



WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 06-HFD-45-1001

Philip B. Schworer
7210 Turfway Road
Florence, KY 41042

Dear Dr. Schworer:

Between June 30 and July 7, 2006, Investigator Thomas W. Nojek, of the Food and Drug Administration (FDA), conducted an investigation and met with you to review your conduct of a clinical investigation (Protocol [] entitled "Prospective, randomized, double-blind, study comparing [] BID for 5 days with azithromycin for 5 days (500 mg PO OD on Day 1, then 250 mg PO OD on Day 2 through 5) in the treatment of patients with acute exacerbation of chronic bronchitis"), of the investigational drug [] performed for []

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, 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, Mr. Nojek presented and discussed with you Form FDA 483, Inspectional Observations. We wish to emphasize that:

You failed to retain records required to be maintained by the clinical investigator 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, if no 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 [21 CFR 312.62(c)].

Specifically, you were not able to provide for FDA inspection the records required to be maintained for the clinical study protocol [] of the investigational drug []

] Your failure to retain records of this clinical study makes it impossible for FDA to verify the integrity of the data and to verify that there was adequate protection of the rights, welfare, and safety of the subjects who participated in the study.

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 must address these deficiencies and establish procedures to ensure that any on-going or future studies will be in compliance with FDA regulations.

Within fifteen (15) working days of your receipt of this letter, you must 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 Leslie Ball, M.D., at (301) 594-1032; FAX (301) 827-5290. Your written response and any pertinent documentation should be addressed to:

Leslie K. Ball, M.D.
Branch Chief
Good Clinical Practice Branch II, HFD-47
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
7520 Standish Place
Rockville, MD 20855

Sincerely yours,

{See appended electronic signature page}

Gary Della'Zanna, D.O., M.Sc
Director
Division of Scientific Investigations, HFD-45
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.**

/s/

Gary DellaZanna
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