

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13477

It should be noted that no manufacturer of oral hypoglycemic drugs has initiated proceedings challenging the Commissioner's authority to require changes in the labeling of its products, or attacking the scientific basis for the specific labeling changes that the agency proposed to require.

After the Court of Appeals vacated the preliminary injunction in July 1973, the Food and Drug Administration undertook additional discussions concerning the labeling of the oral hypoglycemic agents with interested individuals and groups. In October 1973, the Director, Bureau of Drugs, and other members of the Food and Drug Administration met with representatives of the Committee on the Care of the Diabetic, the American Medical Association, the American Diabetes Association, the National Institutes of Health, and manufacturers of hypoglycemic drugs to discuss procedures that would facilitate the issuance of appropriate labeling. Based upon the discussion and input from the agency's staff, proposed labeling revisions were circulated for comments in February 1974 to those who attended the meeting and to other interested persons. Addressees were also invited to meet with agency officials, if desired, to discuss the labeling. Four such meetings were held between March 21 and April 24, 1974. The minutes of these meetings have been placed on public display in the office of the Hearing Clerk.