Mr. AHART. The final authority would rest with OMB.

The CHAIRMAN. All right.

Mr. AHART. On July 16, 1974, the Secretary of HEW advised OMB 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 this, FDA had already formed a high level steering committee to direct and oversee the implementation of the program.

In August 1974, 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 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 system in Federal agencies and to develop and implement a program which would satisfy the quality assurance needs of purchasing agencies within the mandate which it had been given. The overall approach included seven separate, but closely related action plans.

In an April 1, 1975, memorandum to OMB, the Acting Assistant Secretary for Health stated that both HEW and FDA attach great importance to the carrying out of FDA's Government-wide quality assurance responsibilities. He stated also that the progress of FDA's plan is essentially on schedule and that FDA has received excellent cooperation from the Department of Defense, the Veterans' Administration, and the Public Health Service. The Department has established target dates for FDA's implementation of the quality assurance program for drug and biologics as follows:

To undertake all testing—that is, laboratory analyses—for the Veterans' Administration, the Department of Defense, and the Public Health Service, by July 1, 1975; to undertake and assume responsibility for the precontract award evaluations for each of the three agencies by the same date; and to assume the postaward inspectional work for the Department of Defense by the same date with a 60-day phase-in period to allow for a smooth transition.

An FDA official informed us that FDA's ability to meet the target dates would depend on the time required to receive approval—both within HEW and from OMB—of its implementation plans.

The Acting Assistant Secretary stated that planning has begun for FDA's assumption of quality assurance responsibility for medical devices, diagnostic products, and radiological health products.

Based on our discussions with DOD and Veterans' Administration officials, it is obvious that in the 14 months since we last appeared before this subcommittee, the two agencies have devoted much effort to achieving the goals of the GSA-led interagency effort and the objectives of the FDA-led effort in the quality assurance area, thereby responding to the recommendations in our report.

For example, in the area of specification development:

—An official of VA's Department of Medicine and Surgery stated that the agency now develops specifications for all new drugs which