Behind the bureaucracy; how the FDA okayed Nutrasweet. (aspartame).Maura Christopher. ***Scholastic Update*** 118.(Sept 20, 1985): pp23(3). (1466 words)

August in Washington, DC, is usually a quiet month. The U.S Congress takes a recess and other workers flee the city's humid weather. Yet for the employees of the Center for Food Safety and Applied Nutrition, last month was one of the busiest ever. A key part of the U.S. Food and Drug Administration (FDA), the Center for Food Safety (or "Food Center," as employees call it) polices the purity of the food Americans eat. And that work sped up in August because of several crises over tainted foods.

Protecting the nation's food supply is not a job that Food Center employees--800 in Washington and 1,000 elsewhere--take lightly. Research that Food Center scientists do and rules they write have a wide impact. Food Center standards helps keep cheese safe from contamination, for example. They keep fruits and vegetables free of deadly levels of pesticides. And they keep harmful chemical coloring and additives out of packaged foods.

It's not easy for food packagers to get the Food Center to okay a new chemical additive. A look at the way the Food Center handled one additive, the sweetner aspartame, will show you why. And it will help you understand the key roles that civil servants play in American society.

A SWEET DISCOVERY

The story of aspartame, sold today under the brand name NutraSweet, began 20 years ago in a laboratory at G.D. Searle and Company. Searle is a pharmaceutical firm based in Illinois.

One afternoon in 1965, James M. Schlatter, a chemist, stumbled on an exciting discovery. While testing a new drug for ulcers, Schlatter absent-mindedly licked his fingers. He was struck by a powerful taste of sweetness. He reproduced the taste--it was 200 times sweeter than sugar--by combining two amino acids, neither of which is sweet by itself. Amino acids are the building blocks of protein.

After years of testing, Searle asked the FDA in 1973 to approve its new sweetner. A year later, the FDA gave Searle a go-ahead. But a group of consumers and scientists challenged the decision. They charged that the FDA should have checked more closely to see if aspartame might cause brain tumors or brain damage.

The FDA listened and responded. In December, 1975, the agency withdrew its approval until an outside panel of scientists weighed the charges.

For the next few years, scientists scrutinized tests that Searle's scientists had conducted. In 1980, the panel announced it decision. It agreed in part with the FDA, finding that aspartame did not cause brain damage. The panel recommended further tests to see if aspartame could be linked to brain tumor.

Arthur Hayes, the FDA's commissioner at the time, felt that enough studies had been done. In early 1981, he overruled the panel and approved NutraSweet for use in a dry form--in cereals, for

example. Two years later, the FDA approved NutraSweet for use in liquids. Recently, the manufacturer has asked the FDA to approve NutraSweet for products such as frozen orange juice, ice cream, and yogurt.

APPROVAL PROCESS

How does the FDA's approval process work? All requests for permission to sell a food additive go first to a safety officer. The safety officer for NutraSweet is Dr. Tony Brunetti. Brunetti, a chemist, guides Searle's request through the FDA.

"We're talking about something with a 15-year regulatory history," Brunetti told UPDATE. "Sometimes, I have to search for days to find some information I need." The FDA's file on aspartame fills more than 100 volumes.

Manufacturers often complain about red tape. "I get as just as frustrated," Brunetti says, "but I have to deal with the bureaucratic process, too. When you're dealing with human extreme caution. So if it takes time."

Brunetti also writes the regulations that apply to NutraSweet. he tries to simplify the scientific and legal jargon of the FDA's scientists and lawyers. "I aim for an eighth-grade reading level," he says.

But Brunetti never writes a word until FDA scientists have checked the manufacturer's test data. The data must answer two basic questions. First, does the additive work? For example, is NutraSweet really sweet? Second--and most important--is the product safe?

Product safety is the specific concern of Dr. Gary Flamm, who heads the Food Center's office of toxicological science. Searle submitted more than 112 different studies. Flamm's team of toxicologists--scientists who study the effects of chemicals on the human body--pored over every one of the studies.

