DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gregory Gardziola, D.O.
55 Cross Parks Court
Greenville, SC 29605

Ref: 08-HFD-45-0802

Dear Dr. Gardziola:

Between May 9 and 30, 2008, Ms. Karen Kondas, representing the Food and Drug Administration (FDA), conducted an investigation and met with your sub-investigator, Dr. [ ] to review your conduct of a clinical investigation (protocol [ ] entitled [ ] of the investigational drugs [ ] performed for [ ] At the time you performed the study, you were located at [ ] We note that you were responsible for the conduct of the study from October 2003 until you left the practice in May 2006, at which time Dr. [ ] became the clinical investigator.

This inspection is a part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

From our review of the establishment inspection report and the documents submitted with that report, and Dr. [ ] June 12, 2008 letter in response to the Form FDA 483, Inspectional Observations, we conclude that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations and the protection of human subjects. We are aware that at the conclusion of the inspection, Ms. Kondas presented and discussed with your sub-investigator Form FDA 483. Subsequently, Ms. Kondas discussed the inspection findings with you and faxed a copy of the Form FDA 483 to your office. We wish to emphasize the following:

1. You failed to assure that an Institutional Review Board (lRB) complying with applicable regulatory requirements was responsible for the continuing review and approval ofthe clinical study [21 CFR 312.66J.

   Specifically, our investigation revealed that IRB approval for the above-referenced study expired on October 7,2005, and was not renewed until October 19,2006. During this time period, when IRB approval was lapsed, you screened, enrolled, or randomized 16 subjects (1159042, 1159043, 1159044, 1159045, 1159046,1159047,1159048,1159049,1159050, 1159051, 1159052, 1159053, 1159054, 1159055, 1159056, and 1159057) and continued to perform research activities (study visits and phone contacts).

2. You failed to obtain informed consent of subjects involved in research in accordance with the provisions of 21 CFR Part 50 [21 CFR 312.60J.

   21 CFR 50.20 requires that, except as provided in sections 50.23 and 50.24, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. In addition, the FDA regulations require that informed consent be documented by the use of a written consent form approved by the IRE and signed and dated by the subject or the subject's legally authorized representative at the time of consent [21 CFR 50.27(a)].

   Subject 1159037 signed a l }ub-study consent document, but did not sign an informed consent document for participation in the main study.

3. You failed to retain records for the requisite time period [21 CFR 312.62(c)J.

   21 CFR 312.62(c) requires that an investigator retain records required to be maintained under 21 CFR Part 312 for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, ifno application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. A signed informed consent document, which was required to be maintained by 21 CFR 312.62(b), could not be located for subject 1159001. Dr.l]letter of June 12, 2008, indicates that a signed informed consent document was obtained from subject 1159001 on March 5, 2004 and was correspondingly documented in the case report for the subject. However, according to Dr.l Jthe signed informed consent form for this subject was lost.

This letter is not intended to be an all-inclusive list of deficiencies with your clinical study of an investigational drug. It is your responsibility to ensure adherence to each requirement of the law and relevant FDA regulations. You should address these deficiencies and establish procedures to ensure that anyon-going or future studies will be in compliance with FDA regulations.

Within fifteen (15) working days of your receipt of this letter, you should notify this office in writing of the actions you have taken or will be taking to prevent similar violations in the future. Failure to adequately and promptly explain the violations noted above may result in regulatory action without further notice.

If you have any questions, please contact Constance Lewin, M.D., M.P.H., at 301-796-3397; FAX 301-847-8748. Your written response and any pertinent documentation should be addressed to:

Constance Lewin, M.D., M.P.H.
Branch Chief, Good Clinical Practice Branch I
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg 51, Room 5354
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

{See appended electronic signature page}

Leslie K. Ball, M.D.
Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

lsi

LESLIE K BALL
09/03/2008