DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

DEC 11 2015

By Certified Mail - Return Receipt Requested

Emanuel Calenoff, M.D.
(b) (6) (Home Address)

Notice of Disqualification

Dear Dr. Calenoff:

I have reviewed the administrative record of the regulatory disqualification proceeding, including the Notice of Opportunity for Hearing (NOOH), dated April 10, 2015. On the basis of all information available to FDA, and for the reasons set out in the NOOH, I have determined that there is no genuine and substantial issue of fact with regard to whether you repeatedly or deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of investigational new drugs. In accordance with Title 21 of the Code of Federal Regulations (CFR) Parts 16 and 312, I have determined that you are no longer eligible to receive test articles under 21 CFR Part 312. As a result of my determination, 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, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's decision disqualifying you from eligibility to receive test articles under 21 CFR Part 312 and disqualifying you from eligibility 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 to receive investigational drugs reinstated, pursuant to 21 CFR 312.70(f), upon presentation of adequate assurances that you will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with FDA regulations.

Sincerely,

/Jill Hartzler Warner, J.D./
Jill Hartzler Warner, J.D.
Associate Commissioner for Special Medical Programs
Office of the Commissioner
Food and Drug Administration