(Upon the direction of the Chairman, information pertaining to the hearings follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., May 12, 1971.

Hon. GAYLORD NELSON,
Chairman, Subcommittee on Monopoly, Select Committee on Small Business, U.S. Senate, Washington, D.C.

DEAR SENATOR NELSON: This is in reply to your February 23, 1971 request for comments on problems raised by letters sent to Commissioner Edwards on February 10 and 19, 1971, by the Pharmaceutical Manufacturers Association, Washington, D.C. We forwarded an interim reply to you on March 10, 1971.

We are enclosing a copy of Commissioner Edwards' March 18, 1971 response to these letters. If we can furnish any additional assistance, please let us know.

Sincerely yours,

M. J. RYAN, *Director,*
Office of Legislative Services.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., March 18, 1971.

C. JOSEPH STETLER,
President, Pharmaceutical Manufacturers Association, Washington, D.C.

DEAR MR. STETLER: Your letters of February 10, 1971, and February 19, 1971, comment on our testimony before the Nelson Subcommittee on January 18, 1971, and my letter of February 5, 1971, to Senator Nelson.

The first letter charges us with a tendency to escalate the role of the agency in drug therapy, beyond the point where Congress has given us authority. You are particularly concerned with our interest in problems of relative efficacy, overprescribing of drugs, generic equivalency, and class labeling. You also criticize us for removing possibly effective drugs from Federal programs and for our releases explaining the NAS/NRC findings.

We are confident that we are proceeding with the implementation of the 1962 Drug Amendments in the way that Congress intended. We have now substantial judicial support for that belief.

With regard to the question of relative efficacy, it is our interpretation of the intent of Congress that we could not exclude a new drug from the market on the ground that it was relatively less effective than another available drug (except when the benefit-risk ratio requires this), but we can and do require full disclosure labeling and promotion for new drugs which in many instances requires a discussion of precisely where the new drug belongs in relation to other available drugs in safe and effective clinical use. Most advertising of newly-marketed drugs is competitive, requiring us to give consideration to the validity of claims of relative efficacy.

Over-prescribing should be of as much concern to manufacturers as to us. It can only lead to more problems for all of us. Our discussion of this problem was not linked with the social problem of drug abuse, but to promotion, prescribing, and use of drugs of limited or no value and to the consumption of too many drugs, often for no purpose or for the wrong purpose. On drug equivalency, we noted that this problem is being addressed in a number of ways—through good manufacturing practice regulations, intensified drug inspections, and increased surveillance from our National Center for Drug Analysis, for example. And we concluded by saying that on the basis of the evidence available, the quality of marketed drugs in regard to purity and uniformity of composition is not suspect. We think it is a disservice to the public to use a few episodes where drug equivalency was drawn in to question to imply that the whole drug supply is in doubt. We disagree with your conclusion that because a few instances have occurred, this is probably a very frequent phenomena. You raise the question regarding our ability to test all batches of imported antibiotics; this has been going on for several years.

In our opinion class labeling is necessary to provide the profession with reliable and understandable prescribing information. The practice of presenting different