TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C--DRUGS

PART 130--NEW DRUGS

CONDITIONS FOR MARKETING OF DIGOXIN PRODUCTS

In April, 1970, the Food and Drug Administration inaugurated a program to systematically test marketed batches of digoxin tablets after the agency became aware of an apparent potency problem with this cardiac glycoside. As a result of this testing program, from April to November, 1970, there were 79 recalls of digoxin products. In October, 1970, a voluntary certification program was initiated whereby participating manufacturers agreed not to release new batches of digoxin tablets until samples of the batches were tested by the Food and Drug Administration and found to meet The United States Pharmacopeia (USP) requirements for potency and content uniformity.

In December, 1971, John Lindenbaum, M.D. and his colleagues published a paper in The New England Journal of Medicine (Lindenbaum, J., Mellow, M. G., Blackstone, M. D., Butler, V. P., "Variation in Biologic Availability of Digoxin from Four Preparations," The New England Journal of Medicine, 285:1344, 1971) describing a study of the biologic availability in