products which meet all compendial requirements including dissolution. The third action will involve procedures to monitor digoxin product reformulations in order to assure that orderly progress is made towards the marketing of digoxin products which are 100 percent bioavailable. The third action will include means of adequately advising practitioners of changes in digoxin bioavailability resulting from product reformulations.

The Food and Drug Administration is prepared to take the actions necessary to assure the removal from the market of all batches of digoxin tablets in the channels of commerce after November 15, 1973, which do not meet all compendial requirements. The agency has initiated a program for sampling and analyzing batches of digoxin tablets in the channels of commerce. Manufacturers of batches of digoxin tablets which are found not to be in compliance with the compendial requirements will be requested by the Food and Drug Administration to initiate recall of the subject batches from the market. Violative batches which are not promptly and effectively recalled will be subject to regulatory procedures.

Data indicate that a significant number of manufacturers will need to reformulate their digoxin tablets to assure that their digoxin tablets meet the new compendial requirement for dissolution. Because of the narrow margin between therapeutic and toxic levels of digoxin and the potential for serious risk to cardiac patients using digoxin products which may vary in bioavailability, the Commissioner has determined that immediate actions must be taken to assure better uniformity of all digoxin products for oral use. These actions include:

1. Procedures to remove from the market all batches of digoxin