

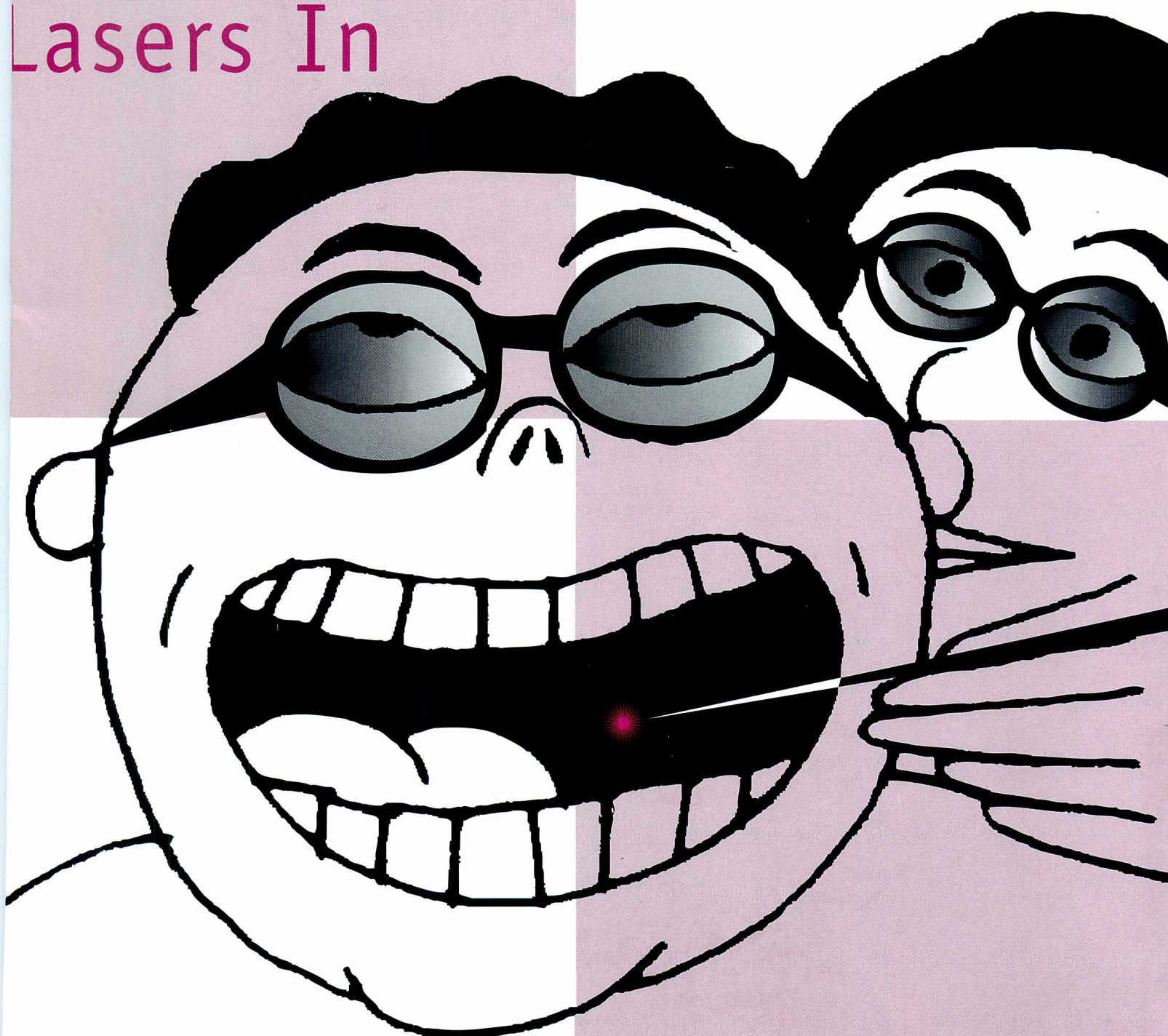
FDA CONSUMER

THE MAGAZINE OF THE U.S. FOOD AND DRUG ADMINISTRATION

• VOL. 29 NO. 1

JANUARY-FEBRUARY 1995 •

Lasers In



Dentistry



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FDA Consumer (ISSN 00362-1332) is published by the Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857, U.S. Public Health Service, Department of Health and Human Services. It is published monthly, except for combined issues for July-August and January-February. Use of funds for printing *FDA Consumer* has been approved by the Office of Management and Budget.

Editorial Matters

Address for editorial matters is *FDA Consumer*, Food and Drug Administration (HFI-40), 5600 Fishers Lane, Rockville, MD 20857. Articles in *FDA Consumer* may be republished without permission. Credit to *FDA Consumer* as the source is appreciated. *FDA Consumer* is indexed in the *Reader's Guide to Periodical Literature*. To obtain a copy of the current *FDA Consumer Index*, write to: FDA, HFE-88, 5600 Fishers Lane, Rockville, MD 20857.

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Hazard Analysis Critical Control Point is a new safety system that helps manufacturers prevent food hazards. About half the members of a major national food processing organization now use the system. FDA is considering whether to make it mandatory.

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Consumers may welcome the growing array of pain relievers available without prescription, but this profusion can cause confusion. Knowing the differences—and similarities—among these products is crucial to making wise choices.

Lasers in Dentistry 15

Dental lasers hold out the promise of less pain, less noise, and less fear in dental procedures. FDA has cleared for marketing certain lasers for use in soft tissue procedures, but others—such as those used to drill teeth—are still under study.

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People on special diets—such as those with kidney disease, food sensitivities, and bowel disease—are among the many who are benefiting from information given in the new food label.

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Each year, FDA must inspect nearly 15,000 U.S. establishments and more than 800 foreign facilities that test, make, pack, and label drugs. What actually goes on during these inspections?

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Inside Front Cover Photo: Carol Reynolds, a Heinz USA employee, documents via computer that she has carried out her assigned food safety duties. For more on food safety progress, see page 5.



Device Approved to Treat Abnormal Heart Rhythms

The first medical device to treat some abnormal heart rhythms with a procedure called radio frequency cardiac catheter ablation received FDA approval last Oct. 31.

Named the EPT-1000 Cardiac Ablation System, the device passes electric current through a catheter threaded into the heart, destroying the heart cells that cause abnormal rhythms.

Usually, abnormal heart rhythms are treated with drugs. In certain severe cases, open-chest surgery is used. The new device gives doctors an alternative for treating fast heartbeats originating in upper chambers of the heart. The device is not intended as therapy for slow heart rhythms, which are often treated with implanted pacemakers. Some patients who undergo catheter ablation may require a pacemaker as a result of the procedure.

In approving the product, FDA endorsed the unanimous recommendation of its Circulatory System Devices Advisory Panel.

FDA approved the device after reviewing safety and effectiveness data submitted by the manufacturer, EP Technologies Inc. of Sunnyvale, Calif. In a study of 456 patients at 12 U.S. medical centers, catheter ablation was successful in 375 (85 percent) of the 439 patients whose abnormal heart rhythm originated at a single site in the heart.

Among the remaining 17 patients, each of whom had two abnormal heart rhythm sites, the procedure yielded complete success in nine patients and partial success in three. Forty-two patients, or

11 percent, who underwent the first catheter ablation procedure required a second procedure or other treatments.

Serious complications occurred in 16 study participants. Of these patients, two died, one had a heart attack and stroke, and others had problems such as perforation of the heart muscle.

Ultrasound for Bone Fractures

The first ultrasound device to speed healing of new bone fractures in the lower leg or lower forearm of adults was approved Oct. 5, 1994.

When used with orthopedic treatments such as a cast or splint, the device, the Sonic Accelerated Fracture Healing System (SAFHS), can stimulate bone growth and promote early healing of fractures. It is not intended, however, for fractures requiring surgery or other methods of fixation, such as the use of pins. Other types of bone growth stimulators for healing other types of fractures are already marketed.

The SAFHS consists mainly of a signal generator (about the size of a laptop computer) and a small, square trans-

ducer, which emits low-intensity pulses of ultrasound. A cable connects the two components.

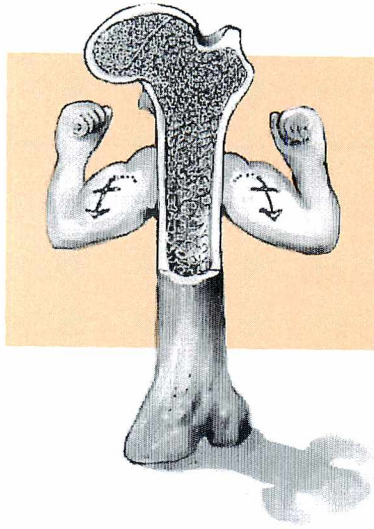
For treatment, the person applies the transducer to the skin over the fracture site—using a gel to improve transmission of the ultrasound signal—for 20 minutes once a day for a varying number of days. Because the device is portable, patients may use it at home.

The SAFHS has not been shown to effectively treat fractures in bones other than those in the lower forearm and lower leg, lower leg fractures in which the gap exceeds 0.5 centimeters, or fractures in children or people with bone diseases. In addition, it should not be used to treat:

- pregnant women
- patients with circulatory problems, abnormal skin sensitivity to electrical impulses, sensory paralysis, or other conditions for which safety and effectiveness have not been established
- patients taking certain drugs, including steroids, anticoagulants, and non-steroidal anti-inflammatory drugs.

FDA based the approval on safety and effectiveness data submitted by the manufacturer, Exogen Inc. of West Caldwell, N.J., and on recommendations and suggested restrictions for use made by the agency's Orthopedic and Rehabilitation Devices Advisory Panel.

Exogen conducted two studies at 20 medical centers in the United States and Israel—one in which 61 patients with lower forearm fractures were evaluated, and the other in which 67 patients with lower leg fractures were evaluated. Although the device accelerated healing in all patients, more improvement was seen among older patients.



Changes Proposed for Drugs, Biologics Reporting

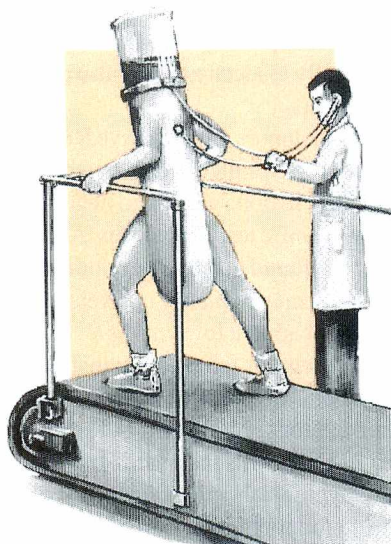
Comments on changes in reporting adverse events with drugs and biologics will be accepted by FDA until Jan. 25, 1995. The changes were published in a proposal in the Oct. 27 *Federal Register* (59FR54046).

They would standardize and speed the process of reporting adverse reactions to FDA by clinical investigators and manufacturers of drugs and biologics undergoing clinical trials and require more frequent and complete reporting of possible problems. Changes would also apply to the way manufacturers conduct safety surveillance of products already on the market.

The proposal for drug and biological products stems in part from the 1993 report of an FDA task force that examined cases of severe liver and pancreatic injury, including five deaths, in patients involved in a clinical study of fialuridine (FIAU) to treat hepatitis B.

The proposed changes to reporting regulations would require:

- sponsors to develop and give to FDA before starting a clinical trial a written description of a specific safety monitoring program
- investigators and sponsors to evaluate and establish as clearly as possible whether an adverse event was attributable to the product under trial or to other causes
- experimental protocols to specify and justify the length and type of post-trial medical follow-up for trial participants
- protocols to include descriptions of the specific adverse events that must be re-



ported to the sponsor immediately by investigators.

For drug and biological products already on the market, FDA proposes that companies provide:

- safety reports every six months for as long as a product is on the market
- data on adverse events beginning with the date of licensure in the first country that approved the product rather than from the date of U.S. approval
- "core safety data sheets," which typically contain what the companies consider all relevant safety information about a particular product
- worldwide marketing status of products, including any compliance actions taken in any country due to a safety concern
- the physical location of adverse event reports.

Written comments about the proposal may be sent to Howard P. Muller, Center for Drug Evaluation and Research, HFD-362, FDA, 7500 Standish Place, Rockville, MD 20855; or Paula S. McKeever, Center for Biologics Evalua-

tion and Research, HFM-635, FDA, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448.

