post-approval, from all clients with positive or inconclusive results and from a random sampling of clients who test negative, and to expedite post-approval the collection of demographic information from all clients who test negative; (3) compare, for 3 years post-approval, demographic data of Confide® HIV Testing Service clients with data obtained from persons using other testing services; and (4) conduct a first year post-approval study to determine the proportion of test cards submitted with adequate samples.

A summary of the safety and effectiveness data on which CBER based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CBER's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CBER's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before December 6, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.53).

Dated: October 18, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–28580 Filed 11–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0305]

Epitope, Inc.; Premarket Approval of OraSure® HIV–1 Western Blot Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by Epitope, Inc., Beaverton, OR, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the OraSure® HIV–1 Western Blot Kit. FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of June 3, 1996, of the approval of the application.

DATES: Petition for administrative review by December 6, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sukza Hwangbo, Center for Biologics Evaluation and Research (HFM–380), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3524.

SUPPLEMENTARY INFORMATION: On June 8, 1995, Epitope, Inc., Beaverton, OR 97008, submitted to CBER an application for premarket approval of the OraSure® HIV–1 Western Blot Kit (OraSure®). The device is intended for use as an in vitro qualitative assay for the detection of antibodies to the human immunodeficiency virus Type 1 (HIV–1) in human oral fluid specimens obtained with the OraSure® HIV–1 Oral Specimen Collection Device. The premarket approval for the OraSure® HIV–1 Oral Specimen Collection Device was announced in the Federal Register of May 24, 1996 (61 FR 26187). The OraSure® HIV–1 Western Blot Kit is indicated for use as an additional, more specific test for HIV–1 antibodies in OraSure® HIV–1 Oral Specimen Collection Device specimens collected from individuals, found to be repeatedly reactive by the Oral Fluid Vironostika® HIV–1 Microelisa System screening test manufactured by Organon Teknika Corp. On June 3, 1996, CBER approved the application by a letter to the applicant from the Director, Office of Blood Research and Review, CBER.

The June 3, 1996, approval letter included two specific conditions of approval for the OraSure® HIV–1 Western Blot Kit. One condition states that an expiration dating period of 18 months at 2–8 °C was granted for OraSure® HIV–1 Western Blot Kit. The protocol used to establish the expiration dating is an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8). The other condition specifies that OraSure® HIV–1 Western Blot Kit is intended for professional use only and that commercial distribution of the device is limited to sale for use within a clinical laboratory setting.

FDA has determined that, to ensure safe and effective use, the device is restricted within the meaning of section 520(e) of the act (21 U.S.C. 360j(e)) under the authority of section 515(d)(1)(B)(ii) of the act (21 U.S.C. 360e(d)(1)(B)(ii)) insofar as the device is intended for professional use only and commercial distribution is limited to sale for use within a clinical laboratory setting. The sale, distribution, and use of the device must not violate section 502(q) and (r) of the act (21 U.S.C. 352(q) and (r)).

A summary of the safety and effectiveness data on which CBER based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CBER's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CBER's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under

§ 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before December 6, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.53).

Dated: October 25, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–28531 Filed 11–5–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability, Joint Environmental Assessment and Restoration Plan

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of availability.

SUMMARY: The U.S. Fish and Wildlife Service (Service), on behalf of the Department of the Interior and States of Indiana and Ohio, announces the release for public review of the draft Joint Environmental Assessment and Restoration Plan (Plan) for the Fish Creek #2 Diesel Fuel Spill. The Plan covers the co-trustees' proposal to restore natural resources injured as a result of the 1993 Fish Creek spill. A public information meeting addressing the plan will be held on November 14, 1996, in Edgerton, Ohio.

DATES: Written comments must be submitted on or before December 16, 1996.

ADDRESSES: Requests for copies of the Plan may be made to: U.S. Fish and Wildlife Service, Ecological Services, 620 South Walker Street, Bloomington, Indiana 47403–2121.

