Chairman expects that the Committee's recommendations regarding the management of drugs will be provided to the agencies for review in the fall of this year and, if accepted, the implementation of the proposed system would begin in early 1976.

HEW

On July 16, 1974, the Secretary of HEW responded to the June 4, 1974, memorandum of the Director, OMB, and stated that the Assistant Secretary for Health would accept the leadership role in developing a Government-wide quality assurance program for drugs and medical items with FDA having direct program responsibility. Even before the Secretary's reply--on July 3, 1974--FDA had already formed a high-level steering committee to direct and oversee the implementation of the program.

In August 1974, at a meeting between the Commissioner of FDA and DOD officials, it was decided that the program initially would include only drugs and biologics and that other medical products would be phased in at a later date. In September, 1974, FDA briefed DOD, VA and Public Health Service (PHS) representatives on the operations of FDA and FDA's philosophy regarding the Government-wide quality assurance program.

FDA also developed a comprehensive plan to study the existing medical products quality assurance systems in Federal