Mr. Chairman:

We are pleased to appear before your Subcommittee this morning to discuss the status of the Government-wide Ouality Assurance Program for Medical Products.

As you know, we stated during the hearing before your Subcommittee last year that the Food and Drug Administration (FDA) was the logical focal point for such a program. The FDA has now been formally assigned the responsibility for this activity and is in the process of developing, in cooperation with the Department of Defense (DOD), the Veterans Administration (VA), and other agencies in the Public Health Service (PHS) a plan to implement this program. Our commitment to perform the functions assigned to FDA by any approved plan is, of course, contingent upon the acquisition from the cooperating agencies, of those portions of their existing quality assurance resources we believe necessary to do the job.

Prior to discussing the status of our progress, I would like to reemphasize some of the points we made last year. First, the basic responsibility to assure the production of high quality products rests with the manufacturer, not the Government. Second, the Government's role is to audit the industry's quality assurance to assure that it is adequate. This is done by:

-- promulgating and implementing meaningful and enforceable Current Good Manufacturing Practice (GMP) regulations for the industry to follow;

-- performing periodic, general and, as necessary particular inspections of firms;