DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 31 2001

WARNING LETTER

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL – RESTRICTED DELIVERY
RETURN RECEIPT REQUESTED

Reference: 00-HFD-45-1001

Peter E. Krumpe, M.D.
1000 Locust Street
Reno, Nevada 89520

Dear Dr. Krumpe:

Between January 10 and 14, 2000, Mr. Edward D. Harris, representing the Food and Drug Administration (FDA), met with you to review your conduct of the following clinical studies:

1. IND [ ] Protocol No. [ ] "A Comparison of Salmeterol versus Theophylline versus salmeterol Plus Theophylline in COPD Patients." This study was performed for Glaxo Wellcome, Inc.

2. IND [ ] Protocol No. [ ] "A Randomized, 3-Period, Crossover Study to Investigate the Safety and Tolerability of [ ] in Patients with COPD." This study was performed for [ ]

3. IND [ ] Protocol No. [ ] "Safety and Efficacy of [ ] in Patients with Moderate to Severe COPD." This study was performed for [ ]

This inspection is part of FDA's Bioresearch Monitoring Program, which includes inspections designed to validate clinical studies on which drug approval may be based and to assure that the rights and welfare of the human subjects of those studies have been protected.

From our evaluation of the inspection report, the documents submitted with that report, and records obtained from the sponsor, we conclude that you did not adhere to all pertinent federal regulations and/or good clinical investigational practices. We note at the conclusion of the inspection, Mr. Harris presented and discussed with you the items listed on Form FDA 483, Inspectional Observations. We wish to emphasize the following:

SUMMARY OF VIOLATIONS RELATED TO FAILURE TO CONDUCT THE STUDY ACCORDING TO THE SIGNED INVESTIGATOR STATEMENT (FDA FORM 1572) [21 CFR 312.53 (c) (l)(vi)(a) and 21 CFR 312.60]

You failed to personally conduct or supervise your clinical study, Protocol No. [ ] Specifically, between February 27 and May 27, 1998, on four separate monitoring visits to your site, the sponsor/monitor observed and documented that your records were maintained in an unacceptable manner. Although observations for each monitoring visit were communicated to you, it was not until the third visit (April 22, 1998) that you took effective action.

SUMMARY OF VIOLATIONS RELATED TO RECORDKEEPING AND CASE HISTORIES [21CFR 312.62 (b)]

You failed to maintain adequate and accurate study related records. Specifically, pulmonary function test results for 3 subjects [redacted] reported in the case report forms and submitted to the sponsor in support of Protocol No. [redacted] contained data entries which differ from their corresponding source documents; in certain instances these entries were important in determining subject eligibility for enrollment.

Because of the departures from FDA regulations discussed above, please inform this office, in writing, within 15 working days of your receipt of this letter, of the actions you have taken or plan to take to prevent similar violations in the future, and provide documentation of any actions, such as revised Standard Operating Procedures, you may have implemented. Failure to adequately and promptly explain the violations noted above may result in further regulatory action.

If you have any questions, please contact Dr. John R. Martin at (301) 594-1026, FAX (301) 827-5290. Your written response and any pertinent documentation should be addressed to:

John R. Martin, M. D.
Branch Chief
Good Clinical Practice I, HFD-46
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place
Rockville, Maryland 20855

Sincerely yours,

Martin H. Cohen, MD

Martin H. Cohen, M.D.
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