In addition to the proposal, FDA published on Oct. 27 a final rule for biological products that is designed to implement the same reporting requirements as for drugs. Under the rule, which became effective Dec. 27, biologics manufacturers must report to FDA within 15 working days all serious and unexpected adverse experiences associated with the use of a biological product, and any significant increase in the frequency of serious, but expected, adverse experiences. In addition, manufacturers will be required to report periodically all other adverse experiences and data on product distribution and disposition. The new rule provides a mechanism under which manufacturers will inform FDA on a timely basis of any unanticipated safety problems with marketed biological products.

Heart Drug Trial Halted Due to Death Rate

A clinical trial on a drug for a select group of heart patients was suspended last November because patients taking the drug were found to have a higher death rate than those receiving a placebo.

The drug d-Sotalol was being tested in almost 3,000 patients who had left ventricular dysfunction following a heart attack, but did not have life-threatening ventricular arrhythmia (irregular heart-beat). Interim analysis of the study found a 3.9 percent mortality rate in patients on d-Sotalol compared with 2 percent in the placebo group.

The d-Sotalol molecule is the mirror image of l-Sotalol, and equal amounts of both compounds are found in Betapace (d1-Sotalol), an anti-arrhythmic drug approved for use in life-threatening cases, but not in patients with recent heart attacks, such as those in the suspended study. The approved use of Betapace is not affected by the suspension of the clinical trial.

The remaining 30 studies of the Bristol-Myers Squibb development program for d-Sotalol continue with FDA's concurrence. These trials involve patients with different illnesses more routinely treated with d-Sotalol-like medications. Betapace is marketed by Berlex, under licensing from Bristol-Myers Squibb.

Blood Products Recalled In Lansing, Syracuse

Blood products collected at the American Red Cross regional blood centers in Syracuse, N.Y., and Lansing, Mich., between May 1993 and May 1994 were recently recalled because of errors in interpreting a blood test for syphilis.

The products recalled last November included whole blood, red blood cells, platelets, and granulocytes (a type of white blood cell). FDA considers it unlikely that the products would transmit syphilis to recipients. Patients should discuss any questions with their physicians.

By not following the manufacturer's directions for interpreting test results, the two centers may have characterized as negative donors who may actually have tested weakly reactive. Weakly reactive blood samples may contain a low concen-

tration of syphilis antibodies but are more frequently associated with false positive test results.

Blood donors with reactive RPR test results for syphilis are deferred but may requalify to donate if found negative by a more specific test for syphilis. Alternatively, if found positive by additional testing, they may requalify one year after adequate treatment for syphilis.

FDA regards the risk of transfusion-transmitted syphilis from the products as unlikely for several reasons: Refrigeration for 72 hours kills the organism that transmits syphilis; the prevalence of syphilis in the donor population is low; and syphilis organisms are not found in the blood by the time antibody tests turn positive.

Hepatitis B Vaccination For Young People

The American School Health Association (ASHA) recently recommended that young people be vaccinated against hepatitis B. The potentially deadly disease infects 300,000 Americans each year, primarily adolescents and young adults.

"It is not enough to vaccinate only those at high risk, since more than one-third of those infected report no known risk factors," said Rosemary K. Gerrans, R.N., M.P.H., president of ASHA.

The hepatitis B virus is spread through blood and other body fluids and is 100 times more contagious than HIV, which causes AIDS. Hepatitis B can cause flu-like illness, nausea, and vomiting, and can lead to cirrhosis of the liver and liver cancer. Statistics from the national Centers for Disease Control and Prevention indicate that 14 Americans die every day from hepatitis B-related liver disease, and 1.25 million Americans are chronic carriers of the virus.

The ASHA recommendations also urge school health professionals to start hepatitis B education programs for students and parents.

Spanish, English FDA Pubs

New free publications available from FDA are: a Spanish language fact sheet on eating disorders, a background on FDA and women's health issues, an *FDA Consumer* reprint on food preservatives, and a reprint on asthma from the magazine's "On the Teen Scene" series.

To order single copies of "La Obsesión de Adelgazar Requiere Atención Médica" ("Eating Disorders Require Medical Attention") (BGS 94-8); "FDA's Role in Women's Health Issues" (BG 94-8); "Being a Sport with Exercise-Induced Asthma" (FDA) 94-1217; or "A Fresh Look at Food Preservatives" (FDA) 94-2277, write to FDA, HFE-88, 5600 Fishers Lane, Rockville, MD 20857. To order two to 100 copies of the reprint, write to FDA, HFI-40, at the same address, or fax your order to (301) 443-9057. Include the publication number for each requested item.

Being A Sport With
EXERCISE-INDUCED ASTHMA

CONSEJOS PARA SU SALUD
DEPARTAMENTO DE SALUD Y SERVICIOS SOCIALES
ADMINISTRACIÓN DE DROGAS Y ALIMENTOS

La Obsesión de Adelgazar Requiere Atención Médica
por Dixie Farley

Por razones no muy claras algunas personas—comúnmente mujeres jóvenes—desarrollan trastornos nerviosos con decremento de la salud que de no ser atendidos rápidamente, pueden traer serias consecuencias. Entre ellos, figuran la anorexia nerviosa caracterizada por una obsesión a perder peso y una marcada aversión a la comida y la bulimia nerviosa que consiste en impulsos por comer desenfrenadamente, para luego eliminar lo ingerido valiéndose de purgantes y diarrea.

FDA Consumer welcomes comments from readers. Send letters to: Editor, *FDA Consumer*, HFI-40, 5600 Fishers Lane, Rockville, MD 20857.

HACCP PATROLLING FOR FOOD HAZARDS

by Paula Kurtzweil

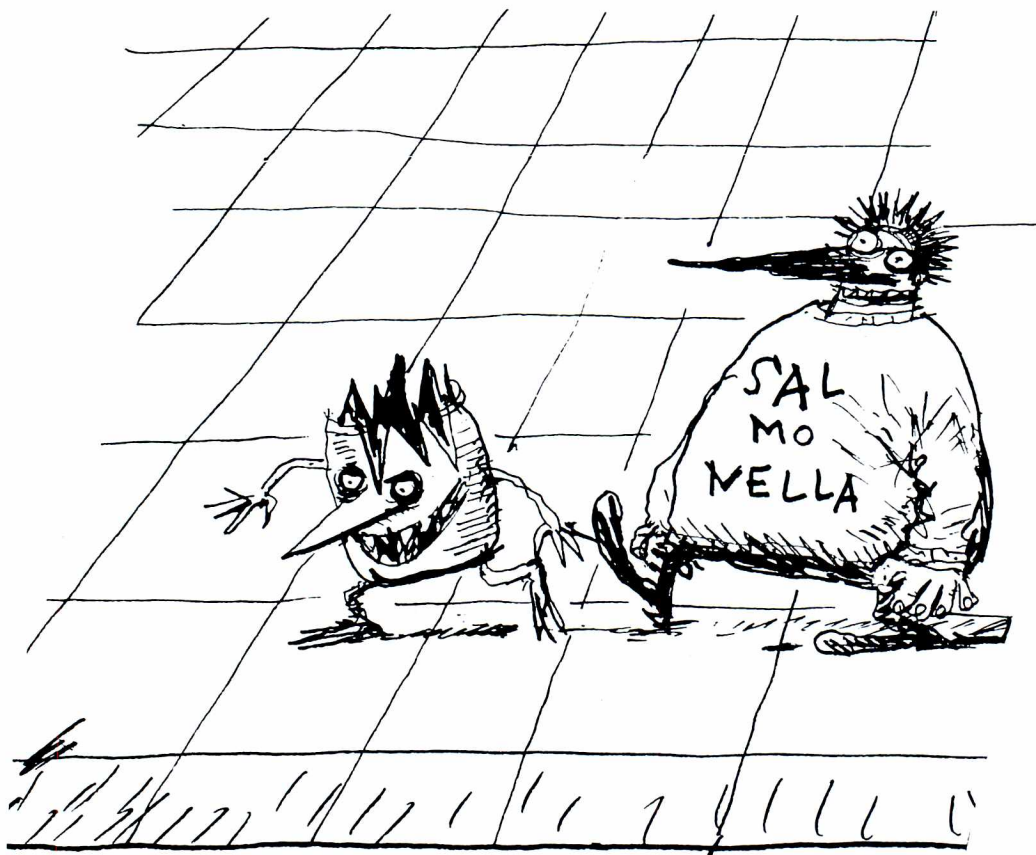
Like a cop on the beat, James Reed patrols his assigned food processing area daily for any wrongdoing. But instead of seeking out thugs on street corners, he's prowling for broken glass and other food hazards lurking inside automated food processing lines.

Reed is a lead person in Heinz USA's Pittsburgh factory, where he oversees the filling and capping of 900 baby food jars a minute. Several times a day he fills in for other employees and stops the processing line, checks the machine for



“This system—though it is simple and based on common sense—signals one of the broadest food safety policy shifts in the last 50 years.”

—FDA Commissioner David A. Kessler, M.D.



glass, documents findings via computer, and, if necessary, withdraws the affected food products for disposal.

Reed's actions are part of a new food safety system that focuses on *preventing* food-borne hazards that can cause illness. The system is known as Hazard Analysis Critical Control Point, or HACCP (pronounced *hassip*), and Heinz is one of a number of U.S. food manufacturers that have adopted it within the last five years. The National Food Processors Association estimates that about half of its 300 member processors use some form of HACCP in their operations.

More may soon join them. In August 1994, FDA announced in an advance notice of proposed rule-making that it was considering whether to make HACCP mandatory for much of the U.S. food sup-

ply. FDA already requires HACCP for the low-acid canned food industry and has proposed it for the seafood industry.

Also, FDA incorporated HACCP into its 1994 Food Code. The Food Code is FDA's guidance and recommendations to state and territorial agencies that license and inspect retail food establishments in the United States and can serve as a model for them. Many restaurants and retail food establishments already follow HACCP principles, some because their local regulators mandate it. (See "New Food Code: A Menu of Modern Safety Standards" in the April 1994 *FDA Consumer*.)

And, the U.S. Department of Agriculture has announced it will propose HACCP for the meat and poultry industry. (USDA regulates meat and poultry; FDA all other foods.)

"This system—though it is simple and based on common sense—signals one of the broadest food safety policy shifts in the last 50 years," said FDA Commissioner David A. Kessler, M.D.

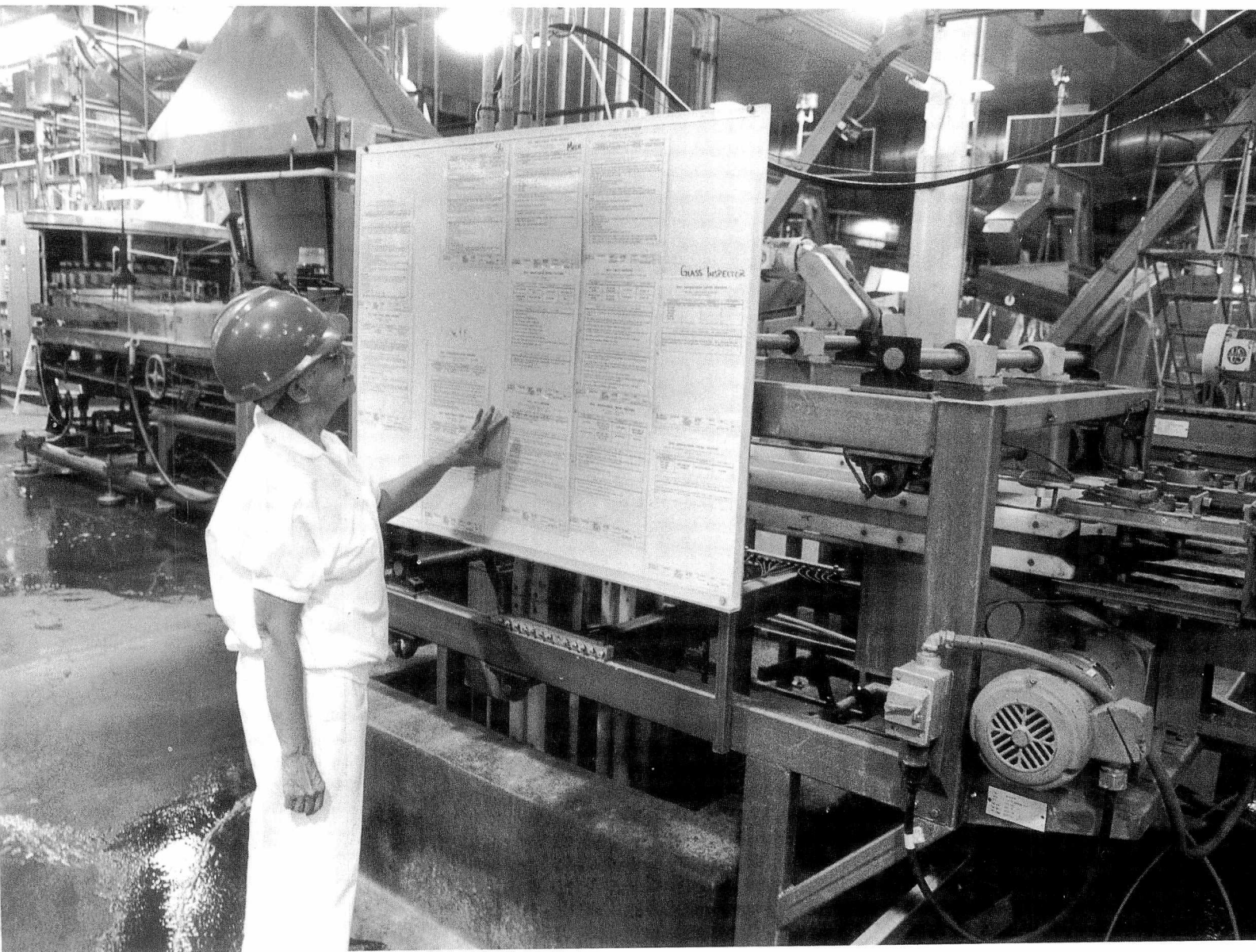
Old vs. New

Traditionally, industry and regulators have depended on spot-checks of manufacturing conditions and random sampling of final products to ensure safe food. This system is seen as more reactive than preventive because it finds problems after they have occurred rather than as the food is being prepared.

