

9086 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

access to records. He explained that, because his firm provided FDA access to records, it ran a greater risk of having products seized. He believed that all firms should be required to provide FDA the same types of information.

An official from another firm stated that his firm cooperated with FDA because the firm believed it was responsible for complying with more than the minimum legal requirements. He said that some firms used the specific language of the law to prevent FDA from making a complete inspection.

FDA, acting on a suggestion by the National Canners Association, published a proposal in the November 12, 1971, Federal Register, which states that FDA personnel should be permitted to inspect canning firms' processing records. These records are needed, the proposal states, to insure that adequate processing and coding of low-acid canned food were performed. As of May 8, 1972, comments on the proposal were being considered before inclusion in the Code of Federal Regulations.

CONCLUSION

The lack of authority to review records relating to the production and distribution of all products under FDA's responsibility severely hampers FDA's ability to identify and remove from the market products suspected or known to be violative; thus, consumers are exposed to an increased risk of using such products. We believe that there is a need for legislation giving FDA access-to-records authority--similar to the authority FDA now has for prescription drugs--for all products under its consumer protection responsibility.

HEW had prepared legislation for such access-to-records authority and submitted it to the Congress on only one occasion--in 1963--9 years ago. Because industry refusals may prevent FDA from identifying and removing products suspected or known to be violative from the market, we believe the Secretary of HEW should again seek legislative changes to the FD&C Act and the Federal Hazardous Substances Act to provide FDA with expanded access-to-records authority.