DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 22 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref. No.: 99-HFD-45-1201

Frederick Coulston, Ph.D.
CEO, Chairman of the Board
Coulston Foundation
1300 La Velle Road
Alamogordo, NM 88310

Dear Dr. Coulston:

Between July 26 and August 19, 1999, investigators from the Food and Drug Administration (FDA) inspected the nonclinical laboratory facilities of the Coulston Foundation to assess adherence to the Good Laboratory Practice (GLP) regulations, Title 21, Code of Federal Regulations, Part 58. This inspection was conducted as part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to monitor the conduct of research involving investigational products.

During the inspection, our investigators observed a number of deviations from the GLP regulations. The deficiencies were listed on a Form FDA 483 (copy enclosed), which was discussed with and presented to you at the conclusion of the inspection.

Following the review of the Form FDA 483, the inspection report, other data collected during the inspection, and your written response dated September 15, 1999, we conclude that the conditions are serious violations of the GLP regulations. The failure of management, study directors, and the quality assurance unit to exercise their responsibilities as required by sections 58.31, 58.33, and 58.35 is a serious violation and has wide spread consequences that adversely affect many other areas of GLP compliance. Unless these deficiencies are corrected, we would consider future studies conducted at your facility to be seriously flawed.

This letter is notification that the FDA may refuse to consider any particular nonclinical laboratory study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the Good Laboratory Practice regulations. Prior to initiation of any further new nonclinical laboratory studies, the observed GLP deficiencies must be corrected and you should request from the FDA Denver District Office that your laboratory be reinspected.

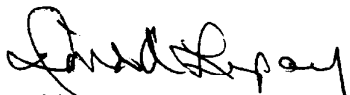
We accept your responses to Items #14, #15, and #21, as adequate corrections of these three violations. However, regarding the other violations, we request that you respond to this letter in writing within fifteen (15) working days of receipt of this letter and indicate to us your intentions to immediately correct those GLP violations or assure the Agency that there will be no further studies conducted that are subject to the FDA GLP regulations until corrections are made and verified.

Your response should include (1) the specific steps you have taken or are taking to correct these violations, including an explanation of each step being taken to prevent the recurrence of similar violations; (2) the date corrections will be completed; and (3) any documentation to indicate that correction has been achieved.

If you have any questions concerning these matters, or the Good Laboratory Practice regulations, please contact:

C.T. Viswanathan, Ph.D.
Associate Director (Bioequivalence)
Chief, GLP and Bioequivalence Investigations Branch
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place
Rockville, Maryland 20855
Telephone: 301-827-5460

Sincerely,



David A. Lepay, M.D., Ph.D.
Director
Division of Scientific Investigations
Center for Drug Evaluation and Research

Enclosure: Form FDA 483