



February 19, 1998

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our ref: 2937601

WARNING LETTER

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

Dear Dr. Lu,

An inspection was conducted of your firm located in Mountain View, California between January 27 and 30, 1998. At that time the investigator determined that your firm manufactures a number of in vitro diagnostic test kits using ELISA technology. These kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality Systems Regulation (QSR) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 820, as follows:

1. You have no written purchasing procedures or specifications for the acceptance of monoclonal antibodies which you receive from [REDACTED] in [REDACTED]. Upon receipt of lot SP077 of Anti-HCG, a few micro well plates were run to verify the identity of the antibody, but this acceptance testing was not documented. [21 CFR 820.80(a)]
2. Your Device Master Record fails to include final acceptance procedures which clearly define the acceptance values for the antibody coated plates. One lot of HCG antibody coated plates, #11B7, actually failed to meet the range of [REDACTED] mIU/ml which United Biotech acknowledges to be an industry standard for measuring performance. The QC

- test record for this lot recorded a value of [REDACTED]. The lot was nevertheless released for distribution. [21CFR820.80(d), 820.86, 820.90, 820.181]
- 3. The document control system at your firm is not effective in assuring that the most recent revisions of procedures have undergone appropriate review and are available to personnel. This is evidenced by lack of approving signature(s) and/or effective dates for your General Audit Plan for Product Quality Assurance, Procedure and Schedules for Periodic Maintenance, and the Complaint Procedure. [21 CFR 820.40(b)]
- 4. Complaint handling procedures were not consistently followed when documenting complaints. Data pertaining to complaints are sometimes not recorded. Additionally, your complaint procedure does not indicate that complaints are to be evaluated to determine whether the event should be reported under Part 803 or 804, Medical Device Reporting. [21 CFR 820.198(a)]
- 5. Your Device History Records were found to be incomplete. For example, the dilution factor had not been recorded for lot #1187 of the HCG Antibody Coated Plates, and there was no indication that the sealing process had been inspected although the lot had been released. Data relevant to processing, such as calculation for total volume of coating buffer, adjustment of the pH, and dilution factor had been omitted from some of the Device History Records reviewed during the inspection. [21 CFR 820.184]

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. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

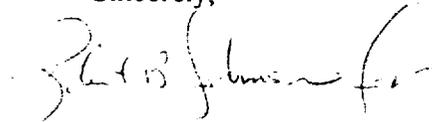
Please notify this office in writing within 15 working days of receipt of this letter, or the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and to assure corrections to any underlying systems problems so that similar

violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to:

Andrea P. Scott  
Compliance Officer  
San Francisco District  
96 North Third St., Suite 325  
San Jose, CA 95112

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia C. Ziobro". The signature is fluid and cursive, with a long horizontal stroke at the end.

Patricia C. Ziobro  
District Director  
San Francisco District