## 10258 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

## SSC-1

Barr Labs.
Bell Pharmaceutical
Bowman, Inc.
Carr Drug
Columia Medical
Consolidated Medical Corp.

Fellows Medical

ICN Kirkman Purepac Richlyn Sheraton Labs. Sherry Labs. Stanlabs Stayner Towne

Ulmer Wolins Zenith

DPSC had occasion to inspect the facilities of 11 of those firms. Six were disqualified in 1973, while four others were rejected prior to 1973 and we have not reinspected. The survey findings of several companies from that list are reviewed.

## Plant Deficiencies

- -One drug container with two labels
  "Ascorbic Acid and Starch"
- -Container and lid had different lot numbers.
- -Loss of lot number traceability.
- -Failure to maintain building free of insects in production and other areas.
- -Incomplete raw material testing
- -Production equipment not cleaned before and after use.
- -Live spider in drying oven.
- -Inadequate quarantine of raw material
- -No calibration program.

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"One cannot equate price without an adequate baseline for quality, and that applies to both plant and product.

The need to scrutinize public statements was vividly magnified when a prominent physician, in his testimony to a State legislative committee, advised the listeners that the basis for the Military's rejects of drug plants is for packaging reasons. The records are well established that a DPSC disqualifies a very substantial percentage of drug producers for serious quality control and house-keeping deficiencies."