Flamm is extremely careful about details. He has to be. "Some of these studies contain as many as 3 million bits of data," he says. "All of this has to be handled like precious eggs."

As it happens, some people can't tolerate one of aspartame's amino acids--phenylalanine. Such people have a condition called phenylketonuria (PKU). The toxicologists recommended that products with NutraSweet carry a warning for PKU sufferers. Still, the FDA concluded that, for most people, aspartame is safe.

FDA nutritionists like Walt Glinnsmann, a physician in the Office of Nutrition, aslo examin NutraSweet. Dr. Glinnsmann recently worked on a study of 517 people who reported side effects after using NutraSweet. Most of them reported stomachaches and headaches--common complaints under any circumstances, Glinnsmann notes. Nonetheless, Searle's scientists are following up the FDA's study.

TIME TO STOP

According to Glinnsmann, the FDA has done more testing on aspartame than on any other substance in the agency's 78-year history. "We are raising safety issues about aspartame that we wouldn't raise about a hamburger," he says. "At some point, we always have to stop doing studies and make a decision."

Scientists aren't the only ones interested in the FDA's tests. Competing companies often try to glean trade secrets from the FDA. They do this by filing for data under the Freedom of Information Act. This U.S. law prohibits the government from withholding unclassified information. Yet it doesn't permit the release of trade secrets, which is what companies like Searle often entrust to the FDA.

Last year the FDA fielded 41,000 requests for information--more than any other agency, Patty Gee, the Food Center's freedom of information officer, answers many of the requests. "Everybody in the world is interested in NutraSweet," says Gee, who researched more than 100 NutraSweet requests over the past 18 months.

Once the FDA's scientists determine that an additive is safe, the FDA's Office of Regulatory Guidance takes over. The head of that office, John Taylor, makes sure that the regulation complies with the FDA's laws.

Taylor, a chemist and former head of the FDA's Boston district, keeps a big stick in his office. It's a humorous reminder that he's also in charge of enforcing the FDA's regulations.

An incident that occurred last year demonstrated the FDA's enforcement power. About 200,000 cans of Diet Coca-Cola failed to carry the warning for PKU Sufferers. The distributor had to pull the cans off store shelves.

Steve Kilker, an FDA inspector in AKron, Ohio, discovered the problem. "The FDA considers the mislabeling significant," Kilker told UPDATE, "because it could make people ill."

THE FINAL STAGES

The FDA has to make sure its own actions are proper, too. That's the job of Marsha Gardner, assistant chief counsel for food. "We have to make certain that the FDA is jumping through all of the hoops," she says. "Some staff people see enforcing proper prcedures as nit-picky. But the courts think details are extremely important. If an issue like aspartame winds up in court, the case is decided on the details."

Gardner was a pharmacist before becoming a lawyer. She credits her pharmacy training with teaching her to appreciate the value of sound scientific procedures. "Any decision in the FDA stands or falls on the quality of the science," she says. Her work has won her three FDA merit awards--one for her efforts with aspartame.

Eventually, all decisions on food safety reach Dr. Sanford Miller. As head of the Food Center, Miller recommends decisions to the FDA's current commissioner, Frank Young.

Miller says that a good part of his job is protecting FDA scientists from political, economic, and public pressures. "We get plenty of pressure from plain old citizens," he says. "It takes us forever to take regulatory action, because our system is built on distrust of government. As an administrator, I hate the outside pressure. But, as a citizen, I know it keeps government in check."

Approving aspartame has proved costly and time-consuming for both Searle and the government. "Literally hundreds of Center scientists have been involved at one time or another with aspartame," Miller says. "It's probably cost several million dollars to deal with the continuing charges against aspartame--every one of which has been answered."

Clearly, Miller and his colleagues are a far cry from the "unresponsive bureaucrats" who often populate cartoons. They're hard-working civil servants whose decisions affect millions of Americans. And millions of Americans can be grateful that they do.