



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

2175

Telephone (973) 526-6009
February 12, 2001

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Mr. Robert Khalil
Director of Marketing
Nubenco Enterprises, Inc.
1 Kalisa Way
Paramus, New Jersey 07652

Dear Mr. Khalil:

File No.: 01-NWJ-17

During an inspection of your firm located at 1 Kalisa Way, Paramus, New Jersey, on November 17, 2000, an investigator from the Food and Drug Administration (FDA) determined that you purchase, relabel/repack and distribute the EasiLisa and EasiDot HIV 1 + 2 test kits, manufactured by [REDACTED] located in [REDACTED]. These test kits are medical devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The inspection determined that the EasiLisa HIV 1 + 2 test kit was in domestic commerce, since a shipment was sent to a distributor in the United States for export. Therefore, the EasiLisa HIV 1 + 2 test kit is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f) of the Act and there is no approved application for premarket approval in effect pursuant to section 515(a), or an approved application for investigational device exemption under section 520(g).

The inspection further showed that the EasiLisa HIV 1 + 2 test does not meet the requirements for either of the applicable export exemptions of the Act, sections 801(e)(2) and 802. As a result, the product may not be legally exported, and is fully subject to the Act's adulteration provisions and other requirements.

During the inspection of [REDACTED], Nubenco's manufacturer of the EasiDot HIV 1+2 and EasiLisa HIV 1 + 2 test, you provided copies to [REDACTED] of what you claimed to be marketing authorizations for Turkey and Egypt. Review of the documentation you provided demonstrates that they are actually test result reports and not valid marketing authorizations. Based on your failure to establish either affirmative marketing authorization or that the EasiDot HIV 1 + 2 and the EasiLisa HIV 1 + 2 test can be legally sold in a listed country, the devices do not comply with the requirements for export in section 802 of the Act. Specifically, you have not demonstrated that export of the devices was in compliance with the requirements outlined in 802(b)(1)(A) of the Act.

Also, the devices do not comply with section 801(e)(2) of the Act since you did not receive permission from the FDA to export the devices.

Additionally, you are in violation of section 802(g) of the Act since you failed to provide simple notification to the Secretary identifying the devices and the country to which such devices were being exported when the exporter first began to export the devices to countries both listed and not listed in section 802(b)(1)(A)(i) or (ii) of the Act. For example, you exported the EasiDot HIV 1 + 2 test kit on October 19, 2000 and the EasiDot and EasiLisa HIV 1 + 2 test kits on November 16, 2000, to Saudi Arabia. You also exported the EasiDot and EasiLisa HIV 1 + 2 test kit to Egypt on October 20, 2000.

All devices must be listed with the FDA. The Center for Biologics Evaluation and Research (CBER) has informed us that the EasiDot and EasiLisa HIV 1 + 2 test kits have not been listed. Please be advised that ALL devices must be listed with FDA.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and regulations. 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. Additionally, no pending applications for premarket approval (PMA) will be approved, no premarket notifications [510(k)s] will be found to be substantially equivalent and no requests for Certificates of Exportability will be approved until violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the Food and Drug Administration without further notice. These actions may 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 the specific steps you have taken to correct the noted violations, including each step that has or will be taken to correct the current violations and the timeframe within which the corrections will be completed. For any corrections that cannot be completed within 15 working days, please state the reason for the delay and the timeframe within which corrections will be completed. Direct your reply to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District Office