A safety cap for drugs

Federal agency tests 60,000 drugs a year at St. Louis laboratory

By Allen Levy
Globe-Democrat Staff Writer

A couple of years ago, the chemists in Thomas P. Layloff's lab finally ran into a suppository that wouldn't melt.

First they tried heating it gently, subjecting it to the same temperatures that it would meet in the body. No go.

Then they dropped it in boiling water and even heated it to extremely high temperatures in an oven.

Still nothing. It just refused to melt.

And that from a medicine that was supposed to melt as soon as it got into the body — at a temperature slightly below 98.6 degrees Fahrenheit.

Obviously, something was wrong.

After a series of tests, the scientists at Layloff's lab figured out that the suppository had been stored for a while in an overheated warehouse. The heat had caused two ingredients of the suppositories to recombine and form a type of nylon that was virtually indestructible.

"It was very safe," Layloff said recently, laughing as he recounted the incident in his offices at the National Center for Drug Analysis in St. Louis. But you could have used "a whole handful (of suppositories) before anything happened."

Instructions on the suppositories, which are designed to treat asthma and are generically known as aminophylline, now warn that they must be kept cold.

The aminophylline story is a perfect example of why the government runs the National Center for Drug Analysis, said Layloff, who is director of the lab.

The center, a branch of the U.S. Food and Drug Administration, has 42 full-time employees, most of them chemists, who test drugs that are sold every day in pharmacies.

Do aspirin tablets really have as much aspirin in them as the manufacturers claim? Will time-release capsules really release their medicine smoothly over a prolonged period? Are any drugs contaminated with impurities?

All of those are questions that the center's chemists have been asking.

If the chemists find that a drug doesn't meet published standards, the Food and Drug Administration can ask the manufacturer to voluntarily recall it, or it can seize the drug, enjoin the manufacturer or prosecute, Layloff said.

The center completes about 60,000 drug tests a year. Approximately 40 times a year, the chemists find drugs that violate the minimum standards, Layloff said. Usually, if there's a mistake, the companies will "say 'we goofed' and pull it off the shelf," Layloff added.

The laboratory, which is on the ninth and 10th floors of the Federal Courts Building downtown at 1114 Market St., contains about $1.5 million in the latest drug-testing equipment. Most of the machines are tied to a computer that automatically tabulates and analyzes the test results.

"For the kind of work we do, we are

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Director Thomas P. Layloff, left, and Deputy Director Lawrence Jones of the National Center for Drug Analysis.

Laboratory keeps safety cap on drugs

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probably one of the best equipped labs in the world," Layloff said.

In fact, the lab is now so well equipped that it's finding drug impurities that never would have shown up a couple of years ago, said Layloff and Deputy Director Lawrence Jones.

For instance, a little over a year ago, the center found that a number of drugs packaged in containers with rubber stoppers were contaminated with one ingredient contained in the rubber. Apparently, the ingredient leaches out of the rubber and into the medicine.

The contamination was found shortly after the center had bought new equipment. The old equipment probably would not have been sensitive enough to detect the slight rubber contamination, Layloff and Jones said.

Although doctors don't consider the problem a health threat, drug companies are taking steps to limit the amount of contamination and are trying to reformulate the rubber so no leaching occurs, they said.

The lab has been operating in one form or another since the early 1900s, Layloff said. Were it ever to close, "there would be an outcropping again of producers of inferior products," he said. "And they would tend to outcompete the quality products, so you'd see a decline in quality."