The ability of PMA member firms to properly evaluate their performance depends in a large measure on the availability of complete information in instances in which their products are allegedly found to be in violation of the statute or regulations. It is for this reason that I most earnestly request your prompt attention to this matter.

Sincerely yours,

C. JOSEPH STETLER.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C. March 15, 1967.

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

DEAR MR. STETLER: This will provide additional information concerning the drug potency survey in response to your letter of February 24, 1967.

The FDA District offices were requested to obtain one or more samples of each dosage form of the drugs in the categories listed from each primary manufacturer. Appropriate analytical procedures were used for non-official preparations, and included procedures submitted with New Drug Applications, AOAC procedures and others published in the scientific literature. The survey was initiated in late March 1966, and continued for approximately two months.

You are correct in your understanding that lot or control numbers are being supplied to each manufacturer on request. Information on the method of analysis is included when requested. The criteria used in evaluating the potency findings were arbitrarily set at 90–110% of the declared amount, except where compendia or NDA's were controlling, as announced in our press release.

As indicated in the release, our samples were obtained from lots ready for sale. We do not believe we would be justified in expending the time and funds required to obtain and list the specific source of each sample.

Sincerely yours,

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 4, 1967.

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs, Department of Health, Education, and Welfare, Washington, D.C.

DEAR DOCTOR GODDARD: As you know from past correspondence and conversations, the Pharmaceutical Manufacturers Association and a number of our member firms are attempting to evaluate the methods and tests employed in and the results of the 1966 FDA drug potency study.

The results of this survey have been given wide publicity by FDA and others, and some of the conclusions reached have frequently been cited in support of generic prescribing and dispensing legislation. On four occasions the study has been referred to in the *Congressional Record* by proponents of such legislation. The most recent reference to the report was made by Senator Gaylord Nelson in his address to the Senate on Wednesday, April 26, 1967. At that time he announced that he will initiate investigative hearings, involving the drug industry in the Monopoly Subcommittee of the Senate Small Business Committee beginning on May 15. Included in Senator Nelson's address was a reference to a newly published book "Handbook of Prescription Drugs" by Dr. Richard Burack, which also contains a reference to the survey. The fact that this survey will no doubt play an important part in the hearings announced by Senator Nelson makes it even more imperative that the information we and individual companies have previously requested be made available as soon as possible.

Many of the PMA member firms involved have still not been informed of the source or sources from which their alleged violative samples were obtained. I respectfully request again, therefore, that this information be made available to them at the earliest possible date. We cannot agree with the conclusion you