First Priorities: Renew and Repair

(Continued from page 1)

ning and policy decisions.

A fourth priority is to develop adequate scientific and medical capabilities to evaluate new biological products, and a fifth is to continue phased implementation of the medical device amendments.

The plan lists the following additional recommendations:

- To improve federal-state cooperation in food sanitation and other areas
- To investigate methods to block the toxic effects of economically important chemicals
- To construct a diet preparation facility at the National Center for Toxicological Research to improve the center's risk-assessment capabilities
- To increase benefit-cost analysis of proposed and existing regulations, as required by executive order 12291 and the Regulatory Flexibility Act
- To seek support in handling FDA's extremely heavy Freedom of Information workload
- To improve analysis of pathogens and suspected chemicals and pesticides in foods, increase testing of approved food and color additives, and evaluate the health risks of naturally occurring toxins
- To increase surveillance and research with animal drugs and feeds
- To evaluate new technologies that would reduce exposure to x rays
- To do an epidemiological study of ultrasound effects on the fetus
- To move toward construction of Module 3A in the Beltsville complex, which would handle pharmaceutical testing programs

The '83 forward plan points out that budgetary restraints for fiscal '81 and '82 have led to a "critical reexamination" of base program priorities, and that FDA's resources must be directed to only its highest priority activities.

Space-Age World of FDA's Drug Analysis Center

The facade of the building which houses the National Center for Drug Analysis doesn't prepare you for what's inside. It's a 1930's-style structure in the middle of downtown St. Louis about a mile west of the famous arch and next door to city hall. But inside—it's a space-age world of modern laboratories full of sophisticated testing equipment and computers.

The National Center for Drug Analysis (NCDA) was established in 1967 to examine large quantities of drug samples for purity and strength. It had become clear to FDA that a whole new approach to drug analysis was needed. Hundreds of thousands of drug products would have to be analyzed—far more than all district and headquarters laboratories could handle—just to keep pace with the burgeoning drug industry.

Now, NCDA uses mass production techniques and instant computer analysis to pinpoint violations for regulatory action and, at the same time, assess the quality of an entire national supply of a given drug.

NCDA would have to be considered an agency success by most standards. Its analytical capabilities have multiplied 16-fold—from 9,000 analyses a year in 1968 to 150,000 a year today—while its staff level has remained constant at about 45 people.

The center's director, Dr. Thomas P. Layloff, attributes the growth in operating capacity to the use of automated high-speed sampling equipment, computers to analyze the data found, and modern management techniques.

"Samples are received and go to our data entry section where sample files are allocated in our minicomputer," Layloff explained. "The computer is programmed to capture data from the automated systems. By the time the chemist sees the finished analytical results, calculations have been performed, and a complete worksheet is printed."

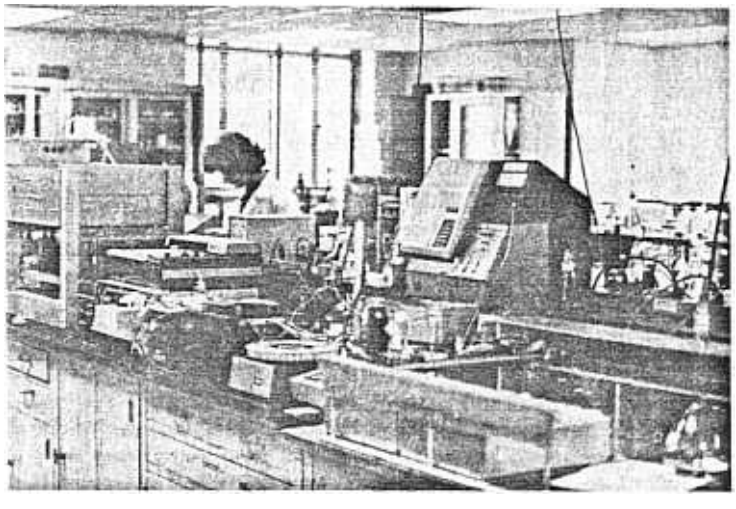
The use of automation has been so successful that NCDA has been able to reassign scientific staff to other projects. Since 1975, chemists at the center have been testing drugs to find out how fast they dissolve and have developed new procedures for such dissolution testing. NCDA staff also review some of the methods and monograph requirements of the *U.S. Pharmacopeia* and *National Formulary*. On one such project, NCDA staff had to survey all aspirin products nationwide—no easy task.

Samples come to the center from a variety of sources. Most are picked up at the pharmaceutical manufacturers by FDA investigators. Others are submitted voluntarily by manufacturers to insure compliance, some are purchased at point of sale when nearing expiration date, and some are tested for Public Health Service hospitals.

After samples are analyzed and the worksheet is printed, the worksheet is reviewed twice. First, by the chemist responsible for operating the automatic analyzer. And then, by the laboratory supervisor.

If the report shows too much variation in the strength of the drug, an analyst is assigned to test the drug manually, using the legally recognized official method. If the variation is confirmed, the batch is not approved for marketing, or compliance action is recommended.

In the future, Layloff promises even greater operating capacity at the center. Prototype high-speed sample preparation and sampling units are being tested that promise to multiply NCDA operating capacity threefold in the next 5 years.



NCDA analyst Yvonne P. Juhl uses the Automated Sample Preparation Module and the X-Y Liquid Sampler (machine in foreground) to test large quantities of drug samples for purity and strength.

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