

9082 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

product from other locations and thereby hampered FDA's ability to protect the consumer.

Refusals delay or prevent FDA evaluation of firms' production and quality controls affecting the quality of products

Refusals hampered FDA's inspection efforts in 68, or 23 percent, of the 290 inspection cases we reviewed by delaying or preventing FDA from obtaining information needed to evaluate the firms' production and quality control procedures affecting the quality of their products. In 36 cases FDA performed additional work attempting to obtain the refused information. Following are two examples of refusals which significantly hampered FDA's inspection efforts.

Example C--A bakery made coconut pies with eggs obtained from a supplier whose eggs had been found to contain salmonella (harmful bacteria which can cause illness and even death). In addition to taking action against the egg supplier, FDA requested the bakery's quality control records which were supposed to show the results of testing pies for salmonella. These records were needed because the pies (the only product in which the suspected contaminated eggs were used) had already been distributed.

The bakery refused FDA access to these records, and FDA was unable to determine whether the pies contained salmonella. In addition, FDA was not able to complete an important part of its inspection--evaluation of the firm's procedures for testing products for salmonella. In fact, FDA could not even determine whether tests for salmonella had been performed.

Example D--A firm which manufactures chemicals used in medical diagnoses refused to provide FDA access to its records which included information on products being recalled by the firm. FDA inspectors had estimated that 20 products were being recalled. After allowing FDA to review the files for four of the recalled products, the firm refused further access to its files. Although three FDA inspectors spent 197 hours trying to identify all the products which the firm was recalling, no information on the estimated 16 remaining products could be obtained. The four products identified were being recalled for the following reasons.