

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11943

Plant Inspection Program

To begin with, the Federal Food, Drug, and Cosmetic Act requires that every drug firm be inspected every two years. Such inspections are done primarily to determine whether the plant is operating in compliance with our current Good Manufacturing Practices (GMP) regulations. These regulations specify the basic standards which a drug manufacturer must adhere to in order to control his production process---stringent process control is essential to the manufacture of high quality drugs.

Considerable effort has been devoted in the past year to updating FDA's regulations. A late draft of these newly amended regulations is on display in the Office of the Hearing Clerk in FDA and will be published as a proposal in the Federal Register in the near future. Among the principal changes in these regulations will be these: