

10616 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

that would be needed to facilitate the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

AGENCY COMMENTS

DOD doubted FDA's capability to perform the types of inspections it requires.

VA stated that it would use the service when FDA was capable of performing inspections on a timely basis. HEW stated that it would discuss the requirements, resources needed, and pertinent issues for carrying out our recommendation with the interested agencies, and, if it found that it would be in the best interests of the Government, it would take the necessary actions to arrange for the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

We believe there is a demonstrated need for serious consideration of transferring drug procurement quality assurance inspection activities to FDA. Although discussions of requirements, resources needed, and pertinent issues are a first and important step, we believe that such discussions should be held with the objective of exploring alternatives that, if proven feasible, would facilitate the transfer to FDA.