

10024 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

COMPANY	DATE	DESCRIPTION OF VIOLATION
Hygeia Products Inc. New York, NY	March 1973	There are no written quality control procedures.
	April 1973	The firm assigns a single lot number to multiple batches and this results in a lack of traceability to source material and manufacturing data for the specific batches.
		The platform scale used to weigh ingredients was inaccurate. The zero reading was plus 5 lbs. The section of the scale holding the weight indicator was shaky.
		There is no hot running water or individual towels in the ladies washroom and there is no hot running water in the men's washroom.
		The platform scale used to weigh ingredients is heavily crusted.
Allergen America Hormigueros, P.R.	April 1973	A sterile 40 liter glass jug previously cleaned and sterilized and awaiting use as a surge vessel in a sterile filtration was found with an oily film and visible oil droplets on the inside surface of the bottle. The oily area was larger than the size of a half dollar. Use of the jug would have contaminated the product with foreign material and compromised the purity of the final product.
Zenith Laboratories Northvale, NJ	June 1973	The general appearance of the "Quarantine area" reflects a lack of adequate general janitorial service. It was heavily laden with dust and dirt. It is not orderly and not arranged to facilitate cleaning and handling of material.
		Failure to maintain building free of insects. Flies were noted in the production and other plant areas.
		Prior labeling was not effaced. A metal drum still bore the label as "Ascorbic Acid" on the container while it was also labeled Starch, lot 11239.