

10664 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

REPORT ON PSYCHOSTIMULANTS

Scope of the Survey

This survey covered five psychostimulant drugs marketed as single active ingredient drugs each in one or two dosage forms as follows: Amitriptyline HCl Tablets and Injection, U.S.P. XVIII; Desipramine HCl Tablets and Capsules, N.F. XIII; Imipramine HCl Tablets, U.S.P. XVII; Nortriptyline HCl Capsules, N.F. XIII; and Protriptyline HCl Tablets.

Of the seven domestic formulators known to produce these drugs, samples of batches from five firms were collected in this survey. The output of two firms, Standard Pharmacal Company and Taylor Pharmacal, was unavailable for sampling.

Sampling Information

Samples were collected under FDA's FORDS (Formulator-Oriented Rx Drug Studies) Program from the formulators (manufacturing plant or primary distribution warehouse) or from their branch warehouses or major accounts. No collections were made at locations more than once removed from the manufacturer. Samples were collected from batches released for distribution by the firms' quality control.

Laboratory Tests

Samples were analyzed for compliance with the specifications in the compendial monograph or NDA by the appropriate semi-automated procedure or other method of analysis deemed appropriate by the National Center for Drug Analysis. Testing was performed on each of six sub-samples from each batch.

Summary of Results

Of the 42 samples analyzed (see Table 1), no samples were found defective.