

10654 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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In addition, when a drug is to be recalled from the market and we determine from distribution reports that the firm has supplied the drug to DPSC, VA, or other Government agency, FDA notifies that agency of the recall. It is then the responsibility of that agency to insure appropriate recall of the drug under its control.

When we receive a report through our Drug Defect Reporting System, the DPSC is notified whenever the report originated from a Federal hospital or other Federal installation, and also where a "Federal Stock Number" is part of the labeling of the product.

GENERAL ACCOUNTING OFFICE (GAO) REPORTS

The Food and Drug Administration has completed actions to implement the recommendations of the March 1973 GAO report on Enforcement of Good Manufacturing Practices for Drugs. We have developed a monitoring system to identify (1) new drug firms that require inspection, (2) existing firms that failed to reregister for the current year, and (3) firms that require an inspection to fulfill the statutory requirement for biennial inspection. In addition, FDA has revised the Administrative Guideline for GMP's to provide more specific guidance to FDA personnel in determining the need for regulatory action. That guideline is under current consideration for further revision.