DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., February 1, 1967.

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

DEAR MR. STETLER: This replies to your letter of December 1, 1966, requesting information on the drug potency study that we conducted some months ago.

The enclosed computer printout release and summary give the results of the survey.

It is not possible to retrieve the lot numbers of individual samples from the computer and we have not undertaken the manual task of reviewing each file to obtain the lot numbers.

The printout is filed in our Office of Education and Information where it is available for review by any interest parties.

Sincerely yours,

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

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., February 24, 1967.

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

DEAR DR. GODDARD: This letter is written in further reference to the drug potency study conducted last year by the Food and Drug Administration and will serve to advise you that, to date, the information we requested in previous correspondence on this subject has not been receivd.

Your letter of February 1, the FDA press release of January 31 and the computer print-out report of the study have been carefully reviewed. This data, however, is not adequate to answer the questions we previously raised. Consequently, we are repeating our request for more complete information in order that members of this Association cited in the report are afforded the opportunity to adequately study the data and undertake whatever action may be indicated.

You will recall that the following information was requested in my letter of December 1, 1966:

(1) The nature of the sampling technique or design.

(2) The source of the sample, i.e., retail pharmacy, hospital pharmacy, wholesaler, manufacturers' 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 anaylsis used.

(5) The limits of potency for non-U.S.P. or non-N.F. drugs.

The information requested on limits of potency for non-U.S.P. and non-N.F. drugs was not supplied but is ascertainable from the speech given by Deputy Commissioner Rankin before the American College of Apothecaries on October 15, 1966. It is also my understanding from our conversation on February 16 that lot and control numbers will be supplied to the firms involved upon request. Information on items 1, 2, and 4 above are prerequisite to a meaningful evaluation of the data thus far provided, however, and I respectively request again, therefore, that it be supplied. More recently questions have arisen as to when the samples in question were obtained by FDA. We would, therefore, also like to have an indication of when the samples identified in the study as violative were acquired by FDA.

The effects of the study in question on the industry and the public are substantial. We are particularly concerned by the publicity given to this material because of the admittedly questionable validity of the study and the improper conclusions drawn from it. We have therefore directed the enclosed letter and questionnaire to PMA firms whose products were found to be violative by the FDA in the study. The replies we receive will be tabulated and analyzed and I shall promptly notify you if additional data from the FDA is needed to confirm or deny the conclusions which have thus far been released.