Inspection of Drug Manufacturing Establishments

The Federal Food, Drug, and Cosmetic Act requires inspection of every drug firm at least once every two years. A major portion of our field inspection time is expended in our efforts to comply with this mandate. In FY 1973, we inspected 2,700 registered human drug establishments and made some 7,000 inspections of registered and related drug establishments. This level of inspectional activity will be maintained during the current fiscal year. It will allow us to inspect not only those firms with identifiable problems, but also 97 percent of major manufacturers of prescription legend drugs, responsible for about 95 percent of marketed prescription legend drugs.

A primary objective of the inspectional program is to determine whether drug manufacturers are following what the law refers to as current good manufacturing practices (GMP's). GMP's are spelled out in regulations, and serve to guide our inspectors when reviewing plant operations.

In addition to providing routine surveillance on a scheduled basis, GMP inspections may be made on a selective basis. We often schedule inspections as a result of information obtained from our own product analysis, or other reports of defective products. A pending new drug application or request for certification of an antibiotic by a firm may also trigger an inspection, as a determination of compliance with GMP is a required condition for approval.