STATEMENT OF THE FOOD AND DRUG ADMINISTRATION REGARDING THE HISTORY OF THE DRUG RECALL ON MYCOSTATIN (RECALL NO. 49)

The antibiotic (Nystatin) potency of most lots of this drug dropped below label strength before the end of the one year expiration date, thus causing a reduction in the antifungal properties of the preparation. No adverse reactions have been reported.

Approximately 1,300,000 cartons containing 15 tablets each were originally manufactured under 26 lot numbers and packaged under 48 package control numbers. A total of 45,876 cartons were frozen at the Brooklyn manufacturing plant. Remaining cartons were distributed domestically and also exported to many countries.

During July of 1965, stability studies by the manufacturer, E. R. Squibb & Sons, found that several lots fell below label strength.

On August 23, 1965, Squibb notified by letter FDA's Division of Antibiotic and Insulin Control that seven lots packaged under 18 controls had fallen below labeled strength. In November and December, 1965, they notified our New York District office by phone of other lots being recalled.

After conferring with the Division of Antibiotic and Insulin Control, the firm had voluntarily sent recall telegrams to their 17 distribution branches. (These telegrams were sent July 20, August 20, September 2, November 11, and December 10, 1965.) In addition to this branch level recall, the firm informally instructed its salesmen to remove recalled lots from retail and wholesale shelves.

FDA monitored the firm's branch level recall and also tabulated returns from salesmen. During September 1965, certification privileges were suspended for this product until labeling and formulation changes were made.

The firm voluntarily destroyed the following recalled merchandise on two occasions by grinding in a Somat waste disposal unit:

75,238 Strips (5 tablets each) frozen plant stock destroyed: November 23, 1965.

45,876 cartons (15 tablets each) frozen plant stock destroyed: November 23, 1965.

13,320 cartons (15 tablets each) branch returns destroyed: November 23, 1965.

15,481 cartons (15 tablets each) salesman returns destroyed: November 23, 1965 and March 9, 1966.

Mr. GORDON. Can we conclude, Dr. Goddard, that when PMA members have a recall, the consequences are considerably more serious because of the firm's size, than when one of the smaller, non-PMA firms has a recall?

Dr. GODDARD. I would have to qualify that by saying all other things being equal. In other words, if we are dealing with a serious hazard, the more units of a drug that are out, the more magnified the effect. So the answer would be yes with that qualification.

Senator NELSON. Go ahead, Doctor.

Dr. GODDARD. Our district offices, in cooperation with our Bureau of Education and Voluntary Compliance, have held 22 regional seminars and workshops involving 912 firms during the past year on this very subject. Five national conferences have also been held on GMP. We hope that voluntary compliance will prevail and that all companies will greatly improve their manufacturing processes.

The FDA's inspection and sampling programs are a necessary safeguard between each company's quality control system and the patient's use of the drug. Members of the drug industry and the Food and Drug Administration recognize that there is much to be accomplished in this area of quality control. My own first inkling of the magnitude of the problem came from the rising recall lists.

I determined that we had two basic problems which needed immediate attention. First, I was not satisfied that all drugs on the market were of the highest quality.