The class of oral hypoglycemic drugs can be grouped into two categories on the basis of chemical structure: the sulfonylurea category (represented by acetohexamide, chlorpropamide, tolazamide, and tolbutamide) and the biguanide category (represented by phenformin hydrochloride). The mode of action and adverse effects are different for these two categories of oral hypoglycemic drugs. Accordingly, separate labeling is proposed for each category of drug.

Under section 505 of the Federal Food, Drug, and Cosmetic Act, the Commissioner is responsible for assuring that all new drugs have been shown to be safe and effective for their intended uses and that their labeling is not false or misleading. Exercise of this responsibility often requires reexamination of the safety, effectiveness, or labeling of drugs previously approved. The statutory scheme contemplates that new information may require the Commissioner to prescribe changes in the labeling of a drug, to reveal newly discovered limitations on use or warn of previously unanticipated hazards. And if labeling can no longer be written to assure that the benefits of use of a drug outweigh the risks of possible harm, the Commissioner is empowered, and obligated, to withdraw marketing approval.

The Commissioner believes that information about potential risks of oral hypoglycemic drugs obtained subsequent to their initial approval for marketing requires revision of their labeling.