DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., May 19, 1972.

DEAR ——— ———: Congressman Paul G. Rogers has made available to me the letter of February 29, 1972, signed by you and 21 colleagues calling for a Congressional review of the Nation's drug regulatory system and the role of the Food and Drug Administration.

We are not strangers to the Congress and we do not shrink from Congressional review. The policies and activities of this Administration are based on a deep and sensitive understanding of our obligations under the laws placed in our charge and we are properly accountable for our stewardship.

We do question, however, the bases for your recommended review. Some of the assertions and implications in your letter (repeated and expanded in a follow-up letter dated March 22, 1972) are particularly disturbing to me—

that "the procedures by which new drugs are evaluated and approved for use in this country is causing us to fall behind in this important area of medical science";

that our drug regulatory system deprives physicians of agents beneficial to patient care and hampers the practice of medicine; and

that the 1962 efficacy requirements have stifled creativity and have perpetuated a continuing decline in the number of new drugs entering the market.

I am surprised that a committee of distinguished scientists and clinicans could make such assertions and publicize them through "exclusive interviews" in the medical press without first communicating with us about their basis in fact.

The publisher of "Medicine Tribune", the circular in which most of the interviews have appeared, has commented: "We do not need a new 'generation' of hysterical drug headlines. . . . We need an open and honest exchange of experiences and ideas." I endorse this view and I would like to invite you and your colleagues to meet with me to discuss your recommendations to the House Committee on Public Health and Environment, specifically those included in your letters of February 29 and March 22, 1972, addressed to Congressman Rogers. I have scheduled this meeting in my office, Room 6821, 200 C Street, S.W., Washington, D.C. at 2:00 p.m., Tuesday, June 6, 1972. I do hope you will attend.

Sincerely yours,

CHARLES C. EDWARDS, M.D.,
Commissioner of Food and Drugs.

Senator NELSON. And then for clarification, Doctor, do I understand the "Dear Doctor" letter sent out by Lilly on Darvon is a violation of the law? Is it or is it not a violation of the regulations?

Mr. HUTT. It certainly appears to me that it is, Senator.

Senator NELSON. It is not statutory; it is the regulations of the FDA?

Mr. HUTT. In my opinion, it does violate the regulations I referred to earlier.

Senator NELSON. And what kind of action do you take in such a violation of such regulations?

Mr. HUTT. I believe the Commissioner mentioned three specific things we intend to do. This matter just recently came to our attention, I believe only 4 days ago, and this is as far as we have proceeded in our thinking at this time.

Senator NELSON. Are there any penalties for violating regulations?

Mr. HUTT. Yes, there are. The agency may take whatever legal action it believes appropriate under the circumstances. All of the penalties under the act could apply.

Senator NELSON. What kind of penalties are those?

Mr. HUTT. Basically, there are three: the product could be seized, which is probably inapplicable in this type of situation; an injunction could be sought in court; or criminal penalties could be requested. Of course, there are informal sanctions that could also be applied, of the