DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 16, 1991

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Chaovanee Aroonsakul, M.D.
Ave.

Dear Dr. Aroonsakul:

Re: Notice of Disqualification to Receive Investigational New Drugs

I have reviewed the record of the regulatory hearing conducted by Freddie Ann Hoffman, M.D., Presiding Officer, on April 23, 1990, concerning your eligibility to receive investigational new drugs. The report of the Presiding Officer which was sent to you on May 11, 1991, provided a 30 day period within which you could submit any comments you had on the report. On June 3, 1991, your counsel, H. Nasif Mahmoud, requested a 60 day extension of time to comment on the Presiding Officer's report. On June 7, 1991, Dr. Hoffman granted a 30 day extension. The original 30 day time period and the 30 day extension have passed and the Presiding Office has not received any comments from you or your counsel. Thus, you had a full opportunity to comment on that report but chose not to do so.

Therefore, I am affirming and adopting the May 1991 Report of the Presiding Officer and have determined that you have repeatedly and deliberately failed to comply with the regulatory requirements regarding investigational new drugs. Specifically:

1. You violated 21 C.F.R. § 312.42(a) by administering the investigational new drug, human growth hormone, to study subjects after your notice of claimed investigational exemption for a new drug (IND) was placed on clinical hold.

2. You failed to obtain review and approval of the proposed IND study from an institutional review board as required by 21 C.F.R. § 312.66.

3. You failed to obtain informed consent from the IND study subjects as required by 21 C.F.R. § 50.20.

4. You failed to maintain adequate records showing the receipt of investigational new drugs as required by 21 C.F.R. § 312.57.

5. You promoted the investigational new drug, human growth hormone, as an effective treatment for Alzheimer's disease in violation of 21 C.F.R. 312.7.

In accordance with 21 C.F.R. § 312.70(b), you are hereby advised that you are no longer eligible to receive investigational new drugs. All such drugs in your possession should be promptly returned to their supplier.

Sincerely,

David A. Kessler, M.D.
Commissioner of Food and Drugs

cc: Cathy Grimes
Office of the General Counsel, GCF-1
Food and Drug Division
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857