

Warnings sections of the labeling proposed in this notice. The representatives of the Committee on the Care of the Diabetic included one of the plaintiffs in Bradley v. Weinberger and the plaintiffs' attorney. The purpose of these meetings was to engage in good faith negotiation in an attempt to resolve outstanding issues in conformity with the intent of the Court of Appeals. Memoranda of these meetings and of subsequent phone calls and drafts of labeling discussed at the meetings are on file in the office of the Hearing Clerk.

IV. REVIEW OF BIOSTATISTICAL ISSUES BY THE COMMITTEE OF THE BIOMETRICS SOCIETY

The UGDP study was subjected to intense adverse criticism (ref. 6 through 12) largely on the basis of its design and the statistical analysis of the results. For this reason, the National Institute of Arthritis, Metabolism, and Digestive Diseases, which financed the UGDP study, sought an independent review of the study. In 1972 a contract was awarded to the Biometrics Society, an international organization of biostatisticians, to make an in-depth assessment of the scientific quality of the UGDP study, particularly the biometric aspects of the design, conduct, and analysis of the trial, and a similar assessment of other controlled trials involving oral hypoglycemic agents. A committee of six members was selected to undertake this task. The committee visited the UGDP coordinating center and two of the clinical centers to study methods used in the trial, reviewed