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Edward C. Froning, M.D.

Dear Dr. Froning:

I have reviewed the transcript of your informal hearing conducted by Dr. John Jennings on November 11, 1975. In addition to the transcript and exhibits offered by you and by the Bureau of Drugs, I have considered other records which directly relate to the issue of your conduct as an investigator, including information obtained from files maintained by the sponsor of the investigation.

I have concluded that you did not inject patients with the investigational drug after receipt of official notification from the sponsor of the suspension of your privileges as an investigator. The mailgram from Dr. clearly states that you are not to inject patients ". . . subsequest (sic) to the receipt of this communication." I find nothing that indicates, as clearly as the mailgram does, that you were formally advised of the sponsor's decision to suspend your privileges as an investigator prior to the April 2, 1975, delivery of the mailgram to your office. As indicated at your hearing, FDA officials requested records (memoranda of telephone conversations, etc.) pertinent to this question and, as promised by Dr. Jennings at the hearing, I am including copies of information which were obtained during our follow-up inquiry.

I have concluded that you repeatedly or deliberately failed to comply with the conditions of the exempting regulation [21 CFR 312.1 (c)] in that you performed reinjections after being informed by the sponsor that a second injection was prohibited. This information was supplied to you in 1970 and reiterated by Dr. in a March 27, 1972, telephone conversation with you (enclosed) in which reinjection was specifically addressed. There are possible mitigating circumstances, involving both the role in the investigation you may have perceived as being filled by Dr. and his expertise in the development and use of the drug. I cannot, however, in view of the record, accept as credible that you felt that you were receiving an update on the reinjections issue in June 1972

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conversations with Dr. Moreover, I find it irresponsible for an investigator to pursue advice which explicitly involves concealment of information from the Food and Drug Administration.

I have further concluded that you repeatedly or deliberately failed to comply with the conditions of the exempting regulations [21 CFR 312.1(c)] in that you did not report the facts of the four reinjections you performed to the sponsor. You failed to report these reinjections even after becoming clearly aware in 1973 that such reinjections were prohibited. This continued concealment is inconsistent with your argument that you were misled by Dr. and ceased your improper behavior in 1973.

I, therefore, find that your responses to the Bureau of Drugs' allegations regarding your conduct as an investigator of the investigational drug, and your presentation at the November 11 hearing are unsatisfactory to mitigate the charge. Therefore, in accord with 21 CFR 312.1(c), you are hereby declared ineligible to receive investigational-use drugs.

Sincerely yours,

Alexander M. Schmidt, M.D.
Commissioner of Food and Drugs

Enclosures (3)