certificates without attachments issued for the same product(s) in response to the same request.

(4) CDRH: $100 for the first certificate; $10 for any subsequent certificates issued for the same product(s) in response to the same request.

With this fee structure, the agency estimates that it will recover most of its costs for preparing export certificates. However, despite Congress' stated intention to make this program pay for itself, the $175 maximum fee will likely have the effect of causing a taxpayer subsidy for a portion of the program. FDA may consider changing the fees for export certificates in the future (within the parameters permitted by statute) if agency costs increase or decrease. For example, FDA does not know whether the agency costs of issuing export certificates for unapproved products (which the agency will now do as a result of the Export Reform and Enhancement Act of 1996) will differ significantly from those for approved products.

III. Request for Comments

Although the FDA Export Reform and Enhancement Act of 1996 does not require FDA to solicit comments on assessment and collection of fees for export certificates, FDA is inviting comments in order to have the benefit of additional views and information. FDA is particularly interested in receiving information about the effect of these fees on small businesses. The agency also would be interested in receiving comments on whether the fee structure should reflect cost averaging across all Centers that prepare export certificates under the act, so that the agency could fully recover preparation costs and avoid the use of taxpayer funds.

Interested persons may on or before February 4, 1997, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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 and a full explanation of the costs included and the methodology employed in determining these fees may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 31, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28529 Filed 11–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0330]

Direct Access Diagnostics; Premarket Approval of Confide® HIV Testing Service Using Dried Blood Spots

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Direct Access Diagnostics, Bridgewater, NJ, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Confide® HIV Testing Service Using Dried Blood Spots (Confide® HIV Testing Service). After reviewing the recommendation of the Blood Products Advisory Committee, FDA's Center for Biologics Evaluation and Research (CBER) notified the applicant, by letter of May 14, 1996, of the approval of the application.

DATES: Petitions 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 December 30, 1987, Direct Access Diagnostics, Bridgewater, NJ 08807, submitted to CBER an application for premarket approval of the Confide® HIV Testing Service Using Dried Blood Spots. The service is intended for self-use by individuals who wish to obtain anonymous human immunodeficiency virus Type 1 (HIV–1) testing and counseling. The HIV–1 assay kits approved for use in the Confide® HIV Testing Service are: Vironostika HIV–1 Microelisa System manufactured by Organon Teknika Corp., Genetic Systems LAV EIA manufactured by Genetic Systems Corp., Fluorognost HIV–1 IFA manufactured by Waldheim Pharmazuetika, and HIV–1 Western Blot Kit manufactured by Cambridge Biotech Corp. The Confide® HIV Testing Service is a single use test kit consisting of aseptic wipes, two finger-stick lancets, a test card precoded with a personal identification number (PIN), an identification (ID) card which also contains the PIN, a postage-paid, pre-addressed mailer and instructions for use. Accompanying the instructions is a brochure explaining important facts about HIV–1 infection and transmission, HIV–1 testing and acquired immune deficiency syndrome (AIDS). An individual will use the test kit to obtain a sample of their own blood. The blood sample is placed on the designated area of the test card, identified only by a unique PIN, and mailed to Direct Access Diagnostics using the provided mailer. Upon receipt, the test is analyzed by Direct Access Diagnostics using enzyme-linked immunosorbent assays (ELISA) licensed for the detection of HIV–1 antibodies. Results are released to the individual in possession of the ID card and PIN. The device is intended for use with individuals 18 years of age or older.

On June 22, 1994, CBER consulted the Blood Products Advisory Committee (BPAC), an FDA advisory committee, for their comments and recommendations regarding issues FDA should address when reviewing home collection testing kits for the detection of HIV and other serious or life-threatening medical conditions. BPAC commented that the benefits of an alternative means of accessing previously unreachable populations of HIV positive individuals or persons infected with other serious diseases, far outweighed any risk to the individual's health posed by the test kit protocol or to the public's health by home testing. BPAC recommended that pilot studies be conducted to assess demographically, qualitatively, and quantitatively the test's effectiveness in targeted populations. BPAC also recommended that pilot studies be performed to determine the test's effectiveness in ensuring client anonymity and providing adequate counseling. CBER considered the BPAC recommendations during its review of the premarket approval application for the Confide® HIV Testing Service. On May 14, 1996, CBER approved the application by a letter to the applicant from the Director, Center for Biologics Evaluation and Review.

The May 14, 1996, application approval letter restated post-approval conditions agreed to by Direct Access Diagnostics in a May 8, 1996, letter to FDA. These conditions incorporate the June 22, 1994, BPAC recommendations. Under the terms of the post-approval conditions Direct Access Diagnostics will: (1) Be fully responsible for product qualifications and acceptance testing of all tests utilized in the Confide® HIV Testing Service and report test results to the agency every 6 months; (2) collect demographic and risk behavior surveillance data, at both the State and national level, for a period of 3 years

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