

11946 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

20,000 human drug samples which requires approximately 250,000 individual assays. In general, FDA has found that only a small percentage of drugs are not in compliance with official standards and require regulatory action.

When these monitoring activities reveal problems with an entire class or type of drug, specific intensive programs are established. The drug classes that have been studied in this sampling program include such important drugs as digoxin, diuretics, antiarrhythmics, anticonvulsants, antibacterials, tranquilizers, oral hypoglycemics, bronchodilators, anti-inflammatories, antihistamines, coronary vasodilators, and sedatives. Many of the multisource drugs in the list of the 200 most frequently prescribed products have been so studied. While some individual products have failed to meet standards, we do not have evidence of any widespread industry problems in meeting appropriate standards of identity, purity, or potency.