

program as no greater than "possibly effective" for use in certain of the Department's programs, such as the direct care programs, contract care programs, and Federal grant programs.

With the Drug Enforcement Administration, which now includes the former Bureau of Narcotics and Dangerous Drugs, we have established procedures for implementing the large-scale DESI review follow-up action against amphetamine-containing drugs not in compliance with current requirements.

These drugs are under the jurisdiction of both the Drug Enforcement Administration and the FDA. Although this cooperative action has not as yet been completed, some 1,755 amphetamine-containing drugs manufactured by 351 firms have been effectively removed from the market. This regulatory action involved 549 drug recalls and five seizure actions under the FDC Act. With cooperating State health officials, a high degree of success has been achieved in the removal of these violative drugs from pharmacy shelves throughout the country.

Liaison for exchange of DESI program information has been established with the Chief Pharmacy Officer of the Public Health Service. In addition, we have received numerous communications from State, foreign government, and United Nations health officials about drug status under the DESI review program. And we routinely forward copies of the DESI announcements to several Government agencies.

The Federal Food, Drug, and Cosmetic Act requires that samples of each batch of antibiotics and insulin be tested and certified by FDA before these products are released for sale. Batch certification is also imposed for other products when it is needed to assure uniform quality. And as we have just previously discussed, digoxin has been subjected to batch certification since our drug surveillance program revealed significant variances from official standards.

The FDA regulations set standards for the facilities and conditions under which drugs are manufactured. Because good manufacturing practices should be "current" and change as drug technology changes, these regulations are periodically updated. The regulations were last revised 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.

Now, to return to the bioavailability or the bioequivalency problem, 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, and this is referred to as either bioavailability or, the drugs lack 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 certain kinds; for example,