

3828 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Among these, the priority for clinical trials was determined on the basis of the following criteria:

1. The product is generally considered as a "critical" drug--that is, required for the control of a disease, rather than for the alleviation of temporary symptoms.
2. It is generally dispensed in solid form--as a tablet or capsule.
3. The active ingredient is relatively insoluble.
4. Particular attention should be given to those drugs which had previously been the subject of reported or suspected nonequivalency or therapeutic failure.

A number of drugs meeting these criteria were selected by the Task Force in consultation with representatives of clinical medicine, pharmacology, pharmacy, brand name and generic name manufacturers, the Food and Drug Administration, and other governmental agencies. Biological equivalency studies on these products in human volunteers began late in 1967 in the FDA laboratories; at Georgetown University, under an FDA contract; and at the Public Health Service Hospital in San Francisco.