HACCP, on the other hand, focuses on problem prevention. Companies analyze their food production processes and determine the "critical control points." These are points in a food's production—from its raw state through processing and shipping to consumption by the consumer—at which hazards can be prevented, controlled or eliminated.

At Heinz USA in Pittsburgh, for example, there are several critical control

HACCP focuses on preventing hazards
from contaminating food.



Delores Krupp reviews Heinz USA's Pittsburgh plant's food safety plan. It lists potentially hazardous points in a food's production, gives instructions on how to prevent the hazard, and tells employees what to do if the hazard occurs. This photo was taken before Krupp retired from the company last September.

***W**hat HACCP doesn't do is replace basic sanitation and good manufacturing practices that are a part of today's food safety system.*



James Reed, a lead person at the Heinz USA plant in Pittsburgh, inspects the inside of a baby food capping machine for glass. This is one of several preventive measures he and other employees take to make sure that the food stays safe during capping.

Between 1973 and 1988, bacteria not previously recognized as important causes of food-borne illness in the United States—such as Escherichia coli O157:H7, Listeria monocytogenes, and Salmonella enteritidis—became more widespread.

points on the “capper,” the machine that places caps on baby food jars. One potential hazard is broken glass. Even though the machine can automatically detect the presence of broken glass, employees stop the line and inspect the machine every half hour for broken glass. This checking is a preventive measure. It helps ensure that glass does not get into the baby food.

Cooking, chilling, sanitizing, preventing cross contamination, and employee hygiene are other examples of critical control points.

What HACCP doesn't do is replace basic sanitation and good manufacturing practices that are a part of today's food safety system, noted Jeffery Rhodehamel, a microbiologist in FDA's division of HACCP programs. “HACCP works in concert with them,” he said.

HACCP Close Up

As it does at Heinz, a HACCP program typically involves seven steps:

- Analyze hazards. Potential hazards associated with food are identified. The hazard could be biological (such as a microbe), chemical (such as mercury), or physical (such as broken glass or metal). Also, establish preventive measures to control identified hazards.
- Identify critical control points.
- Establish critical limits for each preventive measure associated with a critical control point. An example for cooked food might include setting the minimum cooking temperature and time required to ensure a safe product. The temperature and time are the critical limits.
- Establish procedures to monitor the control points. Such procedures might include determining how and by whom cooking time and temperature should be monitored.
- Establish corrective actions to be taken when monitoring shows that a critical limit has not been met. Examples are reprocessing or disposing of

food if the minimum cooking temperature is not met.

- Establish effective record keeping to document the HACCP system. At Heinz USA in Pittsburgh, record keeping is computerized.
- Establish procedures to verify the system is working consistently—for example, auditing records to confirm that all critical limits have been met during a production run.

Each of these steps has to be based on sound scientific and technical knowledge, such as published microbiological studies.

Why HACCP?

A number of national and international organizations have endorsed HACCP, including the National Advisory Committee on Microbiological Criteria for Foods, which includes government and non-government food safety experts, and the Codex Alimentarius Commission, an international food standard-setting organization.

HACCP is viewed favorably because of its potential to help the United States and other countries cope with new food safety challenges. Among the challenges most often cited is an increase in the number of human disease outbreaks due to food-borne microbial pathogens. For example, between 1973 and 1988, bacteria not previously recognized as important causes of food-borne illness in the United States—such as *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella enteritidis*—became more widespread.

“Fifty years ago, we were dealing with only a limited number of food-borne pathogens,” said FDA's Rhodehamel, referring to *Clostridium botulinum*, *Staphylococcus aureus*, *Salmonella*, and the parasite *Trichinella spiralis*. “Today, the list of known food-borne pathogens is much more extensive.”

There also is increasing concern about

***We have a very strong feeling in our minds that
HACCP is doing a good job for us."***

—Ed Sonnet, Heinz USA

chemical contamination, such as the effects of lead on the nervous system.

Another problem is that processing and packaging systems designed to prolong shelf life may introduce new food safety risks.

Also of interest is the increasing size of the U.S. food industry—both in the amount of domestic food manufactured and the number and kinds of foods imported. FDA now lists over 30,000 food manufacturers and processors and more than 20,000 food warehouses in its inventory, and in 1992 alone dealt with more than 1 million imported food items. At the same time, FDA and state and local agencies face severe resource constraints that make it increasingly difficult to ensure food safety.

Advantages

Advocates of HACCP believe that it offers a number of advantages to help deal with these challenges. Most importantly, HACCP:

- focuses on *preventing* hazards from contaminating food
- is based on sound science
- places responsibility for ensuring food safety on the food manufacturer or distributor. Under a HACCP-based inspection system, the food company develops the HACCP plan, and government's role is to verify that the company is carrying out its plan. Government monitoring would ensure that preventive controls are in place and working properly.
- permits more efficient and effective government oversight, primarily because the record keeping allows government investigators to see how well a firm is complying with food safety laws over time rather than how well it is doing on any given day. Under the proposal FDA envisions, the agency would have access to critical control point records.
- helps food companies compete more ef-

fectively in the world market. Members of the European Union and other countries, such as Canada, will soon require imported foods and foods made within their borders to be processed under HACCP requirements.

At the Heinz plant in Pittsburgh, company officials have discovered another advantage: a potential savings to the company. According to Ed Sonnet, technical operations consultant for Heinz USA, the HACCP system seems to have led to a drop in the number of stock cases held at the company's Pittsburgh plant. These are cases of food that are withheld from the market because of poor quality or safety concerns.

"We have a very strong feeling in our minds that HACCP is doing a good job for us," he said. "We think we'll be able to quantify it a lot better when we go into our other plants."

Sonnet said HACCP will be implemented in the company's four other U.S. manufacturing facilities by April 1995.

What's Ahead

FDA has begun reviewing comments it received in response to its August 1994 advance notice of proposed rule-making. At press time, in late 1994, the agency was planning to begin a pilot HACCP program with about six food manufacturing companies. FDA will use information from this program to help decide whether to propose a HACCP system for industry, and, if so, to what extent.

If FDA decides to implement HACCP for the seafood industry, it expects to issue final regulations this year. This program, along with HACCP programs already in use, will likely lay the groundwork for future food safety in the United States and the world. ■

Paula Kurtzweil is a member of FDA's public affairs staff.

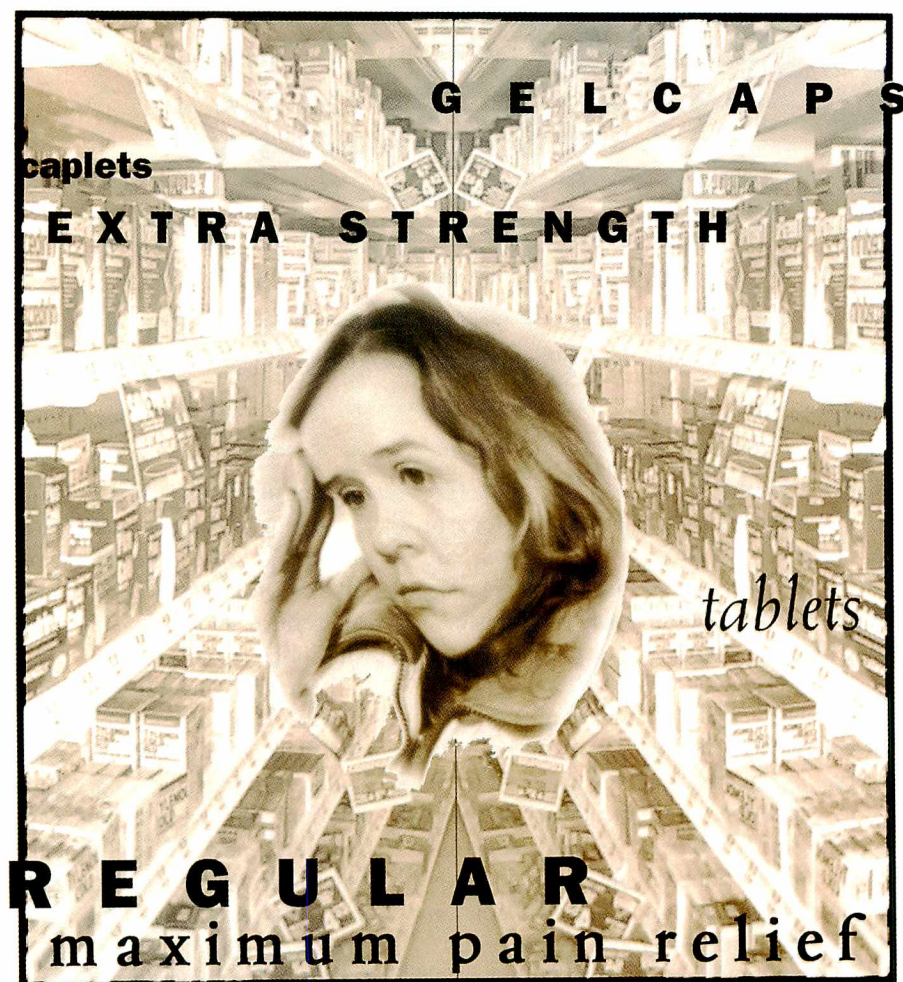
OTC Options

by Ruth Papazian

Pain, Pain Go Away

Used to be, aspirin and other salicylates were the only medications available for nonprescription relief of minor ailments—from headaches and fever to muscle strain and minor arthritis. Today, consumers looking for temporary relief from such garden-variety ills have their pick of what can be a bewildering array of “regular,” “extra-strength,” and “maximum pain relief” tablets, caplets and gel caps on the drugstore shelf.

Though this cornucopia can seem confusing, the products’ pain-relieving ingredients fall into just four categories: aspirin (and other salicylates), acetaminophen, ibuprofen, and naproxen sodium. For the most part, these over-the-counter (OTC) analgesic ingredients are equally effective. However, some may be more effective for certain types of ailments, and some people may prefer one type to another because of their varying side effects. “Knowing the pros and cons of each type of pain reliever will allow you to choose among them,” says William T. Beaver, M.D., professor of pharmacology and anesthesia at Georgetown University School of Medicine in Washington, D.C.



B.C.

by johnny hart

WHAT'S THE STRONGEST OVER-THE-COUNTER PAIN KILLER YOU GOT ?



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Old Faithful

Americans have been reaching for aspirin for almost 100 years as an all-purpose pain reliever (see “Aspirin: A New Look at an Old Drug” in the January-February 1994 *FDA Consumer*). Aspirin (or acetylsalicylic acid) works in part by suppressing the production of prostaglandins, hormone-like substances that have wide-ranging roles throughout the body, such as stimulating uterine contractions, regulating body temperature and blood vessel constriction, and helping blood clotting. “Regular” strength aspirin contains 325 milligrams (mg) per tablet; “extra” or “maximum” strength, 500 mg per tablet. The usual adult (defined as 12 years and older) dosage is one to two 325-mg aspirin tablets every four hours.

