ment, I trust that you will take the requested action at the earliest practicable time.

Sincerely yours,

C. JOSEPH STETLER, *President.*

P.S. I am enclosing a PMA release which discusses the FDA list of "ineffective" drugs for your information. (Enclosure: omitted.)

FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., January 29, 1971.

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

DEAR SENATOR NELSON: Thank you for your January 26, 1971 request for comment on a letter and press release from C. Joseph Stetler, President, Pharmaceutical Manufacturers Association, concerning the Food and Drug Administration's review of the efficacy of drugs approved between 1938 and 1962.

Congress in 1962 clearly expresses its intent that drugs then on the market, or thereafter introduced, be safe and effective. A grace period of two years was allowed for the industry to submit the scientific evidence to support claims made for drugs on the market at that time.

No real effort to comply with this requirement occurred on the part of members of the Pharmaceutical Manufacturers Association or others. Therefore, it became necessary in 1966 for the FDA to turn to the National Academy of Sciences for assistance in evaluating the effectiveness of drugs approved between 1938 and 1962.

Even after the evaluation of those drugs by the NAS–NRC Drug Efficacy Study Group and in view of their criticism of drug labeling and the quality of evidence submitted in support of effectiveness for label claims, industry resistance continued. Our early actions were challenged in the courts.

In the real sense, the industry failed to mount any effort to provide the necessary evidence of effectiveness. Rather, they continued to request hearings, revise labeling, or otherwise avoid the issue of supplying substantial evidence of effectiveness. No drugs of any economic significance were voluntarily removed from marketing, except in those cases where the matter was resolved in the courts, such as some combination antibiotic products. We, therefore, considered it prudent to publish the decisions we made based on the NAS–NRC review.

I do not view with alarm the disclosure that some drugs, found ineffective for label claims, were not in commercial distribution at the time this list was released. I would be surprised or even alarmed if at the time the list was released, all drugs listed were still being marketed. The Drug Amendments of 1962 plainly put drug manufacturers on notice that substantial evidence for effectiveness claims was required. To this end, we applaud those voluntary actions by responsible manufacturers to remove from marketing products lacking the necessary evidence of effectiveness.

The first *Federal Register* announcements of intention by FDA to initiate proceedings to withdraw approval of the new drug applications or to repeal the antibiotic regulations were published early in 1968. Thus a considerable period has elapsed during which evidence supporting effectiveness claims could have been developed. The time for removal of these ineffective products from the market is now overdue. Action must be taken.

However, I believe it would be inadvisable not to exhaust the scientific method before ruling drugs off the market. If data is submitted supporting effectiveness claims, FDA will take steps to reclassify them if warranted by the evidence. I am convinced that it makes good sense to allow the drug companies to conduct the necessary studies to definitely answer the question whether a drug rated as "possibly" or "probably" effective, is effective or ineffective. Procrastination will not provide the answer, we must see progress.

Public confidence in our Nation's drug supply cannot be achieved while