Ketchum Laboratories, Amityville, N.Y.
Lakeside Labs., formerly Davies-Rose-Hoyt, Needham, Mass.
Lannett Co., Philadelphia, Pa.
Lederle Laboratories, Pearl River, N.Y.
Marshall Pharmacal Corp., South Hackensack, N.J.
Parke, Davis & Co., Detroit, Mich.
Park Laboratories, Inc., Fredonia, Wis.
Premo Pharmaceutical, South Hackensack, N.J.
Philips Roxane Labs, Columbus. Ohio.
Rexall Drug Co., St. Louis, Mo.
Rondex Laboratories, Gutenberg, N.J.
Stanley Drug Products, Inc., Portland, Oreg.
ICN Pharmaceuticals, formerly Strong Cobb Arner, Cincinnati, Ohio.
Tablicaps, Inc., Franklinville, N.J.
Towne Paulsen & Co., Inc., Monrovia, Calif.
Vale Chemical Company, Allentown, Pennsylvania.
Vita-Fore Products Co., Ozone Park, N.Y.
Vitarine Co., Springfield Gardens, N.Y.
West-Ward, Inc., Bronx, N.Y.
Wyeth Labs, Philadelphia, Pa.
Zenith Laboratories, Inc., Northvale, N.J.

STATUS REPORT DIGOXIN CERTIFICATION PROGRAM—APRIL 9, 1974

On January 22, 1974, Regulation 21 CFR 130.51, "Digoxin Products for Oral Use; Conditions for Marketing" was published in the *Federal Register* setting forth FDA's position regarding the conditions for the continued marketing or oral digoxin products. The regulation, which became effective on the date of publication, has the following requirements for oral digoxin products:

1. Declared all oral digoxin products to be new drugs.
2. Requires submission of ANDA, including bioavailability tests for all oral digoxin products.
3. Requires a *mandatory*, FDA certification program based on dissolution testing by NCDA. No oral digoxin product may now be released without FDA approval.
4. Requires recall of any previously marketed batch of digoxin tablets found to fail USP dissolution specifications.

A meeting was held on January 21, 1974, at the Parklawn Building prior to publication of the *Federal Register* announcement to advise the industry of the status and importance of the program and to enlist their cooperation for its success.

The current status of the certification program is as follows:

PREVIOUSLY MARKETED BATCHES

1. One hundred and fourteen (114) previously marketed batches of digoxin from twenty-seven (27) manufacturers have been tested for dissolution and the results reported to the manufacturers.
2. Thirty-four (34) manufacturer batches representing fifteen (15) manufacturers and fourteen (14) distributor batches representing ten (10) distributors have been found to fail the requirements of the *Federal Register*, statement and removed from the market place by recalls.

BATCHES SUBJECT TO PREMARKETING CERTIFICATION

1. Thirty-four (34) digoxin manufacturers are involved in the program.
2. Twenty-one (21) batches from five (5) manufacturers have been certified by FDA and released for marketing.
3. One (1) manufacturer has submitted four (4) consecutive passing batches for each of its three (3) digoxin dosage strengths and has been temporarily released from the certification program.
4. One (1) manufacturer has submitted four (4) consecutive passing batches for its one (1) dosage strength and has been temporarily released from the certification program.