

firms are bound by the same regulations governing proper manufacturing processes.

The Bureau of Drugs operates two large modern laboratories for drug research and methodology development and for drug analysis. These two analytical laboratories are the National Center for Antibiotics Analysis, in Washington, and the National Center for Drug Analysis, in St. Louis. Both help assure the high quality of drugs we have in this country.

The National Center for Antibiotics Analysis is a 150-man team working in a highly automated laboratory. It is responsible for testing the potency, purity, and stability of every batch of every antibiotic before it is marketed in this country.

Before marketing, samples of every batch of bulk antibiotics and the finished dosage form are submitted to FDA for analysis. The batches from which the samples are taken are kept in quarantine until FDA completes its analyses. Along with the samples the firm submits data on the batch, such as formula and the firm's own test results.

If the samples meet all of the requirements, the batch is certified by FDA. Only such batches can be released for marketing in this country.

Any qualified firm may decide to make the same product. This is the so-called "me-too" product, since it must meet all the requirements of the original one.

Many "me-too" manufacturers and brand name manufacturers use bulk antibiotic ingredients from the same few bulk producers. After the drug has shown comparability, the firms must put batches on stability test and report every three months for a specified period of time and at least yearly thereafter. Any significant problem with the drug must be reported immediately to FDA. Additionally, we collect post certification samples at random

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from the market as a further check on the continued quality of antibiotics.

Each year our National Center for Antibiotics Analysis receives approximately 20,000 samples for examination. The rejection rate is approximately 1 percent. These rejects cannot be marketed.

*Based on many years of experience with this program, we are confident there is no significant difference between so-called generic and brand name antibiotic products on the American market. Any antibiotic offered for sale in the United States, regardless of whether it is brand or generic, has met the same high FDA standards.*

A similar certification program is conducted for every batch of insulin produced in the United States.

Another important drug quality program conducted by FDA is at the National Center for Drug Analysis in St. Louis. This 50-man laboratory is unique in having automated equipment for the analysis of a large number of tablets of a particular drug product.

Since 1970, our St. Louis lab has completed the study of 19 classes of drugs, including adrenocorticosteroids, major and minor tranquilizers, urinary antibacterial

agents, central nervous system depressants, antithyroid agents, cardiac glycosides, coronary vasodilators, anticoagulants, oral contraceptives, and others.

We have extended the study to 30 drug products representing the top 15 therapeutically significant drug classes. This study will cover every known manufacturer of these products. We believe in this way we will have reliable data upon which we can make meaningful judgments on an across-the-board basis.

Under FDA's new Freedom of Information regulations (see FDA PAPERS, now FDA CONSUMER, June 1972), we intend to begin publishing this data once it has been verified and we have assured ourselves it will present a true picture on a given class of drugs.

*On the basis of the data we have accrued to date, we cannot conclude there is a significant difference in quality between the generic and brand name product tested.*

There have been only a few exceptions turned up by our testing in St. Louis. One of these, digoxin, a heart drug, is the most prominent exception, as our studies showed quality and performance differences between different manufacturers' versions. We are taking action to assure that all digoxin now marketed meets uniform standards of quality.

Another important surveillance program is our Drug Product Defect Reporting Program. This is a jointly sponsored program by the American Society of Hospital Pharmacists, United States Pharmacopeia, and FDA.

It is a voluntary program in which hospital pharmacists across the Nation report defects they encounter in drug products, packaging, and labeling. Through this program, we have received hundreds of reports and have learned of several significant defects. We are finding defects in both brand and generic products.