

Inspections, Compliance, Enforcement, and Criminal Investigations

Gordon, Mark, M.D. 6/26/2009



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Rockville, MD 20857

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

JUN 26 2009

Ref: 09-HFD-46-04-03

Mark F. Gordon, M.D.
C/o Office of Research Compliance
350 Community Drive
Manhasset, NY 11030

Dear Dr. Gordon:

Between January 12 and 29, 2009, Mr. Robert C. Steyert, representing the Food and Drug Administration (FDA), conducted an investigation and met with the current staff, to review your conduct of a clinical investigation (protocol **(b)(4)**) entitled **(b)(4)** of the investigational drug **(b)(4)** performed for **(b)(4)**.

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, the documents submitted with that report, and your February 26, 2009 written 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. We are aware that at the conclusion of the inspection, Mr. Steyert presented and discussed with you Form FDA 483, Inspectional Observations. We wish to emphasize the following:

1. You failed to retain records that record all observations and other data pertinent to the investigation, such as case report forms, progress notes of the physician, and nurses' notes, 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 [21 CFR 312.62(c)].

You failed to retain case report forms (CRFs) and source documents (i.e. the notes you used to fill out case report forms) that are necessary for the verification of data integrity and compliance of study activities with federal regulations for the marketing application of the investigational drug. You are required to keep these study-related records for two years following the approval of a marketing application for the study drug for the indication that was the subject of your investigation, or until the study was discontinued and FDA was notified. Your study terminated in 2000, but because a marketing application has not yet been approved or not approved for **(b)(4)** for the indication of **(b)(4)**, and because FDA has not been notified that the study was discontinued, you were required to retain your study records.

We acknowledge your response to the FDA Form 483 in which you agreed that the photocopied case report forms (CRFs) could not be found. You stated that your staff was able to find the subjects' medical records. However, these medical records are not an adequate substitute for the CRFs and other source documents, which you were required to retain per 312.62(c).

We also acknowledge that with your response you submitted a draft copy of "Register of Archived Research Data & Records" for future use when archiving records at your former institution. However, you have not addressed how you, personally, will ensure that a similar violation does not recur in your conduct of FDA regulated clinical research in the future.

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

Ten of sixteen subjects enrolled (P02, P08, P09, P10, P11, P12, 401, 402, 403, and 404) signed an outdated version of the informed consent documents, as

opposed to a revised version which the IRB had approved prior to the date of signing. Because these subjects were not given the opportunity to sign the revised informed consent documents, which contained new information about study procedures, they did not have sufficient opportunity to consider whether or not to continue their participation in the study, per 21 CFR 50.20. You agreed with this observation in your response to the FDA Form 483. We note that in your written response, you have explained how your former institution will ensure that a similar violation does not recur. However, you have not addressed how you, personally, will ensure that a similar violation does not recur in your conduct of FDA regulated clinical research in the future.

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 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 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,

Leslie K. Ball, M.D.

Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research

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June 26, 2009

Mark F. Gordon, M.D.
C/o Office of Research Compliance
350 Community Drive
Manhasset, NY 11030

Dear Dr. Gordon: By letter dated June 1, 2009, the Food and Drug Administration (FDA), Center for Drug Evaluation and Research, issued a Warning Letter sent by certified mail to you at your former address of 900 Ridgebury Road, Ridgefield, CT 06877-0368.

Per your request, we are re-issuing the Warning Letter to you at your current address. Except for the change of address, this Warning Letter is identical to the one dated April 20, 2009.

Enclosed you will find a copy of the Warning Letter.

Sincerely yours,

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