Some manufacturers add caffeine to aspirin. “There is no evidence that caffeine relieves pain, but it can enhance the effects of aspirin, possibly by lifting a person’s mood,” says Michael Weintraub, M.D.,

director of FDA’s Office of OTC Drug Evaluation. Since a two-tablet dose provides roughly the same amount of caffeine as a cup of coffee, you can get the same effect by taking two plain aspirin with coffee.

To minimize the stomach irritation aspirin can cause, some brands are “buffered” with calcium carbonate, magnesium oxide, and other antacids or coated so the pills don’t dissolve until they reach the small intestine. Buffered formulas may offset aspirin’s directly irritating effects on the stomach lining. They may be useful for people who get heartburn or stomach pain when they take aspirin, as well as for those with arthritis, who need to take as much as 4,000 mg every day.

Aspirin also causes gastrointestinal (GI) upset indirectly (by inhibiting production of a prostaglandin that protects the stomach lining by stimulating mucus production); buffering does nothing to offset this effect.

The downside of coated aspirin products is that they may take up to twice as long to provide pain relief as plain aspirin, according to Weintraub. Last September, an FDA advisory panel recommended that labels on products containing aspirin warn that heavy drinkers are especially vulnerable to developing GI bleeding.

Aspirin should not be taken by people who have:

- ulcers, because it can worsen symptoms
- asthma, because it can trigger an attack in some asthmatics
- uncontrolled high blood pressure, because of an increased risk of one type of stroke
- liver or kidney disease, because it may worsen these conditions
- bleeding disorders or who are taking anticoagulant medication, because it may cause bleeding.

Continual high dosages of aspirin can cause hearing loss or tinnitus—a persistent ringing in the ears.

OTC Pain Relief Primer

<i>Type/Dosage</i>	<i>Common Brands</i>	<i>What It Does</i>	<i>Possible Side Effects</i>
aspirin 325 mg 500 mg	Anacin ¹ Ascriptin ² Bayer Bayer Plus ² Bufferin ² Ecotrin ³	Relieves mild to moderate pain from headaches, sore muscles, menstrual cramps, and arthritis; reduces fever.	Prolonged use may cause gastrointestinal bleeding, especially in heavy drinkers; may increase the risk of maternal and fetal bleeding and cause complications during delivery if taken in the last trimester; can cause Reye syndrome if given to children and teenagers who have the flu or chickenpox.
acetaminophen 325 mg 500 mg	Anacin-3 Excedrin ¹ Pamprin ⁴ Midol ⁴ Tylenol	Relieves mild to moderate pain from headaches and sore muscles; reduces fever.	May cause liver damage in drinkers and those taking excessive amounts (more than 4,000 mg daily) for several weeks.
ibuprofen 200 mg	Advil Motrin-IB Nuprin Pamprin-IB	Relieves mild to moderate pain from headaches, backaches, and sore muscles; relieves minor pain of arthritis; provides good relief of menstrual cramps and toothaches; reduces fever.	Gastrointestinal bleeding, especially in heavy drinkers; stomach ulcers; kidney damage in the elderly, people who have cirrhosis of the liver, and those taking diuretics.
naproxen sodium 200 mg	Aleve	Relieves mild to moderate pain from headaches, backaches, and sore muscles; relieves minor pain of arthritis; provides good relief of menstrual cramps and toothaches; reduces fever.	Gastrointestinal bleeding; stomach ulcers; kidney damage in the elderly, people who have cirrhosis of the liver, and those taking diuretics.

1. Contains caffeine.

2. Contains buffers.

3. Enteric coated.

4. Contains ingredients other than analgesics.

FDA requires products containing aspirin and other salicylates to carry a label warning that children and teenagers should not use the medicine for chickenpox or flu symptoms because of its association with Reye syndrome, a rare disorder that may cause seizures, brain damage, or death.

The label also alerts pregnant women that use of aspirin in the last trimester may increase the risk of stillbirth and of maternal and fetal bleeding during delivery.

One Aspirin Alternative

Twenty years ago, FDA approved acetaminophen (Tylenol, and other brands and generics) in dosages of 325 mg and 500 mg for OTC use. "Nobody knows exactly how acetaminophen works, but one theory is that it acts on nerve endings to suppress pain," says Weintraub. Acetaminophen is as effective as aspirin in relieving mild-to-moderate pain and in reducing fever, but less so when it comes to soft tissue injuries, such as muscle strains and sprains, he adds. The usual adult dosage is

ever, even at moderate doses, acetaminophen can cause liver damage in heavy drinkers. At press time, FDA was planning to require a warning about this on the labels of OTC products containing the drug.

From Rx to OTC

Like aspirin, ibuprofen and naproxen sodium inhibit prostaglandin production. However, they are more potent pain relievers, especially for menstrual cramps, toothaches, minor arthritis, and injuries accompanied by inflammation, such as tendinitis. FDA approved ibuprofen for OTC marketing in 1984 at a dosage level of 200 mg every 4 to 6 hours, and naproxen sodium in 1994 at a dosage level of 200 mg every 8 to 12 hours.

"Ibuprofen and naproxen sodium were converted to OTC status after their manufacturers did the necessary studies to show that these pain relievers were effective at OTC dosages, which are lower than prescription dosages," explains Weintraub. The lowest dosage strength for prescription-strength ibuprofen (Motrin and

However, people who have ulcers or who get GI upset when taking aspirin should avoid both. In addition, asthmatics and people who are allergic to aspirin should avoid ibuprofen and naproxen sodium. An FDA advisory panel has recommended labeling on ibuprofen products like that recommended for aspirin, warning heavy drinkers about increased risk of gastric bleeding and impaired liver function (products with naproxen sodium labels already include this information).

Although ibuprofen and naproxen sodium interfere with blood clotting much less than aspirin does, they should not be used by people who have bleeding disorders or who are taking anticoagulants. Children under 12 should not be given either drug, except under a doctor's supervision, and people over 65 are advised to take no more than one naproxen sodium tablet every 12 hours.

Choosing an OTC pain reliever involves balancing effectiveness for a particular ailment with side effects. Often this is a very individual choice, based in part on your

health history and how the drug affects you. Regardless of which type of OTC pain reliever you choose, remember that it is intended to be used on a short-term

"There is no evidence that caffeine relieves pain, but it can enhance the effects of aspirin, possibly by lifting a person's mood."

—Michael Weintraub, M.D., FDA

two 325-mg tablets every four hours.

Acetaminophen-based products to ease menstrual cramps often contain other ingredients, such as pamabrom (a diuretic) or pyrilamine maleate (an antihistamine used for its sedative effects). "While these ingredients are safe, they have not been proven effective against uterine cramps, although they may relieve other symptoms associated with menstrual pain," says Weintraub.

Though acetaminophen is no better or faster at pain relief than aspirin, the drug is gentler on the stomach and reduces fever without the risk of Reye syndrome. How-

others) is 300 mg per tablet, and 275 mg per tablet for the prescription version of naproxen sodium (Anaprox, for example). "In addition, the pharmaceutical companies had to show that these drugs were safe for use by a larger, more varied group of people [than would have received them by prescription only] and that the drugs were safe to use without medical supervision, as is the case with all nonprescription drugs."

Taken at the recommended adult dosage, OTC ibuprofen (Advil and others) and naproxen sodium (Aleve) are somewhat gentler on the stomach than aspirin.

basis, unless directed by a doctor, cautions Weintraub. The warning labels on these products include limitations on duration of use to ensure that chronic or serious illnesses are not masked. Typically, labels advise against taking the product for more than 10 days to relieve pain (for children, the upper limit is five days), or more than three days to reduce fever. If symptoms worsen, pain persists, or there is redness or swelling, medical attention should be sought. ■

Ruth Papazian is a writer in New York City.

LASERS In Dentistry

by Ricki Lewis, Ph.D.

Lasers are now part of our lives in many ways. They are in our computer printers and compact disc players, they record prices at the supermarket check-out, they light up rock concerts, and they guide weapons and measure distances between planets. Lasers have also revolutionized many surgical procedures, minimizing bleeding, swelling, scarring, and pain. And now they're beginning to blaze a new trail in dentistry.

The potential benefits of laser use in dentistry include procedures done on soft tissues of the mouth. Because laser techniques cause less pain than traditional methods, they are also likely to reduce the fear that many people have of the dentist. At the very least, lasers in some dental applications would eliminate the noise of the instruments that to some patients are nearly as disturbing as the physical discomfort.

However, it may be quite a while before you can have your cavities drilled or root canals cleaned with a painless flash of a laser. "FDA has cleared for marketing certain lasers for soft tissue use, such as gingivectomies [removing excess gum tissue], but not for hard tissues," says Gregory Singleton, D.D.S., senior dental officer in the Center for Devices and Radiological Health at FDA. The hard tissues include tooth and root, while soft tissues of the mouth refer to the gums, the ligaments and fibers that bind tooth to socket, and the tissue supporting the tongue.

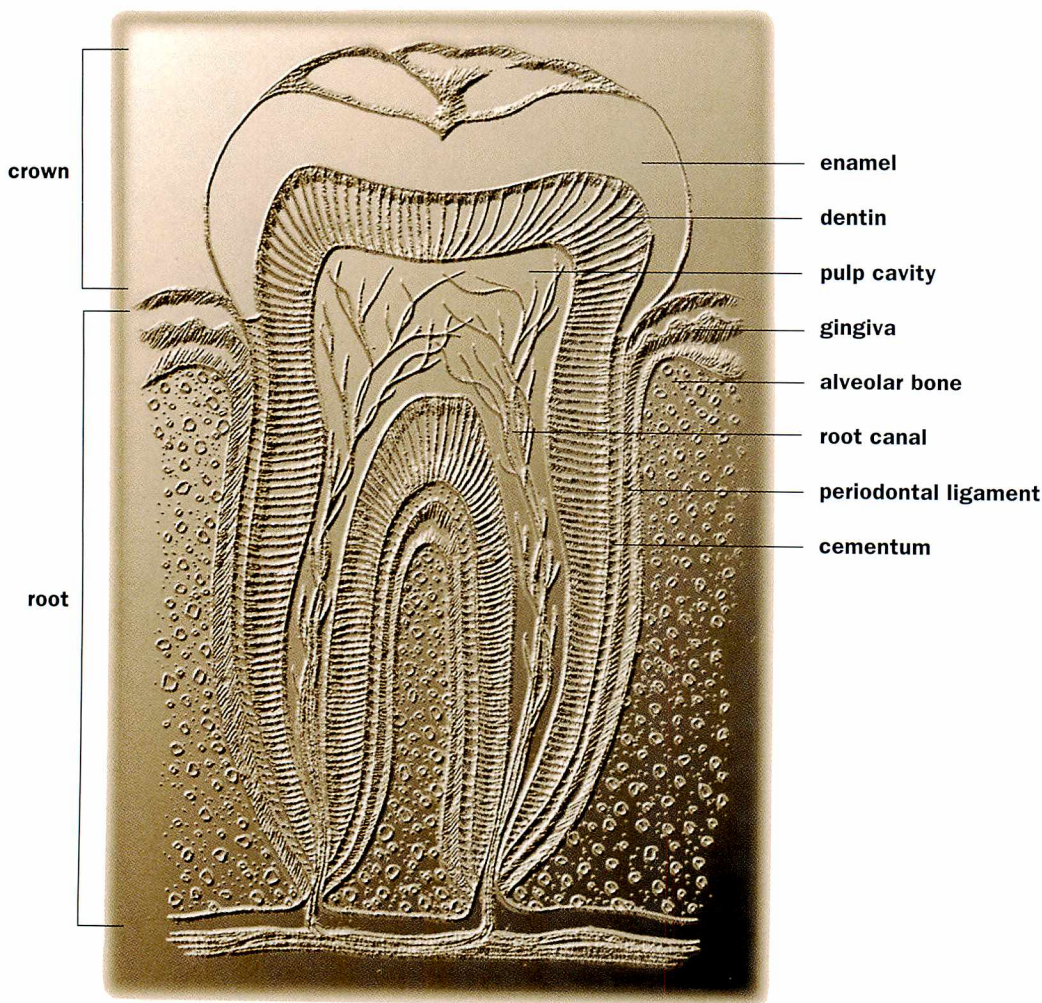


Dentists can now use lasers for soft tissue procedures, such as removing gum tissue. The dentist, assistant, and patient all need to wear protective gear.

