DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

August 16, 2006

CBER-06-009

FEDEX

Mr. Kevin Chen
Tyson
5F #22 Ke East Road
Chu Nan, None 132311
Taiwan

Dear Mr. Chen:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research of the Food and Drug Administration (FDA) has reviewed your Internet websites http://www.hiv-home-test-kit.com and http://www.test-hiv-yourself.com for the HIV Self Test Kits (Home test kit) and the HIV Self Test Kits respectively. Your websites promote your screening devices as rapid home tests to determine the presence of Human Immunodeficiency Virus (HIV) in human blood. Copies of the pertinent Internet website pages are enclosed for your reference.

HIV test kits are medical devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act) because they are in vitro diagnostic instruments intended for use in the diagnosis of disease. Under section 513(f) of the Act, these are class III devices, which under section 501(f)(1)(B) are deemed to be adulterated unless they have received pre-market approval under section 515 or an investigational device exemption (IDE) under section 520(g). These statutory provisions protect the public health and ensure that new medical devices are safe and effective.

The device promoted on your Internet websites is not approved in the Unites States and has not received an investigational device exemption from pre-market approval. The internet websites above do not exclude the sale of the HIV Self Test Kit in the United States. Further, both of your websites appear to promote the HIV Self Test Kit to buyers around the world including buyers in the United States. For example, your websites shipping and billing information page drop down menu lists all the States and territories of the United States. In addition, your websites www.hiv-home-test-kit.com and www.test-hiv-yourself.com include statements such as "$3.95 per order ship to any where in the world *base on us dollar*"; and "1 HIV/AIDS SELF TEST KIT $20; 2 HIV/AIDS SELF TEST KITS $35; and 4 HIV/TEST KITS $65."

If you introduce, or deliver for introduction, the unapproved HIV Self Test Kit into interstate commerce in the United States, you would be distributing an adulterated device in violation of sections 301(a) and 501(f)(1)(B) of the Act.

In addition, product labeling that is false and misleading in any particular renders a device misbranded under section 502(a) of the Act. If you introduce, or deliver for introduction, a misbranded device into interstate commerce in the United States, you would be doing so in violation of sections 301(a) and 502(a) of the Act. We are concerned about the accuracy of some of the statements on both your Internet websites. For example, you state:

- "**HIV Self Test Kits** is a test to determine the presence of HIV (Human Immunodeficiency Virus) in Human Blood.;"
- "**HIV Self Test Kits** is the same test approved for and used in hospitals and clinics nationalwide (sic) to test for HIV;"
- "**Safe to Use** Sterile blood Sampling device included;"
- "**Instant Resort**" (sic); and
- "**HIV Self Test Kit** takes only 5 minutes."

On your Internet website www.hiv-home-test-kit.com you state:

- "It is the only home HIV test and is more than 99.9% accurate!"

In addition, on your Internet website www.test-hiv-yourself.com you state:

- "**How accurate is HIV SELF TEST KIT?** The overall accuracy is 99%."

Such statements, when made in connection with products distributed in the United States, must not be false or misleading in any particular.

The HIV Self Test Kit may not be legally marketed in the United States absent pre-market approval or an IDE. To avoid violating the Act, you must refrain from introducing your product into U.S. interstate commerce, and refrain from delivering your product for introduction into U.S. interstate commerce.

If you have any questions regarding this matter, you may contact Ms. Mary D. Davis-Lopez at (301) 827-6201. Please be advised that only written communications are considered official.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosure:

Internet website pages from http://www.hiv-home-test-kit.com and http://www.test-hiv-yourself.com