

9084 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

PRECEDENCE EXISTS FOR ACCESS-TO-RECORDS AUTHORITY

Several Federal agencies have authority to review records relating to the production and distribution of products under their regulatory responsibility. For example, the Federal Meat Inspection Act, as amended (21 U.S.C. 601), requires meat processors to maintain records and give USDA inspectors access to all records bearing on the quality and distribution of meats. The Wholesome Poultry Products Act (21 U.S.C. 451) also requires firms to open their facilities and records to examination by USDA inspectors.

Access to records is also authorized by law for the Department of Transportation when inspecting automobiles and automobile tires for safety. In addition, the proposed Federal Environmental Pesticides Control Act of 1972 (H.R. 10729) proposes expanded access-to-records authority for use by EPA in controlling pesticides. This bill passed the House of Representatives in November 1971, was approved by the Senate Committee on Agriculture and Forestry in April 1972, and is currently awaiting final Senate action. Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135-135k), EPA already has authority for access to all records showing the delivery, movement, or holding of pesticide products, including quantities of shipments, dates of shipment and receipt of goods, and names of consignors or consignees of shipments. The proposed legislation would provide EPA with additional authority for plant inspection.

In addition, some States have laws which require firms to provide State officials with access to records. California, for example, has a law which requires firms to provide State inspectors with complete access to all records bearing on the quality of a product. Pennsylvania law authorizes its food and drug office access to firms' quality control records and shipping data.

The need for FDA to have access to records was recognized in 1962 when the FD&C Act was amended to require firms which manufacture, process, package, or hold prescription drugs to provide access to records, files, papers, processes, controls, and facilities bearing on whether such drugs are adulterated or misbranded.