

published to give all interested parties an opportunity to comment on how these new resources may best be applied to address public health issues related to the timely approval and safe use of food and color additives. CFSAN will consider administrative and procedural enhancements to ensure that program goals are met while maintaining high standards of safety and scientific credibility.

DATES: Submit written comments by July 19, 2000.

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

FOR FURTHER INFORMATION CONTACT: Alan M. Rulis, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3100, e-mail: arulis@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION: The Office of Premarket Approval (OPA) in CFSAN manages the following programs: Petitions for new uses of food and color additives, consultations on foods developed using new methods of biotechnology, generally recognized as safe (GRAS) notices, threshold of regulation (TOR) exemption requests, and premarket notifications for food contact substances (PMN). In addition to these programs, OPA is the lead technical authority for food additives for the U.S. Government. OPA provides expertise and leadership in the international forums of the Joint Food Agricultural Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives, the North American Free Trade Agreement, and the Codex Alimentarius Commission to define international standards, promote harmonization, and evaluate equivalency agreements for food additives and other food ingredients. OPA also has laboratory research and sample analysis components that provide technical support for the enforcement of the food additive regulations.

The current process of reviewing food and color additive petitions has evolved over 40 years since the passage of the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the act). Approvals of food and color additives have been based on a critical scientific evaluation of safety information submitted by petitioners. The primary components of this evaluation are the review of chemical, toxicological, and environmental scientific data and information and an estimation of the probable human

dietary exposure to additives. During its review of safety of new food additive uses, OPA develops an administrative record that relies on scientific data and information to support the agency's safety conclusions. Although this framework has a high level of scientific credibility, CFSAN recognizes that improvements could be made to ensure that the process is more efficient while maintaining the current high scientific standards. With this notice, CFSAN is soliciting comments on ways to improve the timeliness, transparency, and predictability of its review of food and color additive petitions, and its monitoring of the safety of food and color additives over time.

To help focus comments, FDA requests that comments regarding food and color additive review address the following:

1. The act requires that the agency base its safety decisions for the premarket review of additives on "a fair evaluation of the data" and requires that new uses of food additives be consistent with the agency safety standard of "reasonable certainty of no harm." What specific changes can be made to the current review process to make that process more efficient, i.e., transparent, timely, responsive, and predictable, while preserving these high standards of data review and of safety?

2. On January 5, 1999 (64 FR 517), CFSAN made available a guidance describing a policy to expedite the review of petitions for food additives that are intended to significantly decrease human pathogens or their toxins in/on food. Should the Center consider broadening the criteria for eligibility for such expedited petition review? If so, petitions for what types of uses should be added?

3. How should the increased appropriation to CFSAN that is targeted for the safety review of food and color additives be allocated? For example, to what extent should new resources be allocated to: (1) Performing prefilings consultations with prospective applicants for new uses of food ingredients, (2) adding personnel resources to the review process, (3) enhancing electronic data management systems such as automated workflow management or data warehousing, and (4) acquiring or monitoring new safety information on already approved additives?

4. What specific program enhancements should be given the highest priority?

Interested persons may, on or before July 19, 2000, submit to the Dockets Management Branch (address above) written comments regarding this

document. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.
[FR Doc. 00-11331 Filed 5-4-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oxytetracycline in Shrimp; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of human food safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for the treatment of shrimp with oxytetracycline via medicated feed for bacterial infections. The data, contained in Public Master File (PMF) 5662, were compiled by FDA, Center for Veterinary Medicine (CVM), Office of Research (OR).

ADDRESSES: Submit NADA's or supplemental NADA's to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Copies of the analytical methods used to analyze the feed and tissue samples used in this study are available from the Center for Veterinary Medicine, Office of Research, 8401 Muirkirk Rd., Laurel, MD 20708.

FOR FURTHER INFORMATION CONTACT: Julia A. Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6976.

SUPPLEMENTARY INFORMATION:

Oxytetracycline used for the treatment of bacterial infections in shrimp is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, oxytetracycline is subject to section 512 of the act (21 U.S.C. 360b), requiring that its use in shrimp be the subject of an approved NADA or supplemental NADA. Shrimp are a minor species under 21 CFR 514.1(d)(1)(ii).

The OR and a researcher from the University of Arizona have provided human food safety data for the use of oxytetracycline in shrimp. The OR provided analytical support to complete a tissue residue depletion study conducted by the researcher from the University of Arizona for oxytetracycline in shrimp. The University of Arizona researcher directed the in-life portion of the study. Juvenile Pacific shrimp, *Penaeus vannamei*, were fed 3.4 grams oxytetracycline/kilogram feed for 14 days and then sampled at 0, 12, 24, 36, 48, 72, and 96 hours after treatment.

Feed and tissue samples were sent to the OR laboratory for analysis. The OR analyzed the feed samples by the regulatory high performance liquid chromatography (HPLC) method entitled "Determination of Oxytetracycline in Milk Replacer (FDA/CVM, Revision 1.2, April 1, 1998)." The tissue samples were analyzed by a 1997 version of the regulatory HPLC method for determining oxytetracycline residues in shrimp. While validating the method prior to analyzing the test samples, the OR found that the 1997 method should be revised to emphasize complete collection of the aqueous phase during extraction. The revised regulatory method for analysis of oxytetracycline in shrimp is entitled "Method for the Determination of Oxytetracycline Residues in Uncooked Shrimp Using High Performance Liquid Chromatography," by Steven W. Hadley, Susan K. Braun, and Marleen M. Wekell, FDA, Office of Regulatory Affairs, Division of Field Science, Seafood Products Research Center, December 23, 1999.

At 0 hours withdrawal, oxytetracycline tissue levels ranged from 3.2 to 5.6 parts per million (ppm); at 12 hours, 1.5 to 4.1 ppm; at 24 hours, 1.5 to 2.1 ppm; at 36 hours, 1.2 to 2.0 ppm; at 48 hours, 0.31 to 0.64 ppm; and at 72 hours, <0.25 ppm. The 96-hour samples were not analyzed because residues were below the lowest point on the standard curve by 72 hours withdrawal.

Data and information on human food safety are contained in PMF 5662. Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF to support approval of an application filed under 21 CFR 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF: Effectiveness data, target animal safety data, animal drug labeling, and other information needed for approval. Other information needed for approval may include data supporting extrapolation

from a major species in which the drug is currently approved or authorized reference to such data; data concerning manufacturing methods, facilities, and control; and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA or supplement may contact Julia A. Oriani (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information provided in this PMF to support approval of an application may, upon approval of such application, be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies (TSE) 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 1, 2000, 8:30 a.m. to 5:30 p.m. and on June 2, 2000, 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Ballroom II, Montgomery Village Ave., Gaithersburg, MD.

Contact Person: 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 1, 2000, the committee will discuss policies for deferral of blood and plasma donors because of their possible exposure to the agent of bovine spongiform encephalopathy (BSE). On June 2, 2000, the committee will discuss the scientific merit of leukoreduction as a method to reduce the theoretical risk of Creutzfeldt-Jakob Disease (CJD) and/or new variant CJD (nvCJD) in blood and blood components for transfusions as well as plasma for manufacture into derivatives. In the afternoon, the committee will receive an update on the regulatory status of human dura mater.

Procedure: On June 1, 2000, from 8:30 a.m. to 5 p.m. and June 2, 2000, from 8:30 a.m. to 3:30 p.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 May 15, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9 a.m., and 1 p.m. to 1:30 p.m. on June 1, 2000, and between 8:30 a.m. to 9 a.m. and 1 p.m. to 1:30 p.m. on June 2, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 22, 2000, 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 1, 2000, from 5 p.m. to 5:30 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 is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 21, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-11200 Filed 5-4-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1266]

Report to Congress on Pediatric Exclusivity; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on the pediatric exclusivity program established by the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). This action is being taken to assist the agency in preparing a report to Congress on