

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10645

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Copies of these reports are furnished to the manufacturer or other distributor of the product in question, and to FDA. Based on evaluation of these reports, we issue investigatory assignments to the field when indicated, or in some cases institute special programs or surveys.

During FY 1973, we received 2,750 program reports. The program is expanding at a rapid rate as demonstrated by the fact that we have already received 2,350 reports for the first half of FY 1974.

The kind of correction this program may bring about is illustrated by the interesting story of nitroglycerin. A pharmacist questioned the suitability of a plastic, pen-shaped container for nitroglycerin tablets. Our investigation revealed that the drug was rapidly absorbed into the container walls and after 30 days only seven percent of the tablet potency remained, i.e., the drug was practically worthless. FDA contacted the manufacturer and the plastic, pen-shaped containers were recalled.

We have since issued a regulation requiring that nitroglycerin be packaged in glass containers and dispensed only in the original unopened container.

ADDITIONAL ACTIVITIES CARRIED ON BY FDA TO ASSURE UNIFORMLY HIGH
DRUG QUALITY

In conjunction with our total quality assurance program, the Agency conducts a number of programs which help assure a uniformly high quality for the Nation's drug supply, including: