

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20857

Glen Park, Pharm.D.  
Target Health, Inc.  
261 Madison Avenue, 24<sup>th</sup> Floor  
New York, NY 10016-2303

Dear Dr. Park:

Between May 19 and 22, 2008, Dr. [REDACTED], representing the Food and Drug Administration (FDA), conducted an investigation and met with you to review your monitoring practices of the clinical investigations (protocol #s [REDACTED]01-2005 and [REDACTED]-02 2005, both entitled "A Multi-center, Randomized, Vehicle-Controlled, Double Blind Clinical Trial to Evaluate the Efficacy and Safety of [REDACTED] for the Treatment of [REDACTED]"), of the investigational [REDACTED] ( [REDACTED] ) [REDACTED] [REDACTED], performed for [REDACTED], Inc.

This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

From our evaluation 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 monitoring practices of clinical investigations and the protection of human subjects.

We appreciate the cooperation shown Investigator [REDACTED] 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*

Constance 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  
Bldg. 51, Rm. 5354  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

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/s/

Constance Lewin 7/15/2008 11:54:06 AM