

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11945

I am also pleased to report that FDA's plant inspection activities in the field during the past year have been excellent. While there are some 8,000 drug firms registered with the FDA, the number of prescription drug manufacturers is much lower. There are approximately 400 basic manufacturers of prescription drugs in the country, and each of these is inspected at least every two years. The larger manufacturers are inspected more frequently, as they should be in view of their market impact.

Drug Product Surveillance Program

A second basic approach to assuring the quality of drugs is the FDA's surveillance program of marketed drugs to determine their adherence to compendial standards or standards established in new drug applications (NDA).

The analytical work under this program is carried out by FDA's National Center for Drug Analysis in St. Louis and its 19 field laboratories. Where feasible, drugs of similar composition are assigned to a single laboratory for analysis to permit the use of modern automated testing methods and thus increase laboratory efficiency and reliability. During FY 1975, the FDA will analyze over