The Commissioner also concludes that a patient population exists for which these drugs, properly labeled, can be considered as safe and effective. Marketing therefore may continue. The Commissioner is proposing, however, that this patient population be limited to patients with maturity-onset diabetes whose symptoms or blood glucose level cannot be controlled by diet alone and who cannot take insulin for one or more of the reasons identified in the labeling. This restriction in labeling has been opposed in the past on the ground that it interfered with the practice of medicine. The Commissioner recognizes that drug labeling impacts on the practice of medicine. For this reason the Food and Drug Administration has an obligation to ensure that drug labeling is as correct and accurate as possible and meets the statutory standard of describing the conditions of use under which the drug may be considered safe and effective. Those limitations on use that properly derive from a known hazard or potential risk must, in the interest of safety, be included in drug labeling. This principle is stated in the proposed regulations on prescription drug labeling (published in the FEDERAL REGISTER of April 7, 1975 (40 FR 15392)), time for comment on which has been extended to August 6, 1975, by notice published in the FEDERAL REGISTER of June 11, 1975 (40 FR 24909).

The Commissioner proposes the appended labeling for oral hypoglycemic agents of the sulfonylurea and biguanide categories as labeling providing the essential information for the safe and effective use of these drugs. Comments addressed to any portion of the labeling will be considered.