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

pediatric exclusivity as required by the Federal Food, Drug, and Cosmetic Act (the act). FDA is seeking public input on the pediatric exclusivity program.

DATES: Submit written comments on the pediatric exclusivity program by June 5, 2000.

ADDRESSES: Submit written comments on the pediatric exclusivity program to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of this notice are available on the Internet at http://www.fda.gov/cder/pediatrics.

FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, FAX 301–827–2520, e-mail: crescenzit@cder.fda.gov, or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0641, FAX 301–827–0644, e-mail: esber@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is seeking public comment on the pediatric exclusivity program. Section 111 of the Modernization Act (Public Law 105–115), signed into law by President Clinton on November 21, 1997, created section 505A of the act (21 U.S.C. 355a). Section 505A of the act permits certain new drug applications to obtain an additional 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits information relating to the use of the drug in the pediatric population.

Under section 505A(k) of the act, FDA must submit a report to Congress on the pediatric exclusivity program.

II. Description of the Report

Under section 505A(k) of the act, FDA must conduct a study and report to Congress not later than January 1, 2001, on the experience under the pediatric exclusivity provisions of the act. The study and report must examine all relevant issues, including:

1. The effectiveness of the program in improving information about important pediatric uses for approved drugs;

2. The adequacy of the pediatric exclusivity incentive;

3. The economic impact of the pediatric exclusivity program on taxpayers and consumers and the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and

4. Any suggestions for modification.

III. Request for Comments

FDA invites all interested parties to address the specific topics that will be included in the report or any other general issue appropriate for this report relevant to the pediatric exclusivity provision of the act. Interested persons may submit to the Dockets Management Branch (address above) written comments on the pediatric exclusivity program by June 5, 2000. 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. 00–11328 Filed 5–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–462A/B]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Adverse Action Extract and Supporting Regulations at 42 CFR 483.1840; *Form No.:* HCFA–462A/B (OMB 0938–0655; *Use:* The CLIA Adverse Action Extract will be used by HCFA surveyors (State health department, and other HCFA agents) to report to regional staff and record the adverse actions imposed against a laboratory. The form will also serve to track dates of the imposition of adverse actions, date on which a laboratory corrects deficiencies, and all appeals activity; *Frequency:* On occasion, Biennially; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 52; *Total Annual Responses:* 1573; *Total Annual Hours:* 786.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 26, 2000.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–11215 Filed 5–4–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1957]

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