



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 26, 2010

By Certified Mail - Return Receipt Requested

Manuel Macapinlac, M.D.
65-47 110 Street, 1st Floor
Forest Hills, NY 11375

**Notice of Denial of Hearing and Disqualification of Eligibility to Receive
Investigational New Drugs**

Dear Dr. Macapinlac:

I have reviewed the record of the regulatory proceeding involving you, including the Notice of Opportunity for Hearing (NOOH) Letter received by you on April 27, 2010; your May 10, 2010, written response to the NOOH requesting a regulatory hearing; the Center for Drug Evaluation and Research's (the Center's) Decision Memorandum; the establishment inspection report and supporting documentation; the Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) Letter dated February 23, 2009; the follow-up letter from the Center to you dated April 29, 2009; the July 7, 2009 informal conference transcript; and the documentation submitted by you at the informal conference. Based upon my review, I have concluded that there is no genuine and substantial issue of fact with regard to whether you repeatedly or deliberately violated 21 CFR 312.70 in connection with investigational new drug studies of the following products: (b) (4). I am therefore granting the Center's Request for Hearing Denial and, consistent with 21 CFR 312.70(b), I have determined that you are no longer eligible to receive investigational new drugs. 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 investigational drugs.

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 investigational new drugs solely in compliance with the provisions of 21 CFR Part 312.

Sincerely,

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