Once these plans and agreements have been established and the appropriate resources transferred to FDA, the Agency will, for example:

-- conduct all inspectional work associated with the quality assurance of drugs and biologics. This may in some instances be phased-in over a several month period.

-- conduct all laboratory analysis associated with the quality assurance of drugs and biologics. This also may require a phasing-in period.

-- review all purchasing specifications for prospective contracts as received for any requirements which may impact adversely on quality or seem obviously unnecessary for quality assurance. If any such deviations are identified, the purchasing agency will be advised that the quality specifications are unacceptable unless that agency can supply adequate justification for the requirement.

While initially these reviews will be directed only to specifications which may deviate markedly from existing public (e.g., United States Pharmacopeia (USP)) and private (e.g., New Drug Application (NDA)) standards, subsequent modification of purchasing specifications will also be done as necessary, as part of the continuing systematic evaluation of all drug specifications done by FDA in collaboration with USP.