DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Aziz I. Shaibani, M.D.
Nerve and Muscle Center of Texas
6624 Fannin Street, Suite #1670
Houston, TX 77030

Dear Dr. Shaibani:

This letter informs you of the findings of a U.S. Food and Drug Administration (FDA) inspection conducted at your site from April 28 to May 5, 2016. Ms. Andrea Branche, representing FDA, reviewed your conduct of a clinical investigation (Protocol QSC01-ALS-01, "A Two-Part Study to Explore the Safety and Tolerability of Acthar in Patients with Amyotrophic Lateral Sclerosis") of the investigational drug Acthar, performed for Questor Pharmaceutical, Inc.

This inspection was conducted as 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.

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 Branche 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 Cullity, M.D., M.P.H.
Branch Chief
Good Clinical Practice Compliance Oversight Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51, Room 5354
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

---

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

---

/s/

---

CONSTANCE CULLITY
07/25/2016