

13478 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

The responses to the proposed labeling, including comments received at these meetings, revealed continuing major differences of opinion over the scientific validity of the UGDP study and over the asserted need for "fair balance" and the acknowledgment of "controversy" in the proposed warning. In addition, the Food and Drug Administration was advised that a major outside review, described below, of the UGDP study by a committee of the Biometrics Society was near completion.

The agency therefore decided to postpone implementation of the warning until this review was published. Since the UGDP study was the basis for the proposed warning, the Commissioner believed that this independent review of the statistical validity of the study should be available to all interested persons before taking definitive action. The review by the committee of the Biometrics Society required extensive reanalysis of the data in the UGDP study and was not published until February 10, 1975 (ref. 19). A more detailed report of the UGDP on phenformin was also published recently (ref. 20).

The Commissioner believes that sufficient time has passed to have permitted all interested persons to study these reports. Since no major new information in regard to the UGDP study is anticipated, the Commissioner believes it is now essential to effect all labeling changes that are appropriate and necessary on the basis of the UGDP study.

On June 11, 1975, and June 18, 1975, representatives of the Food and Drug Administration met with representatives of the Committee on the Care of the Diabetic to discuss late drafts of the Indications and