

10650 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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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, 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. Copies of the DESI announcements are routinely forwarded to several Government agencies.

Batch Certification

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. As previously discussed, digoxin has been subjected to batch certification since our drug surveillance program revealed significant variances from official standards.

Current Good Manufacturing Practice Regulations (GMP)

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