PMA relative to Government agency policy on the procurement of drugs listed as "ineffective" and "possibly effective". Attached to your release was a letter to you from Dr. Charles C. Edwards, Commissioner of Food and Drugs, dated January 29, 1971.

This letter purported to review the actions of the pharmaceutical industry with respect to the submission of proof of effectiveness for drugs approved for marketing between 1938 and 1962. In our opinion, Dr. Edwards' letter does not present a balanced review of the history of the drug industry activities in this regard. We would appreciate it, therefore, if you would insert the enclosed letter to Dr. Edwards in the printed transcript of the hearings for the February 1, 1971 session of the Monopoly Subcommittee.

Sincerely yours,

C. JOSEPH STETLER,
President.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., February 19, 1971.

CHARLES C. EDWARDS, M.D.,
Commissioner of Food and Drugs, Department of Health, Education, and Welfare, Rockville, Md.

DEAR COMMISSIONER EDWARDS: This is in reference to your letter of January 29 to Senator Gaylord Nelson commenting on a PMA press release and my earlier letter concerning recent efficacy review actions of the FDA and the Public Health Service.

We take issue with your statement that "no real effort to comply" with the efficacy requirements of the 1962 Amendments was made by pharmaceutical manufacturers.

Prior to your appointment as Commissioner of Food and Drugs, the pharmaceutical industry met with officials of the Food and Drug Administration in order to achieve an orderly compliance with the 1962 Amendments. I wrote to FDA Commissioner Larrick on November 29, 1963, requesting that the Agency and the industry work together to formulate a program that would meet the intent of the law in an effective way. Unless such a program is devised, I wrote, "many companies will be spending time and money wastefully in doing unnecessary things, while others may do nothing and have a rude awakening ten months hence when suddenly they are asked to justify the continued marketing of established products."

Commissioner Larrick agreed to a meeting, and representatives of the Agency and the industry met on January 23 and February 6, 1964. The attitude was one of cooperation and the exchange of ideas was helpful to both sides.

A point of prime significance that was discussed at the meetings was the definition of the "substantial evidence" requirement of the law. FDA General Counsel Goodrich made it clear at both meetings that well-documented clinical experience, which would lead experts fairly and reasonably to conclude that the claims are valid, would be considered in answering the efficacy question. Indeed, such evidence was to be controlling in some situations. Accordingly, clinical studies were not commenced by manufacturers on products for which well-documented clinical experience existed.

I might mention that minutes of these two meetings were reviewed by the Office of the Commissioner and no changes or objections were offered. The minutes were, of course, shared with the member firms of this Association of the time of the meetings for their guidance in attempting to fulfill purposes of the law.

Further evidence of the FDA's willingness to recognize well-documented clinical experience was given in a press release issued by the Agency dated February 28, 1964, which presented the FDA position on effectiveness requirements for pre-1962 drugs. It clearly equated "clinical experience" with "substantial evidence of effectiveness" on its first page.

Moreover, the essence of the policy described at the meetings had already been laid down in FDA regulations published January 10, 1964, concerning permissible claims that could be made in advertisements for pre-1962 prescription drug products. They provided in part that "an advertisement may recommend or suggest the drug only for those uses contained in the labeling thereof . . . for which there exists substantial clinical experience, adequately documented in medical literature or by other data (to be supplied to the FDA, if requested),