Mr. Chairman, we believe this basic philosophy of drug quality assurance is central to the implementation of the Government-wide Quality Assurance Program for all medical products.

GOVERNMENT-WIDE QUALITY ASSURANCE

As I stated earlier, the FDA will have full responsibility for all quality assurance operations for drugs and biologicals in the Federal Government. We will provide the Federal purchasing agencies assurance that the medical products they buy meet appropriate quality standards.

I am very pleased to report that we have made substantial progress toward our goal of developing and implementing a Government-wide Quality Assurance Program for Medical Products. The following is a summary of what has been accomplished in development of the quality assurance program, the present status of our efforts, and what yet must be accomplished to complete the development and implementation of the plan.

On June 4, 1974, Mr. Roy L. Ash, Director of the Office of Management and Budget (OMB), requested the Secretary of Health, Education, and Welfare to assume full responsibility for developing an Executive Branch plan for implementing a consolidated quality assurance program for drugs and medical devices. The OMB study of Federal procurement and distribution of medical and nonperishable substance supplies had concluded that such a program should be implemented and recommended that FDA be responsible for the program. It is evident that careful planning and organization are vital to assure effective implementation of the program and we have therefore devoted substantial attention to these factors.