for some time felt it necessary to develop a monograph system for prescription drugs in the old drug category just as it has developed a monograph approach to the over-the-counter drugs. Major regulations relating to old drug monographs for prescription drugs are in preparation and will be published as proposals later this year.

In anticipation of these regulations, the FDA will announce in the Federal Register that certain well-established prescription drugs reviewed in the Drug Efficacy Study which do not have bioequivalence or special manufacturing problems will in the future be considered as old drugs. For these products, an approved new drug application is not essential to assure the quality of the product. They may be marketed without preclearance by FDA, providing they meet certain conditions. Some have suggested that this policy will result in less effective FDA surveillance over these products, but I assure you this is a mistaken assumption. To the contrary, these regulations will impose strict conditions for the marketing of these drugs. All such products appearing on the market must be listed with the FDA under the Drug Listing Act, and this listing will trigger appropriate plant inspections. Further, all such products must comply with compendial standards and be produced in conformity with current good manufacturing practices; enforcement mechanisms to assure compliance are in operation.

I would emphasize also that this policy will not apply to any drug with a bioequivalence requirement or special manufacturing problem. Manufacturers of such drugs will be required to obtain marketing