DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

John Sonnenberg, Ph.D.
Uptown Research Institute, LLC
1021 West Lawrence Avenue
Chicago, IL, 60640-5017

Dear Dr. Sonnenberg:

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. On 2/5/2015, 2/6/2015, 2/9/2015, 2/10/2015, and 2/11/2015, James Duggan representing the FDA, met with you and your staff to review your conduct of a clinical investigation (Protocol R092670-PSY-3012 entitled "A Randomized, Multicenter, Double-Blind, Relapse Prevention Study of Paliperidone Palmitate 3-Month Formulation for the Treatment of Subjects with Schizophrenia" of the investigational drug Paliperidone Palmitate Extended-Release Injectable, performed for Janssen Pharmaceuticals, 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 Investigator Duggan 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 D. Thompson, M.D.
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