Written comments or materials regarding the Plan should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: David C. Hudak, Field Supervisor, U.S. Fish and Wildlife Service, 620 South Walker Street, Bloomington, Indiana 47403–2121 (Attention: Environmental Contaminants Program).

Interested parties may also call (812) 334–4261 for further information.

SUPPLEMENTARY INFORMATION: On September 15, 1993, a pipeline ruptured and discharged approximately 30,000 gallons of diesel fuel that flowed into Fish Creek, in DeKalb County, Indiana, and spread into Williams County, Ohio. Fish Creek, which is located in northeastern Indiana, northwestern Ohio, and portions of southwest Michigan, supports a diverse mussel fauna. At least 30 species of mussels are known to exist in the watershed. Fish Creek is the only place in the world that the white cat's paw pearly mussel (Epioblasma obliquata perobliqua), a Federally-listed endangered mussel, is known to exist. Fish Creek also is known to harbor two other Federally-listed endangered mussel species, the northern riffleshell (Epioblasma rangiana) and the clubshell (Pleurobema clava). Several state-listed endangered mussels also occur in the affected reaches of Fish Creek. Following the spill, mortality of mammals, migratory birds, fish, reptiles, amphibians, and mussels was observed in the spill plume are of Fish Creek.

In 1996, the United States of America, the State of Indiana, and the State of Ohio settled claims for natural resource damages associated with the 1993 Fish Creek oil spill under authority of the Oil Pollution Act. The settlement proceeds shall be used to compensate for injury, destruction, or loss of natural resources under trusteeship of the Department of the Interior, State of Indiana, and State of Ohio. The Plan is being released in accordance with the Natural Resource Damage Assessment Regulations found at 15 CFR, part 990. It is intended to describe the co-trustees' proposals to restore natural resources lost as a result of this spill.

Restoration efforts will include the combination of protection and enhancement activities that have the greatest potential to restore the natural resources of Fish Creek to pre-spill conditions, with particular emphasis on the endangered mussels. The Plan focuses: (1) on increased endangered mussel recovery efforts; (2) water quality improvement; (3) riparian corridor protection; (4) community outreach and education; and, (5) monitoring to determine if the selected restoration actions are successful.

Interested members of the public are invited to review and comment on the Plan. Copies of the Plan are available for review at the U.S. Fish and Wildlife Service's Ecological Services Field Office in Bloomington, Indiana (620 South Walker Street, Bloomington, Indiana); the Indiana Department of Natural Resources (402 West Washington, Room 273, Indianapolis, Indiana 46204–2748); the Indiana Department of Environmental Management (2525 North Shadeland Avenue, Room 202, Indianapolis, Indiana 46206–6015); the Ohio Environmental Protection Agency (P.O. Box 1049, 1800 Watermark Drive, Columbus, Ohio 43216–1049 or the Northwest District Office, 347 North Dunbridge Road, Bowling Green, Ohio 43402); and the Ohio Department of Natural Resources (1930 Belcher Drive, Columbus, Ohio 43224–1387). Additionally, the Plan will be available for review at the following community libraries: Angola, Indiana; Auburn, Indiana; Bryan, Ohio; Butler, Indiana; Edgerton, Ohio; Edon, Ohio; and Fremont, Indiana.

An informational meeting, open to the public, will be held to explain the Plan, provide information, receive written comments, and to answer any questions. The meeting will be held at the Miller Park Shelter House, Miller Park Drive, Edgerton, Ohio on November 14, 1996, from 7 p.m. to 9 p.m. Written comments will be considered and addressed in the final Plan at the conclusion of the restoration planning process.

William F. Hartwig,

Regional Director, Region 3, U.S. Fish and Wildlife Service.

[FR Doc. 96–28562 Filed 11–5–96; 8:45 am]

BILLING CODE 4310–55–M

Aquatic Nuisance Species Task Force Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.