DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

D1233B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-28

March 3, 1997

Dr. Joseph P. D'Angelo
President, Americare Biologicals, Inc.
20 N.W. 181st Street
Miami, FL 33169

Dear Dr. D'Angelo:

During an inspection of your facility at the above address and at [redacted], between the period of August 23 and October 3, 1996, FDA Investigators Angela K. Rhodes and Philippe L. Noisin determined that you manufacture and distribute Ana-Sal HIV Test Kits for home use which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The devices have been illegally exported in violation of section 801(f)(1) of the Act, since the FDA investigators documented serious violations that cause these devices to be adulterated within the meaning of section 501(h) of the Act.

The devices are adulterated under section 501(h) of the Act in that the methods used in, or the facilities or controls used in the manufacture, processing, packing, storage or distribution of Ana-Sal HIV Test Kits are not in conformity with current Medical Device Good Manufacturing Practices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to test finished kits adequately in that just the icon disc is tested using a known positive designed to be used with a serum test kit. The finished kit is not tested for saliva collection, nor is a saliva based positive control used to test the icon disc.

2. Failure to provide written manufacturing specifications or to implement adequate process controls to assure the device performs as declared in the labeling, e.g.: There is no documentation that the kit will perform as intended with saliva substituted for blood serum; there is no data demonstrating the amount of saliva necessary for an accurate

test, or whether the collector absorbs or delivers the necessary amount of saliva; and, there is no data justifying the difference in test procedures (reconstitution of the lyophilized reagent) between single kits and packages of 20 kits, or why two control reagents are included in the 20 test kit package but are not present in the single test kits.

3. Failure to validate significant manufacturing processes and quality assurance tests, e.g., there is no record of the process validation for: The conversion of serum based icon discs for use with saliva; the procedures used to manufacture the wash and block solution; the procedures used to manufacture the GCP lyophilized reagents; and, the manufacturing process for the saliva collectors.

4. Failure to establish a stability program adequate to support the expiration date listed on the test kits.

5. Failure to prepare or implement quality assurance procedures adequate to assure that a formally established and documented quality assurance program is performed.

6. Failure to establish a device master record for the Ana-Sal HIV test kits.

7. Failure to establish and implement device history records for each lot of test kits manufactured.

8. Failure to test kit components after manufacturing and prior to inclusion in the finished kits.

9. Failure to assure that raw materials used in the manufacture of the test kits meet or conform to specifications.

10. Failure to establish and implement an adequate complaint handling program, nor has a formally designated unit been established to review and evaluate such complaints.

Additionally, 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:

1. 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, Ana-Sal HIV 1 + 2 Test Kits were exported to France on July 26, 1996, without notification.

2. A simple notification was not provided to the Secretary identifying the device and the country to which such device was being exported when the exporter first began to export a device to a country not listed in Section 802(b)(1)(A)(i) or (ii) of the Act. For example, Ana-Sal HIV 1 + 2 Test Kits were exported to Ecuador on May 3, 1996, and to Mexico on May 29, 1996, without notification.

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 Inspectional Observations (FDA 483), issued to you during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems (copy enclosed). You are responsible for investigating and determining the causes of the violations identified by the FDA, and promptly initiating permanent corrective actions.

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

Additionally, no pending applications for premarket approval (PMAs) will be approved and no premarket notifications [510(k)s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

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, of specific steps you have taken to correct the noted violations, including (1) each step that has or will be taken to correct the current violations, (2) the timeframe within which the corrections will be completed, (3) the person responsible for effecting correction, and (4) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Please include in the response your intentions regarding the continued illegal exportation of these kits.

Please direct your reply to Martin E. Katz, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, Ext. #262.

Sincerely,

for Douglas D. Tolen
Director, Florida District

Enclosure