[Docket No. 95N–0212]

Epitope, Inc.; Premarket Approval of OraSure® HIV–1 Oral Specimen Collection Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Epitope, Inc., Beaverton, OR, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the OraSure® HIV–1 Oral Specimen Collection Device. FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of December 23, 1994, of the approval of the application. A revised approval letter was issued on October 18, 1995.

DATES: Petitions for administrative review by June 24, 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 May 9, 1991, Epitope, Inc., Beaverton, OR 97008, submitted to CBER an application for premarket approval of the OraSure® HIV–1 Oral Specimen Collection Device. The device is intended for use in the collection of oral fluid specimens by properly trained individuals for the purpose of testing for the presence of antibodies to human immunodeficiency virus Type 1 (HIV–1). The OraSure® HIV–1 Oral Specimen Collection Device consists of both an absorbent cotton fiber pad treated with a proprietary salt solution and gelatin affixed to a plastic stick, and a preservative solution supplied in a plastic container. OraSure® HIV–1 oral fluid specimens are intended to be used only with the Oral Fluid Vironostika HIV–1 Microelisa System screening test manufactured by Organon Teknika Corp. The device is intended for use with subjects 13 years of age or older.

On December 19, 1992, the premarket approval application (PMA) was referred to the Blood Products Advisory Committee, an FDA advisory committee, for review and recommendation. On June 22, 1994, the PMA was referred to the same advisory committee for discussion of post-approval requirements for surveillance studies.

On December 23, 1994, CBER approved the application by a letter to the applicant from the Acting Director, Office of Blood Research and Review, CBER. In response to additional discussions between the manufacturer and FDA, a revised approval letter was issued on October 18, 1995.

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: (1) Before shipping the device to any customer, Epitope, Inc., must have on file a ''Letter of Agreement for Physician'' signed by the physician who agrees to assume the outlined responsibilities on behalf of the customer; (2) the administration of the device is restricted to individuals who have been trained in the use of the device according to approved labeling; (3) testing of OraSure® samples for HIV–1 antibodies is restricted to the Oral Fluid Vironostika HIV–1 Microelisa System screening test manufactured by Organon Teknika Corp.; (4) the device is not to be provided to subjects for home use; (5) the device is not to be used to screen blood donors; and (6) prior to specimen collection, a test subject must receive a copy of the subject information sheet. The sale, distribution, and use of the device must not violate sections 502(q) and (r) of the act (21 U.S.C. 352(q) and 352(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 (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 June 24, 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: May 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13176 Filed 5–23–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current

information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Science Board to the Food and Drug Administration

Date, time, and place. June 13, 1996, 8:30 a.m., Sheraton—Crystal City, Ballroom A, 1800 Jefferson Davis Hwy., Arlington, VA.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; Susan Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603. Please call the hotline for information concerning any possible changes.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor, and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations must notify the contact person before June 6, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

Open board discussion. The board will continue its discussions related to FDA's approach to toxicity, carcinogenicity and biomaterials testing.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: May 20, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–13105 Filed 5–23–96; 8:45 am]

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Advisory Committees; Notice of Meetings

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