(Photo courtesy American Dental Technologies)

The challenge to dentists is finding the best laser type and strength for a particular application.

ANATOMY OF A TOOTH



So far, lasers seem to be living up to their promise in the latter area. "For soft tissue surgery, lots of patients report less postoperative pain. There are sealed off nerve endings, so recovery is less painful," says Marilyn Miller, D.M.D., co-director of the Princeton Dental Resource Center in Princeton, N.J. But she adds that healing may be slightly slower, because the laser also seals off blood vessels, which would bring in clotting factors to help heal cut tissues.

Laser Basics

Since the mid-1960s, lasers have proven to be powerful surgical tools. The word "laser" is an acronym for "light amplification by stimulated emission of radiation," which means that the intense and narrow beam of light is of one wavelength. Ordinary "white" sunlight, in contrast, is a continuum of light of many wavelengths, corresponding to the colors of the visible spectrum plus the infrared (heat) and ultraviolet wavelengths that sandwich them.

Sunlight passing through a prism separates into its component colors; a laser light remains a single color.

A medical laser device includes a source of electricity, mirrors to direct the beam, a crystal or gas that is stimulated to emit the light, and tubing to deliver the light energy. The nature of the material through which the light passes determines the specific properties of the laser—and therefore what it can do in the human body. Instrument design is tailored to specific uses. Many dental lasers, for example, include long narrow tubing so that the dentist can use it in the narrow confines of a person's mouth.

Types of Dental Lasers

FDA has cleared four types of lasers for dental use: carbon dioxide, Nd:YAG, argon, and holmium:YAG.

A carbon dioxide (CO₂) laser uses CO₂ gas. Watery tissue absorbs this type of laser energy, which doesn't penetrate very deeply, but vaporizes surface cells. A CO₂ laser leaves a residue of carbon, called char. If a dentist leaves char in place, it serves as a biological dressing, maintaining sterility.

Because the beam from a CO₂ laser is invisible, a second laser beam, based on the elements helium and neon, adds a red beam, so the dentist can see the laser energy.

A CO₂ laser is used in gingivectomies, biopsies, and removal of benign and malignant lesions (see accompanying article). A CO₂ laser is particularly good for a frenectomy. "The frenum—the tissue under the tongue—is tight in some people, and it can be quickly loosened up with laser treatment," says Michael Yessik, president of Incisive Technologies, a laser manufacturer in San Carlos, Calif.

For lesions extending into tissue deeper than the 0.1 millimeter that the CO₂ laser penetrates, a neodymium:yttrium-aluminum-garnet (commonly called an

If you dream of having a cavity treated with a painless, soundless zap of a laser, you will have to wait awhile.

Nd:YAG) laser is appropriate. As with the CO₂ laser, an accompanying red beam makes the energy visible. A jet of cool water or air limits possible heat damage that can result when a super-heated gas, called a plasma, forms on the tissue surface as it is being treated. An Nd:YAG laser can harm thin tissue, such as the gum in the lower front of the mouth. The CO₂ and Nd:YAG lasers are used in some of the same procedures that remove soft tissue.

The argon laser is based on gas of the element argon, and emits a bluish-green light. It is cleared for marketing for a different application—curing composite resins. These tooth-colored materials are used in reconstructing chipped teeth, filling cavities in visible areas of the mouth, or sealing teeth to protect them from decay. The dentist paints on the composite, and then focuses a narrow beam of light to harden, or cure, it. The intense light alters the physical properties of the composite, linking its small molecules into longer ones, which adds great strength. Robert Pick, D.D.S., clinical associate professor at Northwestern University Dental School, writes that he thinks the argon laser will soon become the standard method for curing dental composite resins, replacing ultraviolet light.

Another device used on soft tissues is the holmium:YAG laser. Oral and maxillofacial surgeons have used it experimentally to surgically remove the damaged disc separating the condyle of the mandible from the base of the skull. The disc can be damaged due to trauma or chronic inflammatory diseases such as osteoarthritis that can cause symptoms commonly known as temporomandibular joint (TMJ) syndrome. (An oral and maxillofacial surgeon is a dentist specializing in correcting abnormalities of the jaws and face with surgical procedures.) TMJ syndrome can cause facial pain, headaches, pain in front of the ear, noise when the jaw opens, ear congestion, dizziness, ringing

in the ears, difficulty swallowing, nervousness, insomnia, difficulty chewing, sensitive teeth, numb fingertips, and backache.

Choosing the Best Laser

The challenge to dentists is finding the best laser type and strength for a particular application. Lasers can vary in chemical basis (CO₂, Nd:YAG, holmium:YAG, argon, and others), wavelength of emitted light, power, whether it is applied continuously or in short pulses, and whether the laser is applied directly (a contact laser) or through a tip of some sort (non-contact).

The effect of a particular laser must be evaluated for each type of dental tissue—such as enamel, dentin, pulp, bone, and gingiva. Light can have one of four fates when it hits a tissue—it may be absorbed, reflected, scattered within the tissue, or transmitted. This is important, because light energy that is transmitted or scattered may harm surrounding tissue. Reflected laser light dissipates so quickly that it does no damage.

Whether or not anesthesia is needed for soft tissue dental laser procedures depends on the duration of the treatment and the amount of tissue removed. CO₂ laser procedures may require local anesthesia, but Nd:YAG treatment usually does not.

“About 70 to 80 percent of procedures using dental lasers are done without anesthesia. It depends on the power level needed to perform the procedure,” says Yessik.

Safety Measures

Several precautions to dental staff and patient must accompany laser use. Everyone in the room must wear protective glasses—dark green tinted for argon and YAG lasers, and clear for CO₂ lasers. Wet gauze pads are placed in the patient's mouth surrounding the treated area. Reflective surfaces, such as instruments and mirrors, are covered so that stray light

beams cannot ricochet around the room.

It is very important that all anesthetic gases be removed from the room. They are explosive, and could be ignited by a laser beam. The dentist must also suction off vaporized soft tissue, and the smoke, or laser “plume,” emitted during procedures. The plume can carry viruses. This is one reason that some dentists do not like to use a laser to remove herpes lesions in the mouth. Treatment with a CO₂ laser provides rapid pain relief and speeds healing.

Zapping Away Cavities—Not Yet

If you dream of having a cavity treated with a painless, soundless zap of a laser, you will have to wait awhile. Although lasers have great potential for one day replacing the drill, there is still too much danger of their damaging the pulp under the enamel, according to Gerard Kugel, D.M.D., assistant clinical professor of restorative dentistry at Tufts University School of Dental Medicine in Boston. The problem is the amount of heat generated in hard tissue treatment.

“It may take a different intensity or type of laser energy to remove debris from soft tissue than to remove the hard calculus or plaque from a tooth's root,” says Dennis Mangan, Ph.D., director of the Periodontal Research Program at the National Institute of Dental Research in Bethesda, Md. (A periodontist specializes in diseases of the gums and supporting structures of the teeth.) Also, a laser could not produce the uneven edges carved intentionally with a drill so that dental amalgam or other filling materials can be retained properly. Lasers could not be used to repair existing fillings either, because they would vaporize the amalgam component mercury, which would make it highly toxic.

But dental researchers are actively investigating the safety and efficacy of lasers for hard tissue applications on freshly

“About 70 to 80 percent of procedures using dental lasers are done without anesthesia.”

—Michael Yessik, president of Incisive Technologies

Some Current Dental Laser Procedures

Replacing conventional soft tissue dental surgery with lasers often eliminates the need for sutures and anesthesia. Today lasers can:

- Remove excess gum tissue, which can develop as a side effect of taking certain drugs, poor oral hygiene, or orthodontia, in a procedure called gingivectomy.
- Expose dental implants, replacement tooth roots made of steel or titanium sur-

gically embedded in the jawbone, which can become covered with too much soft tissue. A CO₂ laser can quickly expose the implant for the dentist to work on.

- Relieve the pain of aphthous ulcers, mouth sores. Both CO₂ and Nd:YAG lasers can relieve the pain instantly—used on low power, without an anesthetic.
- Remove excess tissue under the tongue in less than two minutes, in a procedure called frenectomy.
- Biopsy or sample tissue from a lesion to see whether it is cancerous. A laser biopsy

does not require suturing and heals well. This is particularly useful on the tongue, where bleeding can be profuse.

- Remove soft tissue in the mouth to even out wrinkles that form when a person smiles.
- Hasten clotting of bleeding caused by other procedures. ■

—R.L.

extracted human teeth and in animal and human trials.

Researchers at the University of California at San Francisco School of Dentistry carried out one human study using a pulsed Nd:YAG laser at relatively low power. They used the laser on 163 cavities in 97 people at three private dental clinics in 1987 and 1988. At follow-up three years later that included 35 participants, the areas where the laser had removed decay had all remineralized well, with no complications.

Still, much more study is needed before the dentist's drill becomes a thing of

the past. "The FDA feels there is not enough support for use of lasers on hard tissues, and dental organizations, such as the American Dental Association, do not support non-FDA-approved laser procedures," says Miller.

A Look Ahead

Despite the slow evolution of lasers in dentistry, researchers say the day will indeed come when a variety of lasers play a more prominent role in maintaining a healthy mouth. "And it won't be just one laser that will do all dental procedures. Researchers envision a laser unit in which

you can switch on or off different types of lasers depending upon the procedure," says Miller.

"It's an exciting technology, and patients are really intrigued at the idea of a laser. The lay press exaggerated, saying now we can throw away dentists' drills. But research is showing that we will be able to do that—eventually," she says. "But we haven't yet found the right laser." ■

Ricki Lewis is a freelance science writer in Scotia, N.Y., and author of college biology texts.

The New Food Label

Better Information For *Special Diets*

by Paula Kurtzweil

This is the fifth and last in a series of articles telling how to use the new food label to meet specific dietary needs.

The right diet is important for everyone, but for Tony Robinson of Orlando, Fla., it truly is his lifeblood.

Robinson has end-stage renal disease. Three times a week, he goes to a local medical center, where a dialysis machine does what his kidneys no longer can: purify his blood.

Between treatments, he's careful about what he eats because some nutrients can cause harmful—sometimes deadly—levels of substances to build up in his blood. He eats a diet low in protein, sodium and potassium to keep those dangerous substances minimal, and high in calories to maintain his weight.

Until recently, he and his wife, who does most of the cooking, kept mainly to foods listed in a brochure of “foods to eat” and “foods to avoid” for people with end-stage renal disease. But now they're using the new food label as another source of information.

“The new label adds to what we already know,” Robinson said. “And mandatory nutrition labeling gives us the information

we need to choose from a wider range of food products.”

