Dates and Time: The meeting will be held on November 2 and 3, 1999, from 8:30 a.m. to 5 p.m. Interested persons and organizations may submit written comments by September 30, 1999, to the Dockets Management Branch (address below).

Location and Addresses: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research, (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: Presentations and committee discussions will address issues related to testing for development of resistant human immunodeficiency virus (HIV–1), with an emphasis on its potential role in antiretroviral drug development. The primary objectives of these deliberations are to obtain advisory committee recommendations on the amount and type of resistance data needed to support both preclinical and clinical development of antiretroviral drugs and product labeling. This 2-day meeting will explore the following scientific issues: (1) Performance characteristics of genotypic and phenotypic assays, (2) definitions of antiviral drug resistance, (3) relationships between the development of mutations or reduced susceptibility and treatment outcome, and (4) available evidence supporting the clinical utility of testing for the development of antiviral drug resistance. In order to prepare presentations and discussions for the meeting, the agency is requesting interested persons to submit in writing the following types of relevant data, information, and views:

- Pre-clinical and/or clinical trial data on the relationship between the development of HIV mutations and changes in susceptibility to antiviral therapies.
- Prospective or retrospective clinical trial data on the relationship between genotype and/or phenotype and treatment outcome.
- Proposals for incorporating HIV resistance testing in clinical trial design.
- Proposals for utilizing information derived from HIV resistance testing to support product labeling.

These submissions should contain the following docket number, 99N–2670, and should be made to the Dockets Management Branch address provided previously in this document.

Procedure: 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 October 27, 1999. Oral presentation from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 3, 1999. Time allotted for each presentation may be limited. Written submissions may be made to the contact person by October 27, 1999. Those desiring to make formal oral presentations should notify the contact person before October 27, 1999, 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.

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

Dated: August 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–21729 Filed 8–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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). The meeting will be open to the public.

Name of Committee: Oncologic Drugs 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 September 16 and 17, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 16, 1999, the committee will discuss: (1) New drug application (NDA) 21–053, UFT® (tegafur and uracil) Capsules, Bristol-Myers Squibb Co., indicated, with leucovorin calcium tablets, for the first-line treatment of metastatic colorectal cancer; and (2) NDA 50–772, Evacet™ (doxorubicin HCl liposome injection), The Liposome Co., Inc., indicated for the first-line treatment of metastatic breast cancer in combination with cyclophosphamide. On September 17, 1999, the committee will discuss: (1) NDA 20–262/S–033, TAXOL® (paclitaxel) Injection, Bristol-Myers Squibb Co., indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard combination therapy; and (2) biologics license application (BLA) 97–1001, Roferon®-A, Hoffman-La Roche Inc., indicated for use as adjuvant treatment of surgically resected malignant melanoma without clinical evidence of nodal disease, American Joint Committee on Cancer stage II (Breslow thickness>1.5 millimeter, N0). In addition, FDA will provide an update on the preliminary results of EST 1690 (ECOG intergroup study of INTRON A for the adjuvant treatment of melanoma) for discussion by the committee.

Procedure: 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 September 8, 1999. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and between approximately 1:15 p.m. and 1:30 p.m. on September 16, 1999, and between approximately 8:15 a.m. and 8:45 a.m., and between approximately 1:15 p.m. and 1:30 p.m. on September 17, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 1999, 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. After the scientific presentations, a 30-minute open public session will be conducted for interested persons who have submitted their

request to speak by September 8, 1999, to address issues specific to the submission or topic before the committee.

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

Dated: August 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–21812 Filed 8–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Applicant: Missouri Department of Conservation, Jefferson City, Missouri.

The applicant requests a permit to take (collect) endangered *Cambarus aculabrum* (cave crayfish, no common name) in the State of Missouri. Activities are proposed for the enhancement of survival of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with this application are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: US Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/713–5343); FAX: (612/713–5292).

Dated: August 17, 1999.

T.J. Miller,

Acting Program Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 99–21844 Filed 8–20–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Aquatic Nuisance Species Task Force Ballast Water Effectiveness and Adequacy Criteria; Committee Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces the second meeting of the Ballast Water Effectiveness and Adequacy Criteria Committee. The meeting topics are identified in the **SUPPLEMENTARY INFORMATION.**

DATES: The Committee will meet from 1:00 p.m. to 4:30 p.m., on Thursday, September 9, 1999.

ADDRESSES: The meeting will be held at the National Oceanic and Atmospheric Administration (NOAA) complex, SSMC–IV, Room 1–W–611 (first floor), 1305 East West Highway, Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: Sharon Gross, Executive Secretary, Aquatic Nuisance Species Task Force at 703–358–2308 or by e-mail at: sharon__gross@fws.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 1), this notice announces a meeting of the Aquatic Nuisance Species Task Force Ballast Water Program Effectiveness and Adequacy Criteria Committee. The Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990.

The Committee was established in 1997 to establish and periodically resolve criteria for assessing the effectiveness and adequacy of the national ballast water management program in reducing the introduction and spread of nonindigenous species. The ANS Task Force is required to develop criteria for determining the adequacy and effectiveness of the voluntary ballast water management guidelines and subsequent regulations promulgated by the U.S. Coast Guard. The focus of this meeting will be to: review the Committee's overall responsibilities; establish objectives and goals for the requirements for which criteria are sought; discuss the process for developing the criteria; and set a preliminary time-frame for developing the criteria.

Minutes of the meeting will be maintained by the Executive Secretary, Aquatic Nuisance Species Task Force, Suite 851, 4401 North Fairfax Drive, Arlington, Virginia 22203–1622, and will be available for public inspection during regular business hours, Monday through Friday.

Dated: August 18, 1999.

Rowan Gould,

Acting Co-Chair, Aquatic Nuisance Species Task Force, Acting Assistant Director—Fisheries.

[FR Doc. 99–21810 Filed 8–20–99; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–040–1220–00]

Closure for Shay Line Trestle, Order ID–060–18

AGENCY: Bureau of Land Management, Upper Columbia-Salmon Clearwater District, Challis Resource Area, Idaho, Interior.

ACTION: Notice of Closure for Shay Line Trestle, Order ID–060–18.

SUMMARY: By order, the historic Shay Line railroad trestle, located on Bureau of Land Management (BLM) administered land, is temporarily closed to all use. This action affects only the historic Shay Line trestle located in T. 6 N., R. 24 E., Sec. 6, NW¼NW¼ Custer County, Idaho. This closure will remain in effect until the structural safety of the trestle can be more completely investigated and a determination made on whether it can be restored to a safe condition or be closed permanently. The purpose of temporarily closing the trestle is for public safety. A preliminary inspection by a professional engineer has disclosed potential problems which require further investigation to determine if the trestle can be restored.

The authority for establishing this closure is Title 43, Code of Federal Regulations, § 8364.1.

This closure is effective August 23, 1999.

Violation of this order is punishable by a fine not to exceed $1,000 and/or imprisonment not to exceed one year.

FOR FURTHER INFORMATION CONTACT: Renee Snyder, Challis Area Manager, Rt. 2 Box 610, Salmon, Idaho 83467. Telephone (208) 756–5400.

Dated: August 10, 1999.

Renee Snyder,

Area Manager.

[FR Doc. 99–21553 Filed 8–20–99; 8:45 am]

BILLING CODE 4310–GG–M