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**Inspections, Compliance, Enforcement, and Criminal Investigations**

**Damien Sanderlin, MD**



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation  
and Research  
1401 Rockville Pike  
Rockville, MD 20852-1448

July 27, 2012

**By Facsimile Transmission and Overnight Delivery**

CBER – 12-08

Damien B. Sanderlin, M.D.  
Lone Star Clinical Research  
8240 Antoine Street, Suite 107  
Houston, Texas 77088

### **Warning Letter**

Dear Dr. Sanderlin:

This letter describes some of the results of a Food and Drug Administration (FDA, the Agency) inspection conducted between June 21, 2012, and July 18, 2012. The FDA investigator met with you to review your conduct of a clinical study entitled *A Multi-Center, Actual Use Clinical Trial of the OraQuick ADVANCE® HIV 1/2 Antibody Test Over-the Counter Product Performance in Untrained Users, Protocol OQ-OTC-5*. The FDA conducted this inspection under the agency's Bioresearch Monitoring Program, which includes inspections designed to review the conduct of research involving investigational devices.

At the end of the inspection, the FDA investigator met with you to discuss the items listed on the Form FDA 483, Inspectional Observations. Based on the Form FDA 483 and other information available to the Agency, we have determined that you violated regulations governing the proper conduct of clinical studies involving investigational devices, as published in Title 21, Code of Federal Regulations (CFR) Part 812, (available at <http://www.gpoaccess.gov/cfr/index.html>). The applicable provisions of the CFR are cited for the violation listed below.

**You failed to ensure that the investigation was conducted according to the investigational plan, the signed agreement, applicable FDA regulations, and conditions of approval imposed by the Institutional Review Board (IRB) or FDA, this, in order to protect the rights, safety, and welfare of the subjects under your care. [21 CFR §§ 812.100 and 812.110(b)].**

The Protocol's Study Design, Section III.L, *Follow-up for HIV Positive Test Results*, requires the

clinical investigator to “comply with all federal, state, and local regulations regarding the reporting of newly-identified HIV positive laboratory results to the Centers for Disease Control and Prevention (CDC).” Eighteen (18) study subjects in Houston, Texas were confirmed HIV positive using FDA-approved methods at the central laboratory, with the first subject being confirmed HIV positive in December 2010, more than 18 months ago. The table below identifies each newly-diagnosed HIV positive subject and the date you signed the central lab report form with a positive HIV test result. Also listed below is the date of Visit 3 for the subjects. According to the protocol, review of the subject’s self test data and laboratory results occurred during Visit 3. All of these subject visits occurred more than one year ago.

<b>Subject #/ Initials</b>	<b>Date the central lab positive HIV test result form was signed by CI</b>	<b>Date of Visit 3</b>
(b)(6)	12/23/2010	12/23/2010
(b)(6)	1/24/2011	1/24/2011
(b)(6)	2/21/2011	2/21/2011
(b)(6)	2/24/2011	2/24/2011
(b)(6)	3/17/2011	3/17/2011
(b)(6)	4/18/2011 and 5/6/2011	4/18/2011
(b)(6)	4/18/2011	4/18/2011
(b)(6)	4/18/2011	4/18/2011
(b)(6)	4/18/2011	4/18/2011
(b)(6)	6/27/2011	6/27/2011
(b)(6)	6/27/2011	6/27/2011
(b)(6)	6/27/2011	6/27/2011
(b)(6)	6/27/2011	6/27/2011
(b)(6)	6/27/2011	6/27/2011
(b)(6)	6/27/2011	6/27/2011
(b)(6)	7/1/2011	7/1/2011
(b)(6)	7/1/2011	7/1/2011
(b)(6)	7/1/2011	7/1/2011
(b)(6)	7/18/2011	7/18/2011

The inspection revealed no documentation that you had reported the subjects with HIV positive laboratory results in accordance with state requirements, specifically, the Texas Administrative Code Title 25, Part 1, Chapter 97, Subchapter F, Rule 97.133, which requires you to submit to the State of Texas information for any specimen derived from a human body that yields microscopic, cultural, serological or any other evidence of HIV. According to the Texas Department of State Health Services’ “Technical Assistance Bulletin: Reporting Rapid HIV Test Results” dated March 2010, you are to report positive HIV test results on the Form STD-27 (Department of State Health Services Confidential Report of Sexually Transmitted Diseases Form), and the completed forms are to be sent to the local or regional health authority within seven days of receiving the positive test result. Contrary to what your staff told FDA during the inspection, the CDC does not accept direct reports from individuals. Instead, state health departments, such as the Texas Department of State Health Services, upon receipt of HIV positive laboratory results from within the state, report such surveillance data to the CDC using an electronic HIV/AIDS reporting system.

Within fifteen (15) business days of receipt of this letter, please provide written documentation to confirm that you reported the eighteen (18) subjects with HIV positive laboratory results to the Texas Department of State Health Services, along with the dates on which you made these reports. If you did not report some or all of the HIV positive laboratory results to the Texas Department of State Health Services, please provide details regarding that information as well.

Please provide specific actions you will take to prevent the recurrence of similar violations in current and future studies for which you are the clinical investigator. Failure to respond to this letter and to take appropriate corrective action could result in FDA taking regulatory action without further notice

to you.

The seriousness of the violation referenced in this letter, and its potential public health implications, has caused us to issue this letter prior to a complete review of all of the violations listed on the Form FDA 483 and, as a result, this letter is not intended to be an all-inclusive list of deficiencies. We are continuing to review information from the two recent inspections conducted at your site (March 27, 2012 through March 29, 2012 and the inspection noted in the first paragraph of this letter). It is your responsibility to ensure adherence to each requirement of the law and relevant FDA regulations.

Please send your written response to:

Janet White  
Division of Inspections and Surveillance (HFM-664)  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research  
1401 Rockville Pike, Suite 200N  
Rockville, Maryland 20852-1488  
Telephone: 301-827-6323

We also request that you send a copy of your response to the FDA District Office listed below.

Sincerely,

/S/

Mary A. Malarkey, Director  
Office of Compliance and Biologics Quality  
Center for Biologics Evaluation and Research

cc: District Director  
Food and Drug Administration  
4040 North Central Expressway, Suite 300  
Dallas, Texas 75204

Texas Department of State Health Services  
PO Box 149347  
Austin, Texas 78714-9347

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