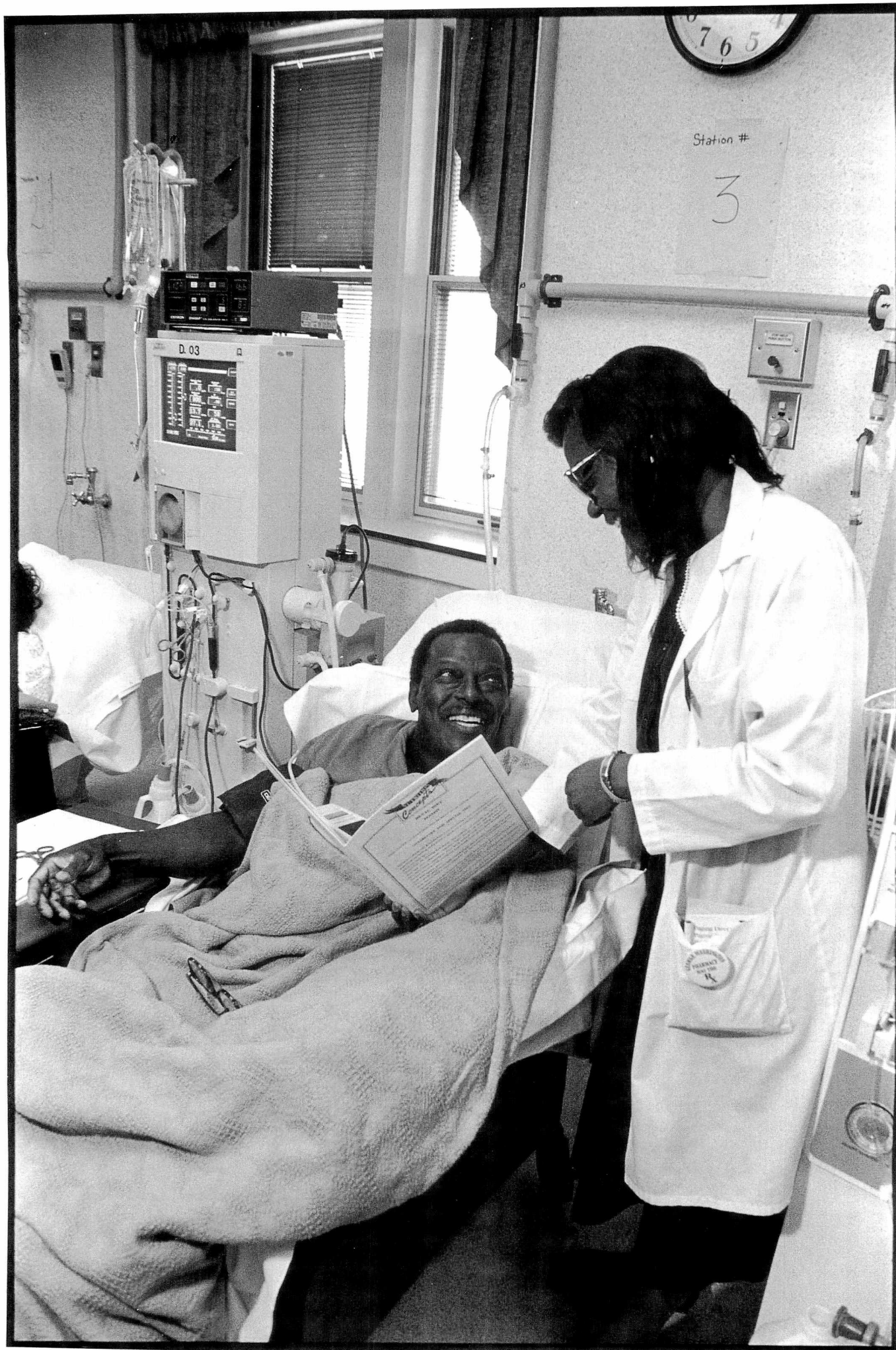
Label Benefits

Under the Nutrition Labeling and Education Act of 1990 and regulations from the Food and Drug Administration and the U.S. Department of Agriculture, virtually all food labels must now give information about a food's nutritional content.

That wasn't always the case. Until 1994, nutrition information was voluntary. Manufacturers had to provide it only when a food contained added nutrients or when nutrition claims appeared on the label. Nearly 40 percent of products didn't carry nutrition information.

“Just to have the information on the label is a big plus for consumers on therapeutic diets,” said Camille Brewer, a registered dietitian and nutritionist in FDA's Office of Food Labeling.

Another group the regulations help is people with food sensitivities. Every product with two or more ingredients must now list the ingredients on the label. That includes standardized foods, such as peanut butter, and some baked goods. These foods previously were exempt from ingredient labeling because at one time, most

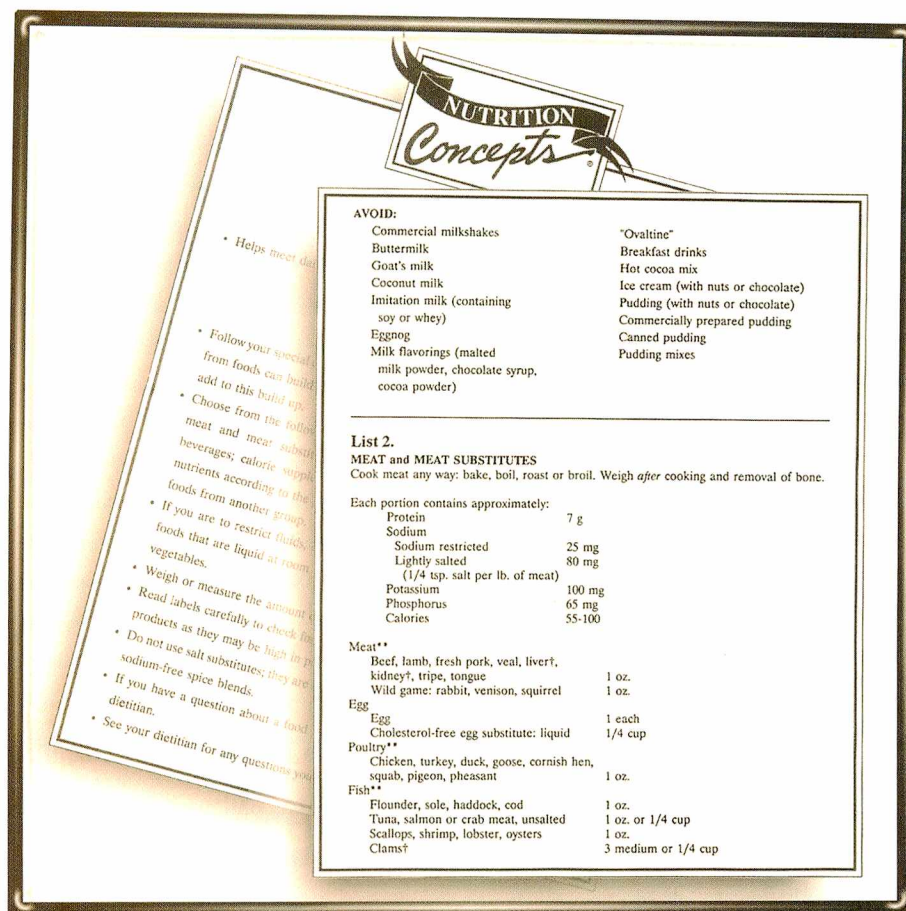


"Just to have the information on the label is a big plus for consumers on therapeutic diets."

—Camille Brewer, FDA nutritionist

At left, Mercy Hammond, a registered dietitian, reviews a strict diet plan with Sylvester Brown, 44, a kidney dialysis patient at the George Washington University Hospital in Washington, D.C. At right are some details of the plan, commonly used by patients with kidney disease. The new food label makes it easier to follow such diets.

(Reprinted with permission of ARAMARK Corp.)



Americans were familiar with the recipes since they were foods routinely prepared at home.

Also, the source of some ingredients (for example, hydrolyzed soy protein) must now be identified.

Get the Nutrition Facts

Consumers looking for nutrition information about a food should first look at "Nutrition Facts," usually on the side or back of the package.

For many people on special diets, the amount of the nutrient in grams or milligrams is most important because their diets are based on a set amount of one or more nutrients a day specific to their needs—for example, 60 grams (g) of protein, 2,000 milligrams (mg) of sodium a day. Special dieters can find the amount by

weight of nutrients listed in the top part of the Nutrition Facts panel.

Some important points about the Nutrition Facts panel: The values listed for total carbohydrate include all carbohydrates, including dietary fiber and sugars listed below it.

The sugars include naturally present sugars, such as lactose in milk and fructose in fruits, as well as those added to the food, such as table sugar, corn syrup, and dextrose. The label can claim "no sugar added" but still have naturally occurring sugar. An example is fruit juice.

Also, potassium may be listed voluntarily with the nutrients listed on the top part of the panel, just below sodium. Its %Daily Value is based on a recommended intake of 3,500 mg a day.

Other vitamins and minerals may be

KEY INFO

Good Source of Fiber
Good Source of Calcium

See side panel for nutrition information.

Whole-wheat Cereal

Low-fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

Net wt: 12¹/₂ oz (350 g)

Look for claims (such as those shown), usually on the front of the package, describing a food's nutritional content or stating a food or health benefit.

Nutrition Facts

Serving Size 1 cup (35g)
Servings Per Container 10

Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	130	170
Calories from Fat	0	0
% Daily Value**		
Total Fat 0g*	0%	0%
Saturated Fat 0g	0%	0%
Cholesterol 0mg	0%	0%
Sodium 200mg	8%	11%
Total Carbohydrate 30g	10%	12%
Dietary Fiber 4g	16%	16%
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	10%	25%
Iron	10%	10%
Thiamin	25%	30%
Riboflavin	25%	35%
Niacin	25%	25%
Vitamin B6	25%	25%

* Amount in Cereal. One half cup skim milk contributes an additional 40 calories, 65 mg sodium, 6g total carbohydrate (6 g sugars), and 4g protein.

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

INGREDIENTS: WHOLE WHEAT, SUGAR, MALT EXTRACT, CORN SYRUP, TRISODIUM PHOSPHATE, VITAMIN C (SODIUM ASCORBATE), IRON, NIACINAMIDE, VITAMIN A (PALMITATE), CALCIUM CARBONATE, VITAMIN B6 (PYRIDOXINE HYDROCHLORIDE), RIBOFLAVIN, THIAMIN, BHT TO PRESERVE FRESHNESS.

Food Label M A T I O N

Check the Nutrition Facts panel, usually on the side or back of the package. It gives more complete nutrition information.

Look at the serving size. It is about the same for similar items. So it's easy to compare the nutritional qualities of similar foods.

Look at the column called "%Daily Value." It tells you at a glance whether a food is high or low in sodium, carbohydrate, fiber, vitamins and minerals, and other nutrients. For products that need additional preparation before eating or that are usually eaten with one or more other foods, such as cereal with milk, manufacturers can give voluntarily a second column of %Daily Values to show the nutritional content of the food as eaten.

Check the ingredient list, especially if you have food allergies or avoid certain foods for religious or other reasons. The sources of some ingredients, such as certain flavorings, now are stated by name.

The ingredient list is a source of information, especially useful for people with food sensitivities.

listed on the Nutrition Facts panel, along with vitamins A and C, iron, and calcium.

Amounts of vitamins and minerals are only presented as percentages of the Daily Value.

Calorie information appears at the top of the Nutrition Facts panel, following serving size information. This information is important for those needing to increase or decrease their calories.

Serving Size

The serving size information gives the amount of food to which all the other numbers on the Nutrition Facts panel apply.

Now serving sizes are more uniform among similar products and are designed to reflect the amounts people actually eat. Also, serving sizes must be about the same for the same types of products—for example, different brands of frozen yogurt—and for similar products within a food category—for example, ice cream, ice milk, and sherbet within the category frozen dairy-type desserts.

Having more uniform serving sizes makes it easier to compare the nutritional values of related foods.

People who follow special diets should be aware that the serving size on the label may not be the same as that recommended for their specific needs. For example, the label serving size for cooked fish is 3 ounces (84 g). A person following a 60-gram protein diet may be allowed only 1 ounce (28 g) of fish at a meal. So, in this case, the nutrient values would have to be divided by 3 to determine the nutritional content of the 1-ounce portion eaten.

Ingredients

The ingredient list is a source of information especially useful for people with food sensitivities. (See Ingredient Labeling: What's in a Food?" in the April 1993 *FDA Consumer*.) Some new requirements

that provide more information in the list are:

- Listing protein hydrolysates by source—instead of "hydrolyzed vegetable protein," the list must state the type of vegetable (for example, "hydrolyzed corn protein").
- Stating FDA food-certified color additives by name—for example, "FD&C Blue No. 1" and "FD&C Yellow No. 6." Before, they could be listed simply as "colorings."
- Declaring caseinate as a milk derivative in foods that claim to be non-dairy, such as coffee whiteners.

On some labels, the ingredient list may state the source of sweeteners, too, although this is voluntary. For example, instead of "dextrose" or "dextrose monohydrate," the ingredient may be listed as "corn sugar monohydrate."

Special Report

Articles cited in this story are among those included in the in-depth and easy-to-understand *FDA Consumer* special report, *Focus on Food Labeling*. Copies cost \$5 each. To order, write to: Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Ask for stock number S/N 017-012-00360-5. ■

Special Diets

Label information can help individuals select foods appropriate for their special dietary needs, determined by a physician, registered dietitian, or nutritionist. Some medical conditions that require special attention to diet are:

- **Kidney Disease**

For many people whose kidneys have failed or are failing, protein, potassium and sodium are restricted. The nutrient phosphorus also may be restricted.

People undergoing dialysis may be encouraged to eat 20 to 25 grams (g) of fiber daily because fluid restrictions, lack of exercise, and some kidney medications can cause constipation. The Daily Value for fiber, which is based on a 2,000-calorie diet, is 25 g.

Daily Values are reference numbers based on recommended dietary intakes to help consumers use label information to plan a healthy diet. (See “‘Daily Values’ Encourage Healthy Diet” in the May 1993 *FDA Consumer*.)

- **Liver Disorders**

People with hepatitis, cirrhosis, and other liver diseases often need a high-calorie, low-protein diet to help rejuvenate the damaged liver and maintain adequate nutrition. They also may need to increase

their intake of vitamins—particularly folic acid, vitamin B₁₂, and thiamin—and minerals.

