

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 9081

unavailability of the product, or the minor nature of the violations.

--In nine of the remaining 11 cases, FDA's efforts to take removal actions were delayed or prevented because the firms maintained their position to refuse FDA inspectors access to information.

Two examples follow.

Example A--A manufacturer of a liquid drain opener refused to provide FDA with shipping records which were needed to show whether the product was shipped in interstate commerce and, therefore, whether the product was under FDA's jurisdiction.

FDA contended that the product violated the Federal Hazardous Substances Act because it did not have an adequate warning on the label. FDA had received several complaints that the product has caused skin burns. One consumer complained that she had suffered serious facial scarring because the product spontaneously exploded when she poured it into her kitchen drain. Had she not been wearing glasses, she might have been permanently blinded. Despite these injuries, the firm refused to cooperate with FDA.

The FDA district office attempted to locate a sample which had been shipped interstate by obtaining consignee names from a trucking company and by requesting another FDA district office to try to locate the product. This attempt was unsuccessful, and FDA was unable to take action to remove the product from the market.

Example B--A firm which processed walnuts refused to provide FDA with shipping data, even though FDA had found that some of the walnuts at the firm were contaminated with filth and *Escherichia coli*--a bacteria found in the intestinal tract of warmblooded animals and an indicator of fecal contamination. After notifying FDA officials in another State, a sample of the firm's walnuts was collected and was found to be contaminated. As a result, FDA removed 36 cases of walnuts at this location. An FDA official advised us that the firm's refusal to provide shipping data delayed the eventual removal of the contaminated product from the market in the one location and prevented FDA from removing the