demonstrated that it could consistently manufacture digoxin in compliance with standards, it had to obtain a batch-by-batch analysis and FDA release prior to marketing.

When we later received information concerning variation in bioavailability of digoxin manufactured by different firms, and a new United States Pharmacopeia (USP) dissolution rate standard was adopted, we instituted a certification program similar to that employed in the content uniformity problem.

New regulations pertaining to the marketing of digoxin became effective on January 22, 1974; a copy is submitted for the record. The regulations require batch-by-batch certification of digoxin until the firm demonstrates that its product consistently meets the new USP dissolution standards. These regulations also require that all firms intending to continue the marketing of digoxin must present evidence of bioavailability within 180 days after filing such notice of intent.

In the case of the large volume parenterals (LVP), we instituted a special program in response to continuing reports of nonsterile products. The program evaluates the quality control and manufacturing procedures in all plants of all firms producing large volume parenterals in the United States. Ten manufacturing plants, representing the four manufacturers (Abbott, Baxter, McGaw, and Cutter) were inspected during May and June of 1973.