Specific procedures will be proposed for the establishment of bioequivalence requirements for individual drugs whenever there is evidence that products made by the manufacturers of that drug are not bioequivalent or whenever there is a clear potential for bioinequivalence of a drug of particular medical importance.

A bioequivalence requirement, once established, will require testing of absorption in humans, in vitro testing of the dissolution rate of each batch by the manufacturer, and the approval of an abbreviated new drug application as a condition of marketing. Once this regulation is established as a final order, it will be strictly enforced to assure that noncomplying products are removed from the market.

Old Drug Monographs

The Federal Food, Drug, and Cosmetic Act provides for a category of drugs which are "generally recognized as safe and effective" and are popularly known as "old drugs" to distinguish them from "new drugs" as defined in the Act. Those drugs in the old drug category include most over-the-counter preparations and most older prescription drugs. The law has always permitted any registered manufacturer