific data that FDA believes will provide an acceptable basis for determining the safety of such compounds, and for designing analytical methods.

Part V in the above-mentioned set of guidances, entitled "Guideline for Approval of a Method of Analysis for Residues," recommended that sponsors develop rugged methods of analysis designed to exceed rather than meet the minimal standards of acceptability. This serves two purposes: (1) To lower the number of method of analysis submissions that pass desk review but fail interlaboratory studies designed to test their effectiveness, and (2) to increase the precision and specificity of safety determination by ensuring a higher quality assay. The guidance then explained the evaluation criteria and data needed for approval of a method of analysis.

The draft guidance entitled "Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues" is designed to complement part V of "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals." The purpose of this document is to facilitate and expedite coordination between FDA's Center for Veterinary Medicine (CVM) and sponsors so the development, evaluation, and application of qualitative mass spectrometric methods will be completed in a consistent and timely manner.

This draft document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the draft guidance defines key terms used throughout the document.

This draft guidance should be used in the development of new methods, the review of methods submitted to CVM, and in the laboratory trial of methods submitted to CVM. The document also should help in making decisions about appropriate methodology in various regulatory situations and ensuring consistency in work done for CVM's purposes.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65

FR 56468, September 19, 2000). This draft 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. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by September 11, 2001. Two copies of any 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. A copy of the draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Comments on the draft guidance may be electronically submitted at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>. Electronic copies of the draft guidance and other guidances discussed in this notice may be obtained at <http://www.fda.gov/cvm>.

Dated: May 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-14813 Filed 6-12-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-297]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested