to market these well established old drugs without obtaining preclearance from the FDA. However, these drugs are subject to full regulatory control by the FDA in terms of their labeling and manufacture. The FDA has 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 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. These drugs may be marketed without preclearance by the 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