DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 15, 2013

BY UPS

Elmore Alexander, D.O.
(b) (6)

Notice of Disqualification of Eligibility to Receive Investigational Drugs

Dear Dr. Alexander:

I have reviewed the administrative record of the regulatory disqualification proceeding involving Dr. Elmore Alexander, including the Notice of Opportunity for a Hearing (NOOH) dated August 15, 2012. On the basis of my review and for the reasons set out in the NOOH, I have determined that you repeatedly or deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of investigational new drugs. I also have determined that you repeatedly or deliberately submitted false information to FDA or to the sponsor in required reports. Therefore, in accordance with 21 Code of Federal Regulations (CFR) Part 16 and § 312.70(b), I have determined that you are no longer eligible to receive investigational drugs. Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this final decision disqualifying you from eligibility to receive investigational drugs. In addition, pursuant to 21 CFR 312.70, you are no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

You may seek to have your eligibility reinstated to receive investigational new drugs and to conduct FDA-regulated clinical investigations pursuant to 21 CFR § 312.70(f) upon presentation of adequate assurances that you will employ investigational drugs solely in compliance with the provisions of 21 CFR Parts 50, 56, and 312.

Sincerely,

Jill Hartzler Warner, J.D.
Associate Commissioner for
Special Medical Programs (Acting)