We have recently read in the press and in the *Congressional Record* about the speech given by Deputy Commissioner Rankin before the American College of Apothecaries on October 15, 1966, in which he states "We collected almost 4,600 samples of drugs last spring representing the output of about 250 manufacturers. We examined these samples for potency . . . 7.8% of the generic-name drugs were not of acceptable potency. 8.8% of the brand-name drugs were not of acceptable potency." Again we would respectfully request information concerning this study, and we would also like to receive clarification of the findings referred to by Commissioner Rankin.

If possible, we would like to know the names of the products and manufacturers involved, and the results of the examination. If this is not suitable for transmission to us, we would think that at least a tabulation of the classes of drugs and the results of examination, by classes of drugs, could be furnished.

We also have at least one specific question related to Commissioner Rankin's speech. He states that about 2,600 of the drugs were sold by generic name only and about 2,000 by brand name. If the results he summarizes are to have significance, with respect to the generic and brand name controversy, it would be necessary to know the proportion of substandard lots made by firms which produce so-called generic drugs almost exclusively, and compare this with the performance of the companies which make both brand-name and generic-name drugs, but which are commonly regarded as brand-name houses. For example, several of the very large pharmaceutical firms offer a complete line of drugs which includes about as many drugs sold by generic names as those sold under trademarks.

We believe it is most important to obtain meaningful information on the performance of drug manufacturers of various kinds, so that mutual efforts can be put forth by the industry and the Food and Drug Administration to raise the level of quality of the drug supply as high as possible. We believe that a discussion of the figures already available to the Food and Drug Administration would provide a useful start for this project.

Sincerely yours,

C. JOSEPH STETLER.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., December 1, 1966.

JAMES L. GODDARD, M.D.
Commissioner, Food and Drug Administration,
Washington, D.C.

DEAR COMMISSIONER GODDARD: The purpose of this letter is to again request information on the drug potency study undertaken several months ago by the Food and Drug Administration which has been referred to in several FDA speeches.

You may recall that I wrote to you on two previous occasions, August 22, and again on October 27 requesting the information. In our meeting in your office on November 1, you indicated that the material would be forthcoming.

I am most anxious to submit the data to careful anlysis and at the earliest possible moment because of the serious nature of the conclusions which have been reached by the FDA and the impact which this study is sure to have in connection with prospective hearings by the Senate Finance Committee next year.

It would be most helpful if you would provide us with a complete list of the drugs that were examined. That is, we are interested in obtaining a list of those drugs which were acceptable as well as those which were found to be subpotent or otherwise did not meet labeling requirements.

It would also be helpful if the following information could be provided to assist us in our analysis:

1. The nature of the sampling technique or design.
2. The source of the sample, i.e., retail pharmacy, hospital pharmacy, wholesaler, manufacturer's distribution point or warehouse, reserve samples, etc.
3. The lot or control numbers of the products found to be subpotent.
4. In the case of nonofficial assays, the method of analysis used.
5. The limits of potency for non-U.S.P. or N.F. drugs.

I recognize that some of the above information may be difficult to supply, however, to the extent possible I would appreciate consideration of as many of these items as possible.

Your prompt attention to this request will be very much appreciated.

Sincerely yours,

C. JOSEPH STETLER.