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Inspections, Compliance, Enforcement, and Criminal Investigations

Thurmond-Anderle, Margaret E. M.D. 2/25/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 11-HFD-45-02-05

Margaret E. Thurmond-Anderle, M.D.
6701 Woodward Street
Amarillo, TX 79106

Dear Dr. Thurmond-Anderle:

Between August 17 and August 20, 2010, Mr. Joel Martinez, representing the Food and Drug Administration (FDA), conducted an investigation and met with you to review your conduct of the following clinical investigations of the investigational drug **(b)(4)** performed for **(b)(4)**:

Protocol **(b)(4)**, entitled "**(b)(4)**";

Protocol **(b)(4)** entitled "**(b)(4)**"; and

Protocol **(b)(4)** entitled "**(b)(4)**."

This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to help 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 written response dated August 23, 2010, 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. Martinez presented and discussed with you Form FDA 483, Inspectional Observations. We wish to emphasize the following:

You failed to conduct the studies or ensure they were conducted according to the investigational plans, and to protect the rights, safety, and welfare of subjects [21 CFR 312.60].

Protocol **(b)(4)** required that a pharmacist or appropriately qualified person prepare and provide infusion bags

containing 200 mg (6.7 mL) of study medication or placebo. Our investigation revealed that your office manager, who is not a pharmacist and does not appear to be appropriately qualified to prepare infusion bags, inaccurately prepared the study drug or placebo for infusion at approximately one-tenth of the protocol-specified dose. You acknowledged this dosage error in your correspondence to the sponsor dated July 21, 2008, in which you explained that the error resulted from the use of an inappropriately-sized syringe. Apparently, your office manager was instructed by the registered nurse to use a 1-mL syringe to achieve greater accuracy of the 0.7-mL measurement. However, she [the office manager] mistakenly used this 1-mL syringe, instead of a 10-mL syringe, for all measurements. You acknowledged the error and admitted to the sponsor that study results for the one subject enrolled into the study were impacted.

In your August 23, 2010, written response, you outlined corrective measures to prevent future recurrence of this finding. We note, however, that in your written response, you did not adequately address the preventive measures you would take to ensure that only appropriately qualified individuals are involved in the preparation of study drugs. In addition, we request that you provide additional information regarding the pervasiveness of the dosage error. In particular, you did not explain whether the dosage error extended to Protocols **(b)(4)** and **(b)(4)**, for which the same office manager prepared study infusion bags; you did not say how many subjects' dosages were impacted; and you did not give the period of time over which the errors occurred. Inaccurate preparation of study drugs not only compromises the reliability of the data captured at your site, but could also significantly jeopardize subject safety.

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 ongoing 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 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 Cullity, 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 Cullity (formerly 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
Building 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
Food and Drug Administration

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

/s/

LESLIE K BALL

02/25/2011

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