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Inspections, Compliance, Enforcement, and Criminal Investigations

John M. Wise, M.D. 8/12/14



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.: 14-HFD45-08-0

John M. Wise, M.D.
Bozeman Urgent Care Center
1006 West Main Street
Bozeman, MT 59715

Dear Dr. Wise:

This Warning Letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection conducted at your clinical site between March 24 and 28, 2014. Mark W. Babbitt, representing FDA, reviewed your conduct of the following clinical investigations of the investigational drug **(b)(4)**, **(b)(4)**, performed for **(b)(4)**:

- Protocol **(b)(4)**, "**(b)(4)**";
- Protocol **(b)(4)**, "**(b)(4)**"; and
- Protocol **(b)(4)**, "**(b)(4)**."

This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, 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, Investigator Babbitt presented and discussed with you Form FDA 483, Inspectional Observations.

From our review of the FDA 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. We wish to emphasize the following:

You failed to retain records required to be maintained under 21 CFR Part 312 for a period of two years following the date a marketing application is approved for the drug for the indication for which the drug is being investigated; or, if no application is filed or if the

application is not approved for such indication, until two years after the investigation is discontinued [21 CFR 312.62(c)].

As a clinical investigator, you are required to retain records of the disposition of the drug, including dates, quantity, and use by subjects, and to retain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. You are required to retain these records for a period of two 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 the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

You failed to adhere to these requirements. Specifically, for Protocols **(b)(4)** and **(b)(4)**:

- You failed to retain records of the disposition of the drug, including dates, quantity, and use by subjects.
- You failed to retain adequate and accurate case histories, including signed and dated informed consent forms, case report forms, and all supporting data.

You were required to retain the study records for both protocols because a New Drug Application (NDA) had been filed for the indication under study, and the application had not yet been decided on (that is, approved or not approved) before you discarded the study records.

During the inspection, you stated that all original study records related to Protocols **(b)(4)** and **(b)(4)** were shredded on January 24, 2014. You stated that your study coordinator "mistakenly included the study files for **(b)(4)** and **(b)(4)**, along with business documents intended for shredding, and provided them to a mobile shredding company"

In addition, you indicated that **(b)(4)** notified you on February 11, 2014, that the company had filed an NDA with the FDA and had included the data from Protocol **(b)(4)** in this submission. You further state that you and your staff were "well aware of regulatory record retention requirements having been involved in clinical research since 2001."

During the inspection, you stated:

"[A]ll study related records and source data pertaining to protocol **(b)(4)** at our site were shredded, including, but not limited to: signed informed consent forms, subject diary cards, records of screening results, documentation of assessments at additional study related visits, and laboratory test results. This data is not retrievable and was not available for inspection. Due to the destroyed study records, [the FDA investigator] was not able to verify the study data for protocol **(b)(4)**, or the existence of signed informed consent forms during the inspection."

During the inspection, your study coordinator provided Investigator Babbitt with a copy of a Standard Operating Procedure (SOP), signed by you and with an effective date of October 30, 2008, for study-record retention. We are concerned that this SOP appears to be insufficiently detailed to prevent similar violations in future studies. Of note, based on the description you provided during the inspection, the boxes of study records that were shredded were labeled with pertinent identifying study information, such as sponsor, date range of the study, subject numbers, and protocol number. Your SOP for study-record retention does not address how you will ensure that boxes of study records that are appropriately labeled will not be shredded erroneously in the future.

Failure to retain study records as required by FDA regulations compromises the validity and integrity of data significantly. Because you failed to retain drug accountability records and case histories for both studies, we consider the data generated at your site for Protocols **(b)(4)** and **(b)(4)** unreliable in support of a research or marketing application.

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 corrective actions you have taken to prevent similar violations in the future. In your response, you should describe the preventive actions you have taken to ensure future compliance with regulatory requirements related to investigator recordkeeping and record retention (21 CFR 312.62). Failure to address the violations noted above adequately and promptly may result in regulatory action without further notice. If you believe you have complied with FDA regulations, include your reasoning and any supporting information for our consideration.

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

Sincerely yours,
{See appended electronic signature page}
Sean Y. Kassim, Ph.D.
Acting Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. 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/

SEAN Y KASSIM
08/12/2014

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