- **Food Sensitivities**

According to the Food Allergy Network (a national nonprofit organization), the most common food allergens are milk, eggs, wheat, peanuts and other nuts, and soy. The treatment: avoiding the food or foods containing them.

- **Celiac Disease**

This is a genetic disorder in which the body cannot tolerate gliadin, the protein component of the gluten in wheat, barley, rye, and oats. So, people with celiac disease must avoid all products containing these grains—even foods that may contain only small amounts of the protein, such as vinegar, bouillon, and alcohol-containing flavorings. The intolerance leads to malabsorption—not only of the offending food but virtually all nutrients.

- **Cancer**

Because weight loss is common during cancer treatment, many cancer patients need to increase their calories and protein intake.

In the case of bowel obstruction—either from surgery, radiation or the tumor—cancer patients may need to eat less fiber. But, they may need more if they become constipated.

To help reduce their risk of developing

cancer again, following treatment, patients may want to choose foods and nutrients whose role in reducing cancer risk has been borne out by significant scientific evidence. (See “Look for ‘Legit’ Health Claims on Foods” in the May 1993 *FDA Consumer*.)

- **Bowel Disease**

Increased fiber is often recommended for people with chronic constipation, irritable bowel syndrome, and diverticulosis. Low-fiber diets may be called for during flare-ups of these and other bowel diseases, such as Crohn’s disease and ulcerative colitis.

- **Osteoporosis**

In osteoporosis, bone mass decreases, causing bones to become brittle and easily broken, especially in later life. A low-calcium intake throughout life is thought to be a major risk factor. The Daily Value for calcium, based on calcium needs for all ages, is 1,000 milligrams. Vitamin D also is important because it aids calcium absorption. The Daily Value for vitamin D is 400 International Units. ■

—P.K.

Nutrient Claims Guide For Individual Foods



Fiber

High-fiber: 5 grams (g) or more per serving

Good source of fiber: at least 2.5 g per serving

More or added fiber: at least 2.5 g more per serving than the reference food. (Label will say 10 percent more of the Daily Value for fiber.)

Protein

High-protein: 10 g or more of high-quality protein per serving

Good source of protein: at least 5 g of high-quality protein per serving

More protein: at least 5 g more of high-quality protein per serving than reference food. (Label will say 10 percent more of the Daily Value for protein.)

Calcium

High-calcium: 200 milligrams (mg) or more per serving

Good source of calcium: at least 100 mg per serving

More calcium: at least 100 mg more than reference food. (Label will say 10 percent more of the Daily Value for calcium.)

Vitamin D

High in vitamin D: 80 International Units (IU) or more per serving

Good source of vitamin D: at least 40 IU per serving

More or fortified with vitamin D: at least 40 IU more than reference food. (Label will say 10 percent more of the Daily Value for vitamin D.) ■

Nutrient Claims

Elsewhere on the label, consumers may find claims about the food's nutrient content. Often, these claims appear on the front of the package, where shoppers can readily see them. These claims signal that the food contains desirable levels of certain nutrients.

Some claims, such as "low-sodium" "high in calcium," or "good source of fiber," describe nutrient levels. (See "A Little 'Lite' Reading," in the June 1993 *FDA Consumer*.) Some, but not all, high-light foods containing beneficial amounts of nutrients for some people with special dietary needs. The same claim may warn other consumers, for whom the nutrient is detrimental, to avoid the product. For example, a product claiming to be an "excellent source of potassium" is not a wise buy

for a person following a low-potassium diet. (See "Nutrient Claims Guide for Individual Foods.")

Health Claims

Health claims describe a relationship between a nutrient or food and a disease or health-related condition. FDA has authorized eight such claims; they are the only ones that can be used in a label. The claims may show a link between:

- calcium and a lower risk of osteoporosis
- fat and a greater risk of cancer
- saturated fat and cholesterol and a greater risk of coronary heart disease
- fiber-containing grain products, fruits and vegetables and a reduced risk of cancer
- fruits, vegetables and grain products that contain fiber and a reduced risk of coronary heart disease

- sodium and a greater risk of high blood pressure
- fruits and vegetables and a reduced risk of cancer
- folic acid and a decreased risk of neural tube defect-affected pregnancy.

Nutrient and health claims can be used only under certain circumstances, such as when the food contains appropriate levels of the stated nutrients.

The intent of the new food label is not just to ensure that label information is truthful but to provide more complete and useful nutrition and ingredient information for consumers' use. People with special dietary needs will likely find the labeling changes a welcome bonus. ■

Paula Kurtzweil is a member of FDA's public affairs staff.

AN INSIDE LOOK AT

FDA ON-SITE

There are nearly 15,000 establishments in the United States that manufacture, test, pack, and label drug products for humans. The Federal Food, Drug, and Cosmetic Act requires FDA to inspect each of these facilities at least once every two years. In addition, 800 to 1,000 foreign facilities are periodically inspected.

Agency investigators, working from field offices in some 160 locations throughout the country, completed 3,142 domestic inspections in 2,618 human drug establishments in the fiscal year that ended Sept. 30, 1993. Another 223 inspections were done at 213 foreign establishments.

During that year, the agency took a number of legal actions to correct deficiencies for failure to meet drug manufacturing and product standards. These included one prosecution, two injunctions, 15 seizures, and 408 warning letters. FDA also monitored recalls involving 406 drug products in various dosage forms.

An inspection can last from one or two days to several weeks, depending on its purpose and scope. There are three primary types of inspections: preapproval, postapproval, and surveillance good manufacturing practice (GMP) inspections.

Preapproval inspections are often initiated by the Center for Drug Evaluation and Research at FDA headquarters. While the center is reviewing a new drug application or abbreviated new drug application, it requests that the field office inspect the drug manufacturing facilities.

This inspection represents a significant step in the drug review process. The investigators must determine if the data submitted in the firm's application are authentic and accurate and if the plant is in compliance with current good manufacturing practice regulations. The district office recommends approval or disapproval of the application, based on its findings.

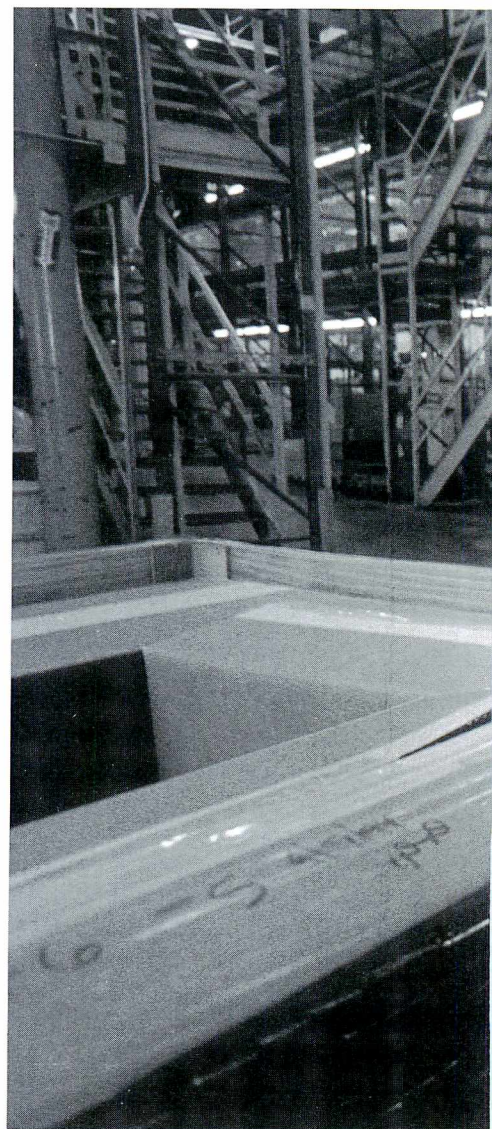
After the center approves an application and the firm is ready to start marketing the drug, FDA conducts a postapproval inspection, intended to evaluate the firm's validation studies. Validation refers to FDA's requirement that the firm show it can consistently manufacture a drug product within tight parameters from batch to batch, day to day, year to year. The investigators also verify that the firm has not changed its manufacturing, labeling, or quality control testing for that drug without filing a supplement to its application, and that the firm has not exceeded a tenfold "scale-up" in production.

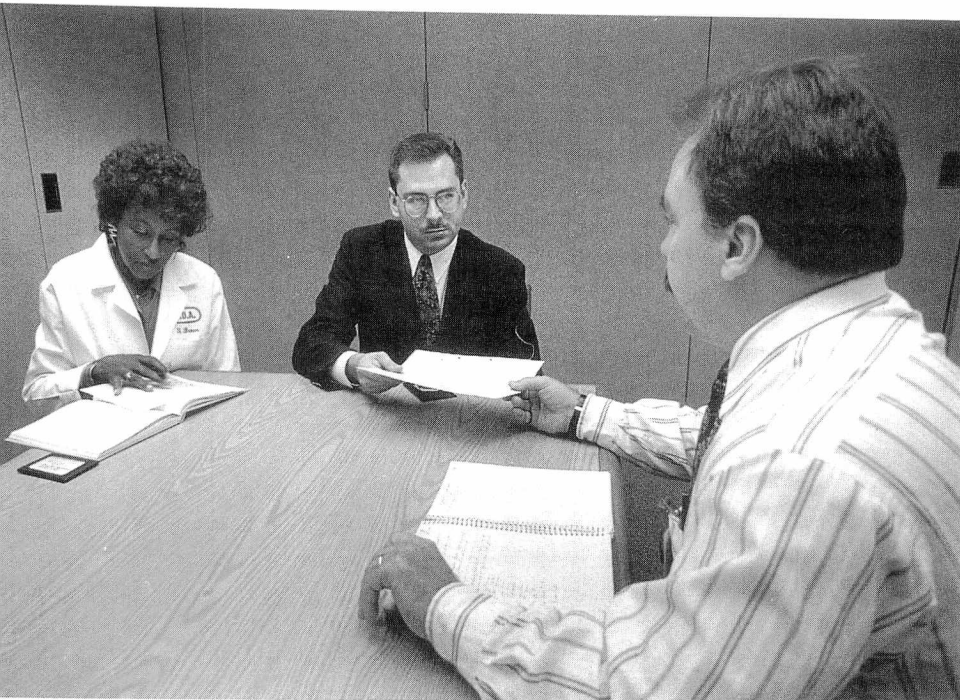
"Scaling up" is the process of increasing the batch size for commercial manufacture. "For commercial production, FDA allows firms to manufacture their product in batches ten times larger than those produced for clinical or bioequivalency testing," Kirk Sooter, investigator with the agency's Morgantown, W.Va., resident post, says. "For example, if tablets were produced in batches of 100,000 during clinical testing, the commercial production batch cannot exceed 1 million tablets."

The investigators collect samples at both preapproval and postapproval inspections for analyses that will compare the composition of the product against known standards. The drug's chemical "fingerprint" must match the standard pattern for the compound. Samples are also collected to verify that the firm's laboratory methods are proper and consistent with the drug application.

Finally, a GMP, or "routine," inspection evaluates the firm's entire operations. Although pre- and postapproval inspections include examination of the firm's manufacturing practices, they are product-specific. GMP inspections, on the other hand, involve a comprehensive review of the firm's manufacturing operations. ■

by Marian Segal





When FDA's Sarah Brown (left) and Kirk Sooter (middle) arrive to inspect Barre-National Inc., a Baltimore drug manufacturer, they show their credentials and issue a written "Notice of Inspection" to the firm's quality assurance manager. A full inspection may take weeks, while a visit to look at one or two specific things may take only an afternoon. An inspection team may comprise several people, including analysts, chemists, microbiologists, and investigators.

Before coming to the plant, Brown, a chemist with the Baltimore district office, and Sooter reviewed the plant's inspection history.



In the plant's receiving section, the investigators make sure the firm is following its written procedures for receiving and handling incoming raw materials. They also evaluate the procedures to make sure they are adequate.

Early in the inspection, Sooter and Brown look over the company's complaint files. These files not only reveal how the firm conducts its complaint investigations, but may help the investigators determine what areas they want to focus on in their inspection.

"If there are substantial problems or complaints about a product, we look at what kind of effort the firm puts into resolving the complaints," Sooter says. "If the firm is responsible for the problem, what sort of corrective action did it take? Did they look at manufacturing batch records? Did they review the laboratory analyses?"

