



Bettina Bergtholdt, M.D.
Clinical Research Department
Wimersdorfer Str. 79
Berlin, Germany

Dear Dr. Bergtholdt:

The purpose of this letter is to inform you of the findings of a Food and Drug Administration (FDA) inspection conducted at your site. This inspection is 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 human subjects of those studies have been protected. We understand you did not perform this study under a U.S. Investigational New Drug Application (IND).

Between February 11, 2013 and February 15, 2013, Ms. Shelley H. Beausoleil, representing the U.S. Food and Drug Administration (FDA), met with you and your staff to review your conduct of Study Lu AA21004-305, entitled "A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Comparing the Efficacy and Safety of 3 Doses of Lu AA21004 in Acute Treatment of Adults with Major Depressive Disorder," a clinical study of the investigational drug vortioxetine hydrochloride sustained-release capsules sponsored by Takeda Pharmaceuticals USA, Inc.

From our review of the establishment inspection report and the documents submitted with that report, we conclude that you adhered to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations and the protection of human subjects.

We appreciate the cooperation shown to Investigator Beausoleil during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below.

Sincerely,

{See appended electronic signature page}

Susan Leibenhaut, M.D.
Acting Team Leader
Good Clinical Practice Assessment Branch
Division of Good Clinical Practice Compliance
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JONG HOON LEE
07/07/2013

SUSAN LEIBENHAUT
07/08/2013