



29 JAN 1988

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Ronald R. Fuller, D.V.M.
Animal Hospital
Street

Dear Dr. Fuller:

**Notice of Disqualification to Receive
Investigational-Use New Animal Drugs**

I have reviewed the record of the regulatory hearing conducted by Stuart L. Nightingale, M.D. on March 31, 1987 concerning your eligibility to receive investigational-use new animal drugs. The record does not contain any satisfactory explanation for the discrepancies observed in your clinical reports as set forth in the March 11, 1986 Notice of Opportunity for Hearing.

The report of the Presiding Officer was sent to you for comment on August 20, 1987. I find, based on DHL Airbill No. 49715702, that the report was received by your office by on August 21, 1987. Thus, you had a full opportunity to comment on that report but chose not to do so.

Therefore, I am affirming and adopting the October 1987 Report of the Presiding Officer and have determined that you have repeatedly and deliberately submitted false information on case report forms thereby violating the regulations on investigational new animal drug use. Specifically:

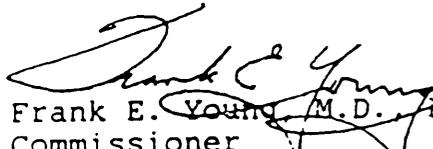
1. The affidavits from the owners of the dogs supposedly enrolled in the study fail to support the case report entries. The owners either denied or could not remember any injury suffered by or any treatment given to their pets. In contrast, the case report forms frequently noted the cause of the injury.

2. The medical records for the animals supposedly enrolled in the study also fail to support the case report forms. The entries in the medical records are inconsistent with the dates during which the animals were supposedly participating in the study.
3. The medical records were altered during the course of an FDA inspection.

In accordance with 21 CFR 511.1(c), you are hereby advised that you are no longer eligible to receive investigational-use new animal drugs. All such drugs in your possession should be promptly returned to their supplier.

For your information, I have enclosed copies of letters which have been sent to all sponsors of investigations in which you have been named as a participant. These letters inform the sponsors that you are not entitled to receive investigational new animal drugs.

Sincerely,


Frank E. Young, M.D., Ph.D.
Commissioner
Food and Drug Administration

Enclosures

cc: HF-1
HF-2
HFA-1
HFY-1
GCF-1
HFV-1
HFA-225