

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 8027

An examination of 21 preaward survey or product sample reports listed the following specific explanations for disqualification by area:

<i>Area of disqualification</i>	<i>Specific reasons cited</i>
Quality control.....	Inadequate inspection program. Inadequate production records. Inadequate testing or testing program. Inadequacies in packaging. Inadequacies in written quality control procedures. Unauthorized people having access to label room. No program for maintenance and calibration of scales.
Housekeeping.....	Spillages not immediately removed from production area. Uncovered trash bins in bottle packaging area. Trash barrel emptied too close to production line. No program for periodic employee medical examinations.
Product sample.....	Unsanitary raw material containers. Container, container caps, or container labeling did not comply with purchase description requirement. Product failed specification requirements such as hardness test, storage test, color test, consistency, material defects, solubility test, etc.
Unacceptable subcontractor.....	Subcontractor was not required to issue adequate inspection instructions.
Capacity.....	Unsatisfactory production capability—no production plan; inadequate test equipment; plant fully utilized for current and future production; employees on strike. Inability to meet required delivery schedule—no production plan; time required to correct quality control deficiencies would jeopardize delivery; plant has insufficient capacity to meet the delivery schedule; plant has a bad performance record; firm had not obtained a commitment for glass. Unsatisfactory performance record—delinquencies on past contracts; production problems in manufacturing specification item. Unsatisfactory plant facilities and equipment—firm did not have necessary punches and dies; on-hand equipment fully committed to other orders.

NOTE. The above schedules do not reflect the relative seriousness of the deficiencies. The preaward survey is an evaluation of the proposed contractor's capability to perform. Each deficiency reported is evaluated as to its effect on the proposed award. The contracting officer must weigh all of the information and advisory recommendations supplied to him in selecting a contractor.

Senator NELSON. It raises several questions, I would suppose: Are the standards being used sound, and then if they are sound, are the same companies putting the same drug into the retail marketplace? Is there any exchange of this information between the Defense Supply people and the Food and Drug Administration?

Mr. AHART. I understand that there is no routine mechanism by which the Defense Department's inspection results get to the Food and Drug Administration or to the Veterans' Administration, as