written submissions made in response to this notice, and the transcript of the oral hearing made by the Food and Drug Administration. The administrative record of the proceeding shall be made available for public examination.

VIII. PROPOSED REGULATION FOR THE LABELING OF ORAL HYPOGLYCEMIC DRUGS

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a), 52 Stat. 1050-1053, as amended, 1055 (21 U.S.C. 352, 355, 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 310 of Subchapter D of Title 21 of the Code of Federal Regulations be amended by adding a new § 310.510 as follows:

§ 310.510 Labeling for oral hypoglycemic drugs.

(a) An adequate and well-controlled clinical trial (the University Group Diabetes Program study) has indicated that there appears to be an increased risk of cardiovascular mortality associated with the administration of tolbutamide and of phenformin (oral hypoglycemic drugs of the sulfonylurea and biguanide categories, respectively) to maturity-onset diabetic patients as compared to treatment with diet alone or diet plus insulin. The Commissioner concludes that in view of the great similarities in chemical structure and mode of action for drugs within each of these two categories, it is prudent from a safety standpoint to consider that the possible increased