STATEMENT OF ALEXANDER M. SCHMIDT, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY RICHARD MERRILL, CHIEF COUNSEL, FOOD AND DRUG ADMINISTRATION; J. RICHARD CROUT, M.D., DIRECTOR, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION; JAMES M. BILSTAD, M.D., GROUP LEADER, DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION; AND ROBERT WETHERELL, DIRECTOR, OFFICE OF LEGISLATIVE SERVICES, FOOD AND DRUG ADMINISTRATION

Dr. SCHMIDT. Thank you, Mr. Chairman.

Because the statement I have is relatively brief, I thought I would go through it. I am accompanied this morning by Dr. Richard Crout, Director of the Bureau of Drugs, on my right and your left, and Mr. Richard Merrill, Chief Counsel of the Food and Drug Administration, behind me. To my left is Mr. Robert Wetherell, Director of our Office of Legislative Services, and to my right, Dr. Bilstad, our Group Leader of the Division of Metabolism and Endocrine Drug Products. We are pleased to be here this morning to discuss our current actions regarding the oral hypoglycemic drugs.

As you are well aware, labeling for this class of drugs has been the subject of extended public controversy and legal challenge for a number of years. The Agency has now published a proposed regulation providing new labeling for this class of drugs. The proposal appeared in the Federal Register on July 7, 1975, and asked for comment on the labeling. It also announced a public hearing to be held on August 20, of this year to afford interested persons a further opportunity to comment.

Last September, I summarized before this subcommittee the actions of the FDA that followed the report in 1970 of the results of the university group diabetes program study. Today I will review the events that have taken place since my previous testimony and will discuss, in some detail, of course, aspects of the proposed labeling.

Mr. GORDON. May I interrupt you for just a second, Dr. Schmidt?

As I understand it, new labeling was originally proposed by the FDA in 1972. Is that correct?

Dr. SCHMIDT. That is correct.

Mr. GORDON. So, you have already had comments on that labeling. You stated in your statement which appeared in the Federal Register, that you did not expect any major new information. In fact, it is on page 15 of the Federal Register insertion. You have the results of other studies including animal studies which support the UGDP study.

Why do you, then, have to go through the same long procedures again, that is, proposing changes, having 60 days for comments, having administrative hearings, and so on? Is that for legal purposes?

Dr. SCHMIDT. Well, we spent a considerable amount of time discussing and deciding on the best procedure to use in going ahead with the labeling change and quite deliberately chose the formal rulemaking procedure which in effect this is. And I think the reason the rulemaking procedure is clearly the best way to go is that the goals