FDA QUALITY ASSURANCE PROGRAM

Mr. Chairman, last year we advised your Subcommittee that we believe the quality of drugs in this country is the highest in the world and that we would continue to take additional measures to further strengthen our quality assurance programs in the months ahead. We recognized that there would be problems in the future, that this was to be expected, and when they were found, we would correct them. I would like to bring you up-to-date on some of our activities in quality assurance that have occurred in the intervening year.

Current Good Manufacturing Practice Regulations for Drugs

Considerable effort has been devoted in the past year to updating these regulations. A draft of these newly amended regulations is on display in the Office of the Hearing Clerk in FDA; we will publish a proposal for amending the GMP's in the Federal Register in the near future. Among the principal issues to be considered in these proposed regulations will be:

-- Requirements for written procedures for manufacturing and control operations;

-- The use of statistical sampling techniques for quality control testing;