CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JUN 14 1979

William L. Doss, Jr., M.D.

Notice of Disqualification To
Receive Investigational New Drugs

Dear Dr. Doss:

I have reviewed the attached report of the presiding officer and the record of the attempts to schedule your hearing concerning your eligibility to receive investigational-use drugs. Several attempts have been made by the presiding officers, Dr. John Jennings and Dr. Mark Novitch, to schedule your hearing at a time convenient for you, taking into account your stated physiological and psychological disability. Your hearing has now been scheduled on six separate occasions and on five of these occasions has been postponed at your request. No response has been received to the requests by the presiding officer that you provide an indication from your physician as to when you might be able to attend and participate at your hearing.

In his April 11, 1979, notification to you of opportunity for hearing, the presiding officer advised you that your failure to submit a written reply before May 1, 1979, providing either a statement from your physician as to your medical condition or your agreement to a May 15, 1979, hearing date would be interpreted as a refusal by you to exercise the opportunity for hearing. You have not responded to the presiding officer's request of April 11, 1979. I am accepting the presiding officer's recommendation, as contained in the enclosed copy of the Report of the Presiding Officer and have concluded that by failing to respond you have refused the opportunity for a hearing.

Accordingly, on the basis of all available information, I have determined that you have repeatedly and deliberately failed to comply with the conditions of exemption for new drugs for investigational

use. Specifically, you have not provided adequate explanation of the deficiencies observed in your clinical investigation of the investigational new drug ) IND p44, ). These deficiencies, as set out in the Bureau of Drugs' November 11, 1977, letter to you, are as follows:

1. Physical examination records did not contain dates on which examinations were performed, signatures of the attending physician, or reference that the recorded examinations were, in fact, performed by a physician.

2. Patients were admitted into the study without the required blood samples being taken.

3. Laboratory tests necessary to complete Pretreatment Urinalysis/Vital Signs Records were not completed for all patients whose records were reviewed.

4. Vital signs of several subjects were either not taken or not recorded as required on the patients' Pretreatment Urinalysis/Vital Signs Records.

5. Urinalysis results were incorrectly transcribed for several patients.

6. The required Global Evaluation Record and Early Termination Record were not completed for patients who had dropped out of the study.

7. Required records were not completed for patients who were terminated from the study, but who were available in the area for physical examinations and laboratory tests.

8. There were omissions in recording the initial dose of drug for several patients.

Therefore, 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 promptly be returned to their supplier.

For your information, I have enclosed copies of the letter we have sent to the sponsors of the investigations in which you have been named as a participant, giving notice that you are not entitled to receive investigational new drugs.

Sincerely yours,

Donald Kennedy
Commissioner of Food and Drugs

Enclosures