PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., August 22, 1966.

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

DEAR COMMISSIONER GODDARD: Considerable publicity was generated by your comments at the recent annual meeting of the Drug and Allied Products Guild that "We have to conclude that one out of every fourteen drug units manufactured is violative just on potency alone." This conclusion was based, according to your talk, on the results of FDA analyses of 4,200 drug samples representing 20 major therapeutic categories.

As you know from my letters of June 4 and August 18, requesting background data on your statement that one third of the PMA membership is involved in violation of the advertising regulations, we are deeply concerned with reference to statistics of this type without making available to the industry substantiating data. The PMA and our member firms should be in a position to know the source of and more details concerning these generalizations to determine what corrective action, if any, is indicated.

We respectfully request, therefore, that you forward a copy of the tabulation of the 4,200 samples involved, including name of products and manufacturers and the type and degree of deviation from labeled potencies involved. We, of course, are willing either to reimburse the Food and Drug Administration for any expenses involved or provide personnel to prepare the compilation from your analysis records.

In the alternative, we would appreciate a tabulation including only those instances involving members of P.M.A. In your letter of June 30, you stated that you deemed it inadvisable to submit names of companies involved in conduct allegedly violative of the Federal Food, Drug and Cosmetic Act in instances where FDA had determined that no action involving publicity should be taken. While we would prefer that you reconsider that decision, our companies' compliance efforts would be assisted even if you would transmit the types and number of violations involving PMA members without divulging the names of companies involved.

Sincerely,

C. JOSEPH STETLER.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., August 25, 1966.

Mr. FRED J. DELMORE,
Director, Bureau of Education and Voluntary Compliance, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C.

DEAR GENERAL DELMORE: It was certainly a pleasure for Mr. Stetler and me to talk with you the other day on plans of the Bureau of Education and Voluntary Compliance, and to discuss possible ways in which the pharmaceutical industry could be of assistance to the Bureau in its future program.

During our conversation I mentioned that it would be helpful to have certain information on results of F.D.A. examination of samples of drug products obtained in the field. It was concluded that I should send you a letter discussing some of these points.

The discussion was prompted, of course, by public comments from Commissioner James L. Goddard and others on results of analyses of 4,200 samples recently obtained in an F.D.A. survey. Concerning the specific group of 4,200 samples, Mr. Stetler wrote to Doctor Goddard on August 22, stating in part "We respectfully request, therefore, that you forward a copy of the tabulation of the 4,200 samples involved, including name of products and manufacturers and the type and degree of deviation from labeled potencies involved". Mr. Stetler then said "In the alternative, we would appreciate a tabulation including only those instances involving members of P.M.A." . . . "Our companies' compliance efforts would be assisted even if you would transmit the types and number of violations involving P.M.A. members without divulging the names of companies involved".