



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

REGISTERED MAIL
RETURN RECEIPT REQUESTED

FEB 28 1979

Abraham A. Chaplan, M.D.
Place

Dear Dr. Chaplan:

Notice of Disqualification to Receive Investigational New Drugs

I have reviewed the record of the regulatory hearing conducted by Dr. Mark Novitch on November 15, 1978, relating to your eligibility to receive investigational-use drugs. At the hearing you were unable to offer satisfactory explanations for the deficiencies observed in your clinical investigations of investigational new drugs as set forth in the September 7, 1978, Notice of Opportunity for Hearing on this matter. Therefore, on the basis of all information, I am affirming and adopting the January 17, 1979, Recommended Decision and Report of the Presiding Officer and have determined that you have repeatedly and deliberately failed to comply with the exempting regulations for new drugs for investigational use in that:

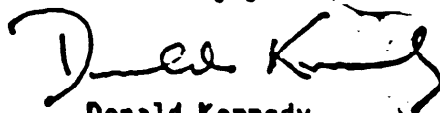
1. Patient records for the [redacted] study which you conducted are inadequate.
2. Patient records for the [redacted] study which you conducted are inadequate.
3. Patient records for the [redacted] study which you conducted are inadequate.
4. Patient records for the [redacted] study which you conducted are inadequate; further, there are inconsistencies between the patient records that do exist for patients in this study and patient case reports prepared for submission to the sponsor.

Page 2 - Abraham A. Chaplan, M.D.

In accordance with 21 CFR 312.1(c), you are hereby advised that you are no longer entitled to receive investigational new drugs. All such drugs now in your possession should be promptly returned to their supplier.

For your information, enclosed are copies of letters which have been sent to all sponsors of investigations in which you have been named as a participant, notifying them that you are not entitled to receive investigational-use drugs.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donald Kennedy". The signature is written in a cursive style with a large initial "D".

Donald Kennedy
Commissioner of Food and Drugs

Enclosures

cc: HF-1 (2)
HF-2
HF-4
HF-1
GCF-1
HFY-1 R/F
HFY-21 (Chaplan Files)
HFA-225
HFJ-1
HFJ-5 (TRAC #7900473)