(9) That any other relief be granted that the Food and Drug Administration may deem meet and proper to fulfill the spirit and letter of this petition.

Respectfully submitted.

ROBERT F. BRADLEY, M.D.,
Medical Director, Joslin Clinic, Boston, Mass.
HENRY DOLGER, M.D.,
Professor of Clinical Medicine, Mount Sinai School of Medicine, City University of New York, New York, N.Y.
PETER H. FORSHAM, M.D.,
Chief of Endocrinology, Professor, Department of Medicine, University of California Medical Center, San Francisco, Calif.
HOLBROOKE S. SELTZER, M.D.,
Chief of Endocrinology, Professor of Internal Medicine, Veterans' Administration Hospital, University of Texas, Southwestern Medical School, Dallas, Tex.
NEIL L. CHAYET, Esq.,
Attorney for the Committee.

(Note.—Appendixes supplied by the FDA were too voluminous to be incorporated in this volume, and were retained in Committee files.)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., June 5, 1972.

NEIL L. CHAYET, *Esq.*,
Chayet & Flash,
Boston, Mass.

DEAR MR. CHAYET: This is in response to your petition filed on behalf of the Coordinating Committee of the Committee on the Care of the Diabetic, requesting the Food and Drug Administration to rescind its decision to require new labeling for oral hypoglycemic agents. We have considered both the submission filed on October 7, 1971, and the additional material filed on January 10, 1972.

We have considered your petition in two parts. The petition first questions the legal authority of the Food and Drug Administration to require the labeling in question on the ground that this regulates the practice of medicines. This aspect of the petition is considered in Part I below. The petition then questions the scientific reliability of the UGDP Study and argues that it is not adequate support for the proposed labeling. This aspect of the petition is considered in Part II below, as supported by Appendix A and its attachments.

I. THE LEGAL ISSUES

Your petition contends that, because FDA's legal authority extends solely to the regulation of the safety and effectiveness of drugs, and not to the control of medical or scientific practices, the Agency may not legally require the use of labeling for oral hypoglycemic agents which limits their recommended use to selected cases under specified circumstances. You also argue that such labeling would violate the statute by failing to state that there is a large body of opinion contrary to this proposed labeling. Each of these arguments is considered separately below.

A. *The legal status of the package insert.* Your first argument, that FDA is without legal authority to require the labeling in question, misconceives the scope of the Federal Food, Drug, and Cosmetic Act, as intended by the Congress.

Section 502(a) of the Act states that a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the Act further states that, in considering whether labeling is misleading, the Food and Drug Administration must take into account the extent to which the labeling fails to reveal facts material in the light of other representations or material in the labeling, with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use contained in the labeling or that are customary or usual. Both of these provisions were included in the statute as enacted by Congress in 1938.