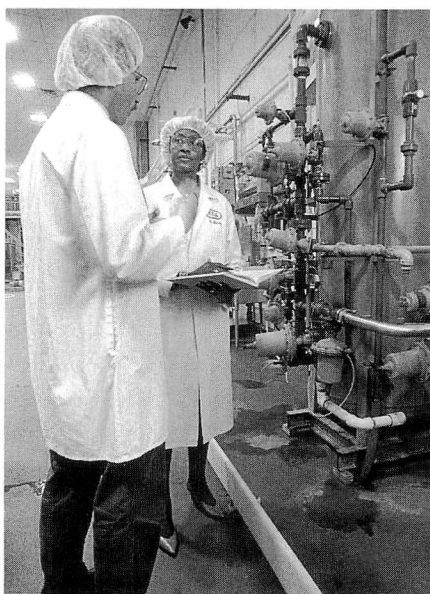
"If there are excessive complaints about a particular product," Brown adds, "the investigator may collect a sample from a store shelf and have it analyzed at FDA's laboratory. A product that doesn't meet standards may be removed from the marketplace."



***I**n the weighing station, precise amounts of raw materials are weighed for compounding when formulating products. A technician hands Sooter a weighing slip showing the weight of the material on the scale. Sooter will check to see that the scales are calibrated, start at zero, and are steady at the registered weight.*

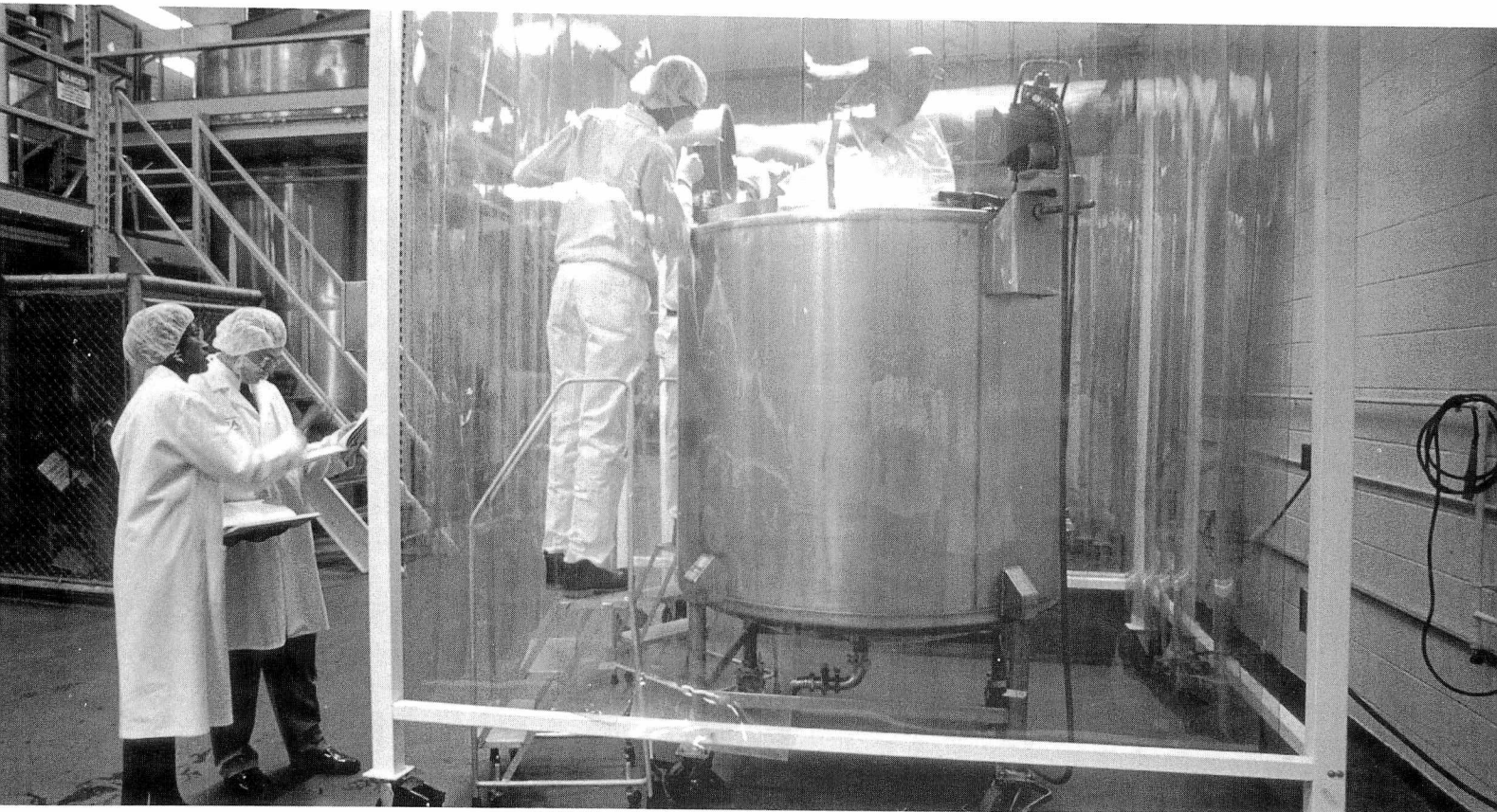
"It's also important to make sure that proper procedures are followed to prevent cross-contamination of chemicals in production areas," Sooter says. "For example, in the weighing station, do they use the same scoop for two materials? Is one chemical container open while another chemical is being weighed out, leaving the potential for cross-contamination?"

In production areas, hair must be covered to prevent product contamination. Men must also cover beards and mustaches. Here, the two wear masks also to prevent inhalation of fine particles of the powdery material.



***B**rown discusses with a quality control officer how the firm's water purification system works, how it's monitored, and how frequently the water is tested. Water used as an ingredient in any drug product must meet chemical and microbial standards.*

"They need to test not only for microbial contaminants," Brown says, "but for pH levels and levels of chemicals that can cause production problems down the road."



While a technician adds an ingredient to a product in a compounding tank, Brown consults the batch production and control record and Sooter checks employee signatures to see that ingredients have been added and mixed as prescribed.

“Certain ingredients should be added slowly because of chemical reactions; others need to be added quickly, but cooled to a certain temperature, or the mixing needs to be stopped or speeded up,” Sooter explains.

The curtain around the tank defines a “controlled” area. The curtain helps keep foreign substances out of the area and keeps other substances, such as dust rising from powders dumped in the tank, from escaping and getting into other equipment.



Sooter inspects one of the large compounding tanks for cleanliness and will check to see that the equipment log accurately reflects the usage and cleaning of that particular vessel. Proper cleaning between uses is important to avoid contamination of products.



Sooter and Brown review batch records for products that have reached the filling line where labels are affixed.

"A batch record is one of the most important documents in drug production because it tells the whole history of that batch," says Peter Smith of FDA's division of field investigations at agency headquarters. "It's a copy of the master record, the approved way to manufacture a particular product in a particular batch size. The record literally follows the batch production from one process-area to the next and records every step from beginning to end. Employee signatures document that the steps in

manufacture, processing, packaging, or holding were completed."

The record contains everything that happened concerning production of that batch—what went into it, where samples were taken, problems during manufacturing (such as equipment failure or power failure or a broken hose)—down to the exact batch yield.

If there is a problem with a product after it's on the market, Smith says, one of the first things investigators do is examine the batch record for any problems—even those seemingly unimportant at the time—that may have occurred during manufacture.



In the laboratory, a technician shows Brown the results of a high performance liquid chromatography (HPLC) assay she's doing on a finished product sample. The test is done to ensure the product conforms to standards and contains no impurities.

HPLC detects the active ingredients of a formulation. "Every formulation has its own 'chemical fingerprint' that appears on the chromatogram as a distinct pattern of peaks," Brown says. "If the pattern does not match the known standard, then a problem is apparent. Further tests can determine what the abnormal peaks represent."

"When we go into the laboratory," Brown says, "we make sure the HPLC and other instruments are working properly, check the quality of chromatograms, review what analytical methods are used for what purposes, and if they are appropriate and calculated correctly."

Marian Segal is a member of FDA's public affairs staff.



Sooter waits while some boxes stored in the high bay warehouse area are brought down for him to check. Here, the firm may store products not yet distributed or failed products that haven't yet been destroyed.

"An investigator may want to look at the 'morgue'—the area where failed product is kept—early on in the inspection for clues about what to key in on," says Sooter. For example, he says, if batches of a particular product have failed or been rejected, that product will warrant a closer look.



The Notebook: a potpourri of items of interest gathered from FDA news releases, other news sources, and the Federal Register (designated FR, with date of publication). The Federal Register is available in many public libraries.

■ **Electronic submission** of new drug applications is the subject of a revised manual, "Computer Assisted New Drug Application (CANDA) Guidance Manual." To obtain a free copy, send two self-addressed labels and a written request to: CDER Executive Secretariat Staff, HFD-8, FDA, 7500 Standish Place, Rockville, MD 20855. (FR Oct. 28)

■ **The "Advisory Committee Information Hotline"** has been established by FDA. The hot line, which provides the most current information available on committee meetings, can be reached at (1-800) 741-8138, or (301) 443-0572 in the Washington, D.C., metropolitan area. (FR Oct. 27)

■ **Tar, nicotine, and carbon monoxide** content of American cigarettes is the subject of a new report available from the Federal Trade Commission. Free copies of the "Report of the Tar, Nicotine, and Carbon Monoxide Content of 933 Varieties of Domestic Cigarettes" are available by writing: FTC Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave., N.W., Washington, DC 20580; telephone (202) 326-2484. (FR Oct. 25)

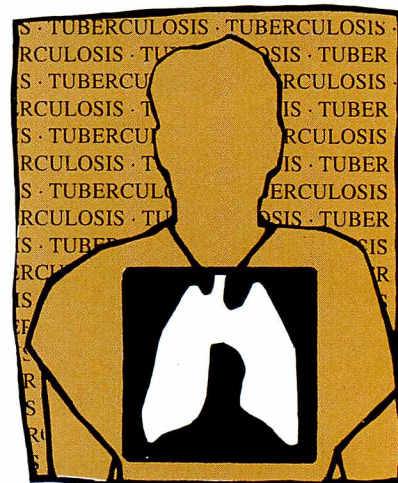
■ **GrantsNet**, an on-line grant information service, was established by the Department of Health and Human Services. The free

public access computer network helps persons find and exchange information about HHS and other federal grant programs. For more information, contact: Suzanne Neill, Division of Grants Policy and Oversight, Room 517-D, 200 Independence Ave., S.W., Washington, DC 20201; telephone (202) 690-5731; E-mail: sneill@os.dhhs.gov. (FR Oct. 27)

■ **A breast and cervical cancer** advisory committee was established last Sept. 12 by the National Institutes of Health. The Breast and Cervical Cancer Early Detection and Control Advisory Committee will coordinate the activities of the U.S. Public Health Service and other federal government agencies aimed at reducing the death rate from breast and cervical cancer in the United States by the year 2000. (FR Oct. 13)

■ **A revised AIDS classification system** for children under 13 was issued by the national Centers for Disease Control and Prevention. The new system classifies infected children according to infection status, clinical status, and immunologic status. CDC also issued revised pediatric definitions for HIV encephalopathy and HIV wasting syndrome. Free single copies are available from CDC, National AIDS Clearinghouse, P.O. Box 6003, Rockville, MD 20850; telephone (1-800) 458-5231. (*Morbidity and Mortality Weekly Report*, Sept. 30)

■ **Tuberculosis** transmission prevention guidelines for health-care facilities were published by CDC. The new guidelines cover control measures, early identification and management of persons with TB, screening programs for health-care



workers, worker training and education programs, and infection control program evaluation. For free copies, call CDC's Voice Information System at (404) 639-1819, or write to CDC, Information Services Office, Mailstop E-06, Atlanta, GA 30333. (FR Oct. 28)

■ **Clinical practice guidelines** and other documents useful in health-care decision making are available electronically from the National Library of Medicine's (NLM) Health Services/Technology Assessment Text, or HSTAT. For more information, contact the National Information Center on Health Services Research and Health Care Technology, NLM, 8600 Rockville Pike, Bethesda, MD 20894; telephone (301) 496-0176; E-mail: nichsr@nlm.nih.gov. (*Public Health Reports*, September-October 1994)



Orange Juice Scheme Gone Sour

by Paula Kurtzweil

A scheme to produce and sell bogus orange juice concentrate via secret rooms, hidden pipes, and deceptive record keeping has left two Kentuckians with prison terms of more than six years each. These are the longest sentences ever imposed for adulteration of orange juice.

Four other people also were sentenced, and two still await sentencing.

