

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10667

REPORT ON ANTIEMETICS

Scope of the Survey

This survey covered four different drugs marketed as single active ingredient preparations; three in tablet form and one in both capsule and injectable form. Drugs in this study were: Cyclizine HCl Tablets U.S.P. XVIII, Meclizine HCl Tablets U.S.P. XVIII, Dimenhydrinate Tablets U.S.P. XVIII, and Trimethobenzamide HCl Capsules and Injection N.F. XIII.

Of the twelve domestic formulators known to produce these drugs, samples of batches from eleven firms were collected and analyzed in the survey. The output of one firm, Bowman Pharmaceutical, 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 chemical specifications in the compendial monographs. Initial chemical analyses were performed by methods 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 33 samples analyzed (see Table 1) no defective samples were found.