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CBER-98-008

WARNING LETTER

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

NOV 28 1997

CERTIFIED -- RETURN RECEIPT REQUESTED

Bosco T. Fong
President and COO
Peninsula Laboratories, Inc.
611 Taylor Way
Belmont, CA 94002

Dear Mr. Fong:

The Food and Drug Administration (FDA or the agency) conducted an inspection of Peninsula Laboratories, Inc., 611 Taylor Way, Belmont, CA, on September 24, 1997. During the inspection, the FDA investigator observed significant violations of Section 351(a) of the Public Health Service Act (PHS Act), and Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), and the applicable standards and requirements of Subchapter F, Part 600, Title 21, Code of Federal Regulations (21 CFR), and your product license, as follows:

1. Failure to meet the standards and requirements prescribed in your license, in that:
 - a. batches of Human Immunodeficiency Virus Type 1 (For Further Manufacturing Use) [Lys-13-Cys (Cyclized)], lot 036415, were labeled with an unapproved storage temperature of -20°C and an unapproved expiration period of April 1998. Lys-13-Cys (Cyclized) is approved to be stored only at 4°C for 19 months; and
 - b. stability samples for Lys-13-Cys (Cyclized), lot 036415, were stored in amber, Type I, glass vials. However, the stability protocol entitled "Analytical Methods and Parameters for Auxillary Stability Study," for this lot, indicates that the stability samples were to be stored in clear, Type I, USP glass vials.
2. Failure to promptly report errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any product, in that an error and accident resulting from the improper labeling of batches of Lys-13-Cys (Cyclized), lot 036415, with an unapproved storage temperature of -20°C and an unapproved expiration period of April 1998, was not reported to the Center for Biologics Evaluation and Research [21 CFR 600.14(a)]. The batches of Lys-13-Cys (Cyclized), lot 036415, were distributed on or about May 30 and June 14, 1996.

The above violations are not intended to be an all-inclusive list of deficiencies at your establishment. It is your responsibility, as management, to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction, and/or civil penalties. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We acknowledge receipt of your October 10, 1997, response to the Form FDA-483, that was issued at the conclusion of the most recent inspection of your firm. The promised corrections appear to be adequate and will be verified during follow up inspections of Peninsula Laboratories, Inc.

You should 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 and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Additionally, please include, as part of the response, your plan to address the status of any extant product that was labeled with the unapproved storage temperature and expiration period and was subsequently distributed. You may reference your October 10, 1997, letter in responding to this Warning Letter.

Your reply should be sent to my attention at the following address: Food and Drug Administration, Center for Biologics Evaluation and Research, HFM-600, Suite 200N, 1401 Rockville Pike, Rockville, Maryland 20852-1448.

Sincerely yours,


for. James C. Simmons
Director
Office of Compliance
Center for Biologics
Evaluation and Research