

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11915

- Assume responsibility for performing all laboratory analysis relating to quality assurance.
- Review purchasing specifications to assure they are acceptable from a quality standpoint.
- Develop with DOD and VA an information exchange mechanism covering:
 - ° contract administration
 - ° new data which may impact adversely on quality assurance of a product or firm
 - ° specific requests for inspectional or analytical work
 - ° drug defect reporting systems

This proposed plan has been discussed informally with VA and DOD. Based on these discussions, FDA has drafted proposed interagency agreements which have been submitted to VA, PHS, and DOD for their preliminary review. We are optimistic that these draft agreements will receive favorable consideration. We will then formally transmit the plan to HEW and OMB for final approval. We are hopeful that final approval from all parties will be obtained so that our projected implementation date of July 1, 1975, can be met.