



U.S. Department of Health & Human Services



U.S. Food and Drug Administration

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Inspections, Compliance, Enforcement, and Criminal Investigations

Lippton, Howard M.D. 10/20/10



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-45-10-01

Howard L. Lippton, M.D.
2326 Line Avenue
Shreveport, LA 71104-2131

Dear Dr. Lippton:

Between February 2 and February 4, 2010, Ms. Barbara Wright and Ms. Tiana McKinley, representing the Food and Drug Administration (FDA), conducted an investigation and met with you to review your conduct of the following clinical investigation of the investigational drug **(b)(4)**, performed for **(b)(4)**:

- 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.

At the conclusion of the inspection, Ms. Wright and Ms. McKinley presented and discussed with you the items listed on Form FDA 483, Inspectional Observations. We have reviewed the inspection report, the documents submitted with that report, and your written response to the Form FDA 483 dated February 5, 2010. We conclude that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations. We wish to emphasize the following:

1. You failed to assure that an Institutional Review Board (IRB) that complies with the requirements set forth in part 56 was responsible for the initial review and approval of Protocol (b)(4) [21 CFR 312.66].

FDA regulations at 21 CFR 312.66 require investigators to assure that an IRB that complies with 21 CFR part 56 reviews and approves a proposed clinical investigation. FDA regulations at 21 CFR 56.109 require that IRBs review research activities subject to FDA oversight. In order for IRBs to conduct such reviews effectively, IRBs need accurate information regarding the clinical investigations under their review. Therefore, as part of an

investigator's obligation to assure IRB review, that investigator must provide the IRB with accurate information; if the investigator does not provide the IRB with accurate information, the IRB cannot effectively review the research activity, and the investigator has not assured that an IRB has reviewed the proposed investigation.

The Research Site Submission Form that you signed and certified as true and accurate on April 2, 2009, and submitted to the **(b)(4)** Institutional Review Board (**(b)(4)** IRB) for approval to conduct Protocol **(b)(4)**, was inaccurate. Specifically, you incorrectly answered "no" to questions 29(d) and 29(e) on that form. These questions asked, "Since your last submission to **(b)(4)** or if this is your first submission to **(b)(4)**, for any investigator associated with this study ... (d) Has he/she been convicted or charged with a crime (misdemeanor or felony)? ... (e) Has a state medical board taken a disciplinary action against his/her license, or is there a current investigation pending?" According to the **(b)(4)** IRB, your last submission to the **(b)(4)** IRB before April 2, 2009, was in October 2000. On February 6, 2002, you entered a plea of guilty and were convicted of one count of health care fraud (18 USC 1347), and on June 19, 2002, you were sentenced to be imprisoned for 18 months. On June 17, 2003, the Louisiana State Board of Medical Examiners suspended your license to practice medicine in the state of Louisiana for a period of 2 years, starting from the date of your incarceration (July 15, 2002). Therefore, your responses to questions 29(d) and 29(e) on the April 2, 2009 Research Site Submission Form should have been "yes," and, as instructed by the form, you should have attached a written explanation and copies of all the relevant documentation regarding your conviction and medical license suspension.

After the **(b)(4)** IRB learned that your April 2, 2009 Research Site Submission Form was inaccurate, it withdrew its approval for Protocol **(b)(4)** and denied your application for approval to conduct a second proposed clinical study. In an August 7, 2009 letter to the **(b)(4)** IRB,¹ you stated that a study coordinator completed the April 2, 2009 Research Site Submission Form, and completed questions 29(d) and 29(e) without your input. However, by signing the April 2, 2009 Research Site Submission Form, you certified that you "ha[d] reviewed all responses provided in this 'Research Site Submission Form' and that all responses are true and accurate." (emphasis in original) Therefore, the fact that a study coordinator completed the form did not relieve you of your responsibility for ensuring its accuracy before you signed it. Moreover, in your August 7, 2009 letter to the **(b)(4)** IRB, you admitted that the responses to questions 29(d) and 29(e) in the April 2, 2009 form were inaccurate, and that you were "not diligent to the level required to certify complete accuracy of the forms."

Your failure to ensure that the April 2, 2009 Research Site Submission Form provided accurate information to the **(b)(4)** IRB impeded the IRB's ability to review your application to conduct Protocol **(b)(4)**, and make a determination regarding the adequacy of that application. Therefore, you failed to assure IRB review of Protocol **(b)(4)** as required under 21 CFR 312.66.

2. You failed to protect the rights, safety, and welfare of the subjects under your care [21 CFR 312.60].

Under 21 CFR 312.60, an investigator is responsible for protecting the rights, safety, and welfare of human subjects under the investigator's care. Compliance with 21 CFR part 56, including the requirement for IRB review under 21 CFR 56.109, is intended to protect the rights, safety, and welfare of human subjects involved in clinical investigations (21 CFR 56.101). In order to adequately protect the rights, safety, and welfare of human subjects, IRBs need accurate information about the proposed investigations they are reviewing and the individuals who will be involved in conducting those investigations. Therefore, as part of an investigator's responsibility to protect the rights, safety, and welfare of human subjects, an investigator must provide accurate information to the IRB so that the IRB can fulfill its responsibilities with respect to protecting the rights, safety, and welfare of human subjects.

As explained above, the Research Site Submission Form that you signed and certified as accurate on April 2, 2009, provided false information to the **(b)(4)** IRB about your 2002 conviction and medical license suspension. By failing to ensure that the Research Site Submission Form provided accurate information to the **(b)(4)** IRB, you failed to protect the rights, safety, and welfare of the human subjects under your care, as required by 21 CFR 312.60.

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 violation 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

1□

Your August 7, 2009 letter appealed the **(b)(4)** IRB's decision to deny your application for approval to conduct the second proposed clinical study.

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
10/20/2010

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