products which do not meet current good manufacturing practice and compendial requirements.

2. Procedures to require manufacturers to submit samples of all new batches of digoxin tablets to the Food and Drug Administration for analysis and certification prior to release of these batches for distribution.

3. Procedures to monitor digoxin product formulations to assure that any reformulation will result in compliance with all in vitro test requirements and in uniform batch-to-batch bioavailability.

4. Procedures to require manufacturers to conduct in vivo bioavailability tests.

5. Procedures to assure uniformity in the labeling of all digoxin products for oral use.

The Commissioner is of the opinion that, in view of the questions that have been raised regarding the bioavailability of digoxin products and the need for some manufacturers to reformulate their products to meet the new requirements for dissolution, these drug products cannot properly be considered generally recognized as safe and effective within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. Therefore, all digoxin products for oral use are new drugs for which approved new drug applications are required. All persons marketing such drug products must submit an abbreviated new drug application for these products on or before (insert date 30 days after the date of publication in the FEDERAL REGISTER) if marketing is to continue. After this date, any such drug product then on the market which is not the subject of an abbreviated new drug application submitted for such drug product will be