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.

[FR Doc. 00–11329 Filed 5–4–00; 8:45 am]

BILLING CODE 4160–01–F

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. These 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]

BILLING CODE 4160–01–M

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