whose symptoms or blood glucose abnormalities cannot be controlled by diet alone and who cannot take insulin for one of a number of specified reasons. Let me discuss each of these sections in greater detail; they are reproduced in full in an attachment.

The Warning describes the UGDP study and its findings. It has been contended that certain studies said not to support the findings of the UGDP study should be mentioned in the warning section to provide "fair balance." We have concluded, however, and made clear in revised section 1.3 of our regulations (also published July 7, 1975), that if scientific data exist to support a warning, the warning must be presented in unambiguous terms without disclaimers or qualifications that would undermine or destroy its usefulness. There is, therefore, no mention in the proposed warning of other studies involving the oral hypoglycemic drugs. The mention of studies in which increased cardiovascular mortality was not found, would serve only to encumber the warning.

The Warning also points out that although only one sulfonylurea and one biguanide were included in the UGDP study, it is prudent from a safety standpoint, in view of the similarities in chemical structure and mode of action of drugs within each of these two categories, to consider that the UGDP findings may apply to all other products in each category. The Warning is thus identical for all the sulfonylurea drugs; only one biguanide drug is marketed in this country.