required to issue certificates for foods, feed additives, nonmedicated feeds, pet foods, and cosmetics, the agency intends to continue to provide this service. In addition to issuing export certificates for products that are approved, licensed, or otherwise in compliance with the applicable requirements of the act, FDA will issue export certificates for products that meet the requirements for export of section 801(e) or 802 of the act (21 U.S.C. 381(e) or 382) but may not otherwise be marketed, sold, offered for sale, or distributed in interstate commerce.

Revised CPG 7150.01 ''Certification for Exports'' describes current agency views on issuing certificates requested by firms to facilitate the export of FDA-regulated products to other countries. While the agency recognizes the current importance of fulfilling requests for export certificates, FDA's long-term goal is to reduce or eliminate export certificates by finding other means to satisfy other countries' needs for reassurance about imported products. The new CPG replaces CPG 7150.01, entitled ''Certificates for Export'' that was issued in 1994.

Although this CPG does not create or confer any rights or benefits for or on any person and does not operated to bind FDA or industry, it does represent the agency's current thinking on issuing export certificates.

Dated: October 31, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28528 Filed 11–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0383]

Export Certificates; FDA Export Reform and Enhancement Act of 1996; Certification Fees for Drugs, Animal Drugs, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fees for issuing export certificates. The FDA Export Reform and Enhancement Act of 1996 provides that any person who exports a drug, animal drug, or device may request FDA to certify in writing that the exported drug, animal drug, or device meets certain specified requirements. It further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification, and that FDA may charge up to $175 for each certification that is issued within the 20 days. This notice describes the fee schedule for export certifications, the costs that form the basis for those fees, and the billing and collection processes. The agency requests comments on the fee schedule and its effects on small business.

DATES: The fees described herein for export certificates for drugs, animals drugs, and devices became effective October 1, 1996. Written comments should be submitted by February 4, 1997.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lance S. Siegall, Office of Financial Management, Accounting Reports and Analysis Branch (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1768.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Export Reform and Enhancement Act of 1996 became law on April 26, 1996 (Pub. L. 104–134, amended by Pub. L. 104–180, August 6, 1996). The principal purpose of the new law is to expedite the export of FDA-regulated products (both approved and unapproved) through amendments to sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e) and 382). The new law adds a new subsection 801(e)(4) to the act that provides that any person who exports a drug, animal drug, or device may request FDA to certify in writing that the exported drug, animal drug, or device meets the requirements of sections 801(e)(1) or 802 of the act, or other applicable requirements of the act. Upon a showing that the product meets the applicable requirements, the new law further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification, and that FDA may charge up to $175 for each such certification that is issued within the 20 day period.

Export certificates are issued for: Drugs, biologics, animal drugs, and medical devices by FDA's: Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Veterinary Medicine (CVM), and the Center for Devices and Radiological Health (CDRH), respectively. Although FDA's Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for food products and cosmetics, and CVM issues export certificates for feed additives, nonmedicated feeds, and pet foods, the export certificates for these products are not covered by the new law.

II. Agency Costs and Fees to be Assessed for Export Certificates

FDA has determined the costs to the agency for preparing export certificates based upon the following:

(1) Direct personnel for the research, review, tracking, writing, and assembly;

(2) Purchase of equipment and supplies used for tracking, processing, printing, and packaging. Recovery of the cost of the equipment is calculated over its useful life;

(3) Billing and collection of fees; and

(4) Overhead and administrative support.

These costs vary with the Center issuing the certificates, largely because of differences in the types of products, and the procedures used in evaluating the compliance status of the manufacturing site(s). As mentioned above, the agency may charge up to $175 for each certificate. Certificates for some classes of products cost the agency more than $175 to prepare. Subsequent certificates issued for the same products in response to the same request generally cost the agency less than $175. The fee for the second certificate for the same product(s) issued in response to the same request reflects the agency cost for preparing the second certificate plus the difference (if any) between the agency cost for preparing the first certificate and the $175 maximum fee. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects agency costs for preparing those certificates only. The agency has developed the following fee structure, which reflects agency costs for the following Centers:

(1) CBER: $175 for the first certificate; $175 for the second certificate for the same product(s) issued in response to the same request; $85 for each subsequent certificate for the same product(s) issued in response to the same request.

(2) CVM: $175 for the first certificate; $155 for the second certificate for the same product(s) issued in response to the same request; $70 for each subsequent certificate for the same product(s) issued in response to the same request.

(3) CDER: $175 for the first certificate; $90 for the second certificate with attachments for the same product(s) issued in response to the same request; $40 for any subsequent certificates with attachments for the same product(s) issued in response to the same request; $15 for second and subsequent

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