in 1970 and are currently under further revision. Among changes being actively considered is a requirement that all drug products bear an expiration date based on adequate stability data, and also addition of GMP regulations for specific classes of products such as large volume parenterals.

Bioavailability and Bioequivalency

It has been shown in recent years that in a few instances chemically equivalent drugs, even though they meet all official standards, produce significantly different blood levels in man. In scientific terms they differ in bioavailability or, to use another term, they are lacking in bioequivalency.

To assure the bioequivalency of chemically equivalent drugs we are taking three steps:

First, we will shortly publish in final form regulations describing standards and procedures to be followed in conducting bioavailability studies.

Second, we will shortly publish proposed regulations requiring bioavailability studies for all drugs of the following kinds:

--Those for which the precise dosage is particularly critical and where a bioavailability problem would create a health hazard.