VI. DISCUSSION OF PROPOSED LABELING FOR ORAL HYPOGLYCEMIC DRUGS

The judgment of the Commissioner that changes must be made in the labeling of the oral hypoglycemic drugs to reflect the findings of the UGDP study is well known from previously published statements. The Commissioner is therefore proposing labeling in this notice for public comment and scheduling a public hearing to receive additional data, information, and views. After consideration of all materials submitted, the Commissioner will publish final labeling for oral hypoglycemic drugs in the FEDERAL REGISTER.

The warning proposed in this labeling for oral hypoglycemic drugs is based primarily on a thorough review and evaluation of the UGDP study. In proposing the overall labeling, the Commissioner has also carefully considered:

1. Published reviews, criticisms, and rejoinders to criticisms of the UGDP study.

2. Other scientific and clinical investigations of the oral hypoglycemic agents.

3. The advice of experts.

4. Comments submitted to the agency by interested persons.

The Commissioner reaffirms his conclusion that the UGDP study is an adequate and well-controlled clinical trial, which is the most extensive and detailed examination of long term administration of hypoglycemic agents yet undertaken. Although the study has shortcomings, which might be expected in any clinical trial of this complexity,