



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6732

August 29, 1997

WARNING LETTER

Certified Mail
Return Receipt Requested

Our Ref: 2937601

Dr. Wuan Lu, President
United Biotech, Inc.
110 Pioneer Way # C
Mountain View, California 94041-1517

Dear Dr. Lu:

We are writing to you because on June 16 and 18, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as "UBI-Magiwel *** HIV I/II Spot Test", which is repackaged and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act, this product is considered to be a device because it is used to diagnose a medical condition. HIV test kits have been classified as class III devices by the Food and Drug Administration in accordance with Section 513 (f) of the Act. The law requires that manufacturers of class III devices obtain approval of either a premarket approval application pursuant to Section 515 (a) or an application for investigational device exemption (Section 520 (g)) prior to marketing the device or distributing the product. This helps protect the public health by ensuring that new medical devices are safe and effective.

Our records show that you have not submitted a premarket approval application or application for investigational device exemption. Our investigator determined that you have already distributed the devices to [REDACTED]. Distributing these unapproved devices is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) of the Act in that it is a class III device under section 513(f) and you do not have an approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g).

Your device is misbranded under the following sections:

Section 502(o) of the Act in that a notice or other information regarding the device was not provided to FDA as required by section 510(k) and the device was not included in listing information required by section 510(j).

Section 502(f)(1) of the Act in that the labeling fails to bear adequate directions for use in that the insert bears the statement "For Research Use Only", but it does not bear the statement "Not For In Vitro Diagnostic Procedures" which is required by 21 Code of Federal Regulations (CFR) 809.10 (c)(2)(i) for a device that has not been shown effective as an in vitro diagnostic device. On the contrary, the plastic case is labeled "For In Vitro Diagnostic Use". 21 CFR 809.10 (c)(2)(i) requires that all labeling, not just the package insert, bear the statement "For Research Use Only, Not For Use In Diagnostic Procedures".

The inspection also disclosed that the devices have been exported in violation of Section 801(e)(2) of the Act since you did not receive permission from the FDA to export the devices or failed to comply with the export requirements of Section 802 of the Act, in that you have not demonstrated that the export of the devices was in compliance with the requirements outlined in Section 802(b)(1)(A), 802(f), and 802(g) of the Act.

You are in violation of Section 802(g) of the Act since you have failed to comply with the requirements outlined in the statute, as follows:

- a. A simple notification was not provided to the Secretary identifying the device and the country to which such devices were being exported when the exporter first began to export the devices to a country not listed in Section 802(b)(1)(A)(i) or (ii) of the Act. For example, you exported the kits to [REDACTED] in May, 1997 without notifying FDA.
- b. A simple notification was not provided to the Secretary identifying the device when the exporter began to export such device to any country listed in Section 802(b)(1)(A)(i) or (ii) of the Act. For example, you exported the kits to [REDACTED] in February 1997 and March 1997 without notifying FDA.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

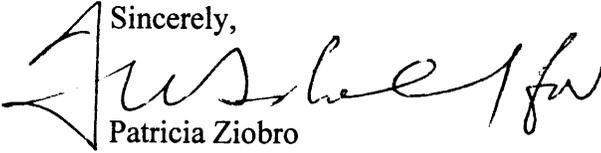
You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Warning Letter
August 29, 1997
United Biotech, Inc.
Mountain View, California

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It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the noted violation, including: (1) the time frame within which the corrections will be completed; (2) the person responsible for effecting correction; and (3) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and time frame within which corrections will be completed.

Your response should be sent to Philip R. Lindeman, Compliance Officer, US Food And Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502, telephone no. (510) 337-6847.

Sincerely,

Patricia Ziobro
Director, San Francisco District