After careful evaluation of the inspection reports and review of the scientific literature pertaining to principles of sterilization, etc., we met with the individual firms during September and October of 1973. In these technical sessions, we identified problem areas and separated them into those which could and should be corrected immediately and those which would require longer-term improvements in production practices.

The FDA then prepared summary papers identifying the significant problem areas and proposed solutions. These have subsequently been commented upon by each firm, and we have now prepared a summary document designed to establish common standards for the industry as a whole.

The latter has been submitted to all the firms (in January 1974) for final comment. The FDA expects that from this program will evolve specific guidelines for FDA inspections of LVP manufacturers and revisions of our good manufacturing practice regulations.

Drug Product Defect Reporting Program

Another program for monitoring drug quality is a joint effort involving various pharmaceutical associations, the United States Pharmacopeia and FDA. Under this program, pharmacists across the Nation report apparent product defects or problems to the USP.