The Secretary of HEW, in a 1963 letter to the Speaker of the House of Representatives, submitted a legislative proposal to give FDA authority for access to records concerning all products covered by the FD&C Act. The President, in a 1964 message to the Congress, reiterated this request, stating that FDA lacked the needed authority to fully inspect the factories in which products were produced.

FDA officials have stated that access-to-records authority is essential if FDA is to provide consumers with the protection intended by the Congress. FDA officials told us that the lack of cooperation by some firms had increased the cost of inspections or had made them ineffective.

On January 19, 1972, the proposed Pure Food Act of 1972 (H.R. 12478) was introduced in the House of Representatives. This bill would amend the FD&C Act to give FDA access to all records for food commodities.

INDUSTRY AND MANUFACTURING ASSOCIATION COMMENTS

During our review we discussed FDA's authority with officials of 20 food, drug, and cosmetic firms. We also discussed our review and tentative conclusions with representatives of five manufacturing associations. Comments from these officials varied--some agreed that FDA needed additional access-to-records authority; while others disapproved of FDA's access to any records. A major concern of some officials was the protection of trade secrets and formulas from their competitors. Other industry officials, however, told us that this was not a valid concern. The majority of the firms whose officials we interviewed had provided FDA information, including some trade secrets, without any problems.

Another concern expressed by some officials was that additional authority would allow FDA to require firms to provide information without justification or cause. Other officials, however, stated that increasing FDA's access to records would not affect the amount of information they were providing FDA.

An official of a drug manufacturer told us that some firms were not as cooperative as his firm in providing FDA