



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

January 31, 1997

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Re: HIV-1 Urine EIA Test Kit
() HIV-1 Urine EIA)
Our File: RFD 96.032

Dear Mr. ()

This responds to your letter of November 22, 1996, on behalf of Calypte Biomedical Corporation (Calypte), concerning the prospective regulatory treatment of Calypte's HIV-1 Urine EIA test kit.

The product is an *in vitro* diagnostic test kit designed to detect antibodies to HIV-1 in human urine specimens, using standard microwell enzyme immunoassay (EIA). The product includes pre-coated microwell plates, an enzyme-labeled conjugate, substrate tablets, diluents and various other *in vitro* diagnostic materials. The product is intended for use as an aid in the clinical diagnosis of Human Immunodeficiency Virus (HIV) infection, rather than for use as a blood screening test or as a confirmatory test.¹

While the HIV-1 Urine EIA test kit was approved as a biological product, you argue that the primary mode of action of the product is as a medical device. Your request notes that there are a number of other HIV assays not intended for blood screening that have been approved by the Center for Biologics Evaluation and Research (CBER) under the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You urge that the product be regulated as a device so that the regulatory treatment of the HIV assays are "brought into conformity." You

¹ The confirmatory test used for this kit is proposed to be a Western blot assay. Also, a set of HIV-1 urine controls have been developed as an accessory to the Western blot for use when urine specimens are assayed. Your November 22, 1996 letter did not propose any change in the regulatory treatment of either the Western blot confirmatory test or the accessories.

did not suggest that the product be regulated other than by the Center for Biologics Evaluation and Research (CBER), which currently has primary responsibility for the review of HIV-1 test kits for diagnosis or blood screening.

We have discussed your request with staff in CBER, the Center for Devices and Radiological Health (CDRH), and the Office of the Chief Counsel, and agree that the HIV-1 Urine EIA test kit may be reviewed and regulated as a medical device, under the premarket approval application (PMA) provisions of the Act, 21 U.S.C. 360e. The Office of Blood Research and Review (OBRR) in CBER will remain the agency component with primary jurisdiction for this product.

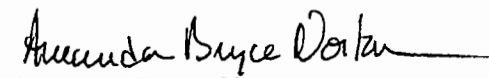
To effect the change to PMA status, Calypte should submit a PMA cover letter to CBER that (1) incorporates by reference the data in the approved license application and (2) requests voluntary revocation of the license at the time PMA approval is effective. We are advised by OBRR that minor labeling changes will also be necessary. Consistent with the regulation of other devices intended for use in the clinical diagnosis of HIV infection, lot release requirements will apply. OBRR is prepared to provide additional guidance. For further information, contact Leonard Wilson, Ph.D., Branch Chief, Biologics Devices Branch, at the Division of Blood Applications, OBRR, CBER, 1401 Rockville Pike (HFM-370), Rockville, MD 20852-1448 or at 301-827-3524.

Please submit a copy of this letter in your next submission to CBER.

Please note that this letter applies only to the HIV-1 Urine EIA test kit intended to be used as an aid in the clinical diagnosis of HIV infection, and not for blood screening or as a confirmatory test. If Calypte is interested in expanding the intended use to include blood screening, confirmatory testing, or other indications, Calypte should seek a new agency determination of the applicable regulatory requirements.

If you have any questions concerning this matter, please contact Ms. Andrea Chamblee, of this office, at 301-827-3390.

Sincerely yours,


Amanda Bryce Norton
Chief Mediator and Ombudsman

cc: Leonard Wilson