DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CBER–00-008

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

WARNING LETTER

NOV 29 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Neil Marshall, Ph.D.
College of Notre Dame
Department of Natural Sciences
1500 Ralston Avenue
Belmont, California 94002-1997

Dear Dr. Marshall:

During an inspection ending on October 26, 1999, Mr. Carl Anderson, an investigator with the San Francisco District Office of the Food and Drug Administration (FDA), documented that your product, *Triatoma protracta* salivary antigen, has been introduced into interstate commerce in violation of the Public Health Service Act (PHS Act) and the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The inspection revealed that on August 13, 1998 and March 7, 1999, you shipped *Triatoma protracta* antigen to ———————— in Oregon. The inspection disclosed that skin testing or immunotherapy with salivary gland extracts of *Triatoma* species has been performed in human subjects. There is no investigational new drug application (IND) in effect for this biological product, nor is there an approved product license application (PLA).

As defined in the section 351(i) of the PHS Act, a biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment or cure of a disease or condition of human beings. *Triatoma protracta* salivary antigen is a biological product within the meaning of section 351(i) of the PHS Act. *Triatoma protracta* salivary antigen is also a drug within the meaning of section 201(g) of the FD&C Act in that it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

The inspection revealed that section 351(a) of the PHS Act is being violated in that an unlicensed biological product is being introduced or delivered for introduction into interstate commerce, and *Triatoma protracta* salivary antigen is not the subject of an approved product license application or IND. Section 505(a) of the FD&C Act is being violated through introduction into interstate commerce of a new drug, *Triatoma protracta* salivary antigen, without an investigational new drug application in effect, pursuant to section 505(i) of the FD&C Act.

The filing of an approved IND application with the FDA exempts a new drug shipped in interstate commerce (including importation of new drugs) for clinical testing from the requirement that an approved new drug/biologic application be on file with the FDA.

Triatoma protracta antigen is also misbranded under section 502(f)(1) of the FD&C Act in that the labeling fails to bear adequate directions for use for the purposes for which the drug is intended.

The violations cited in this letter are not necessarily intended to constitute an all-inclusive list of deficiencies observed at your facility. It is your responsibility to ensure adherence to each requirement of the FD&C Act, PHS Act, and applicable regulations.

You should notify this office in writing within fifteen (15) business days after receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 business days, state the reason for the delay and the time within which the corrections will be completed. Corrective actions would include, but are not limited to, discontinuing administration of *Triatoma protracta* antigen, halting the interstate shipment of *Triatoma protracta* antigen to colleagues, and the submission of an IND if you determine to conduct clinical research.

Questions regarding submission of an IND application and assistance may be directed to Dr. Paul Richman in the Division of Vaccines and Related Products Applications at (301) 827-3070.

Your response to this letter should be sent to the following address:

Jose Javier Tavarez, M.S.
Food and Drug Administration
Office of Compliance and Biologics Quality
Division of Inspections and Surveillance
1401 Rockville Pike
Rockville, Maryland 20852-1448
Tel. (301) 827-6221

Sincerely,

Steven A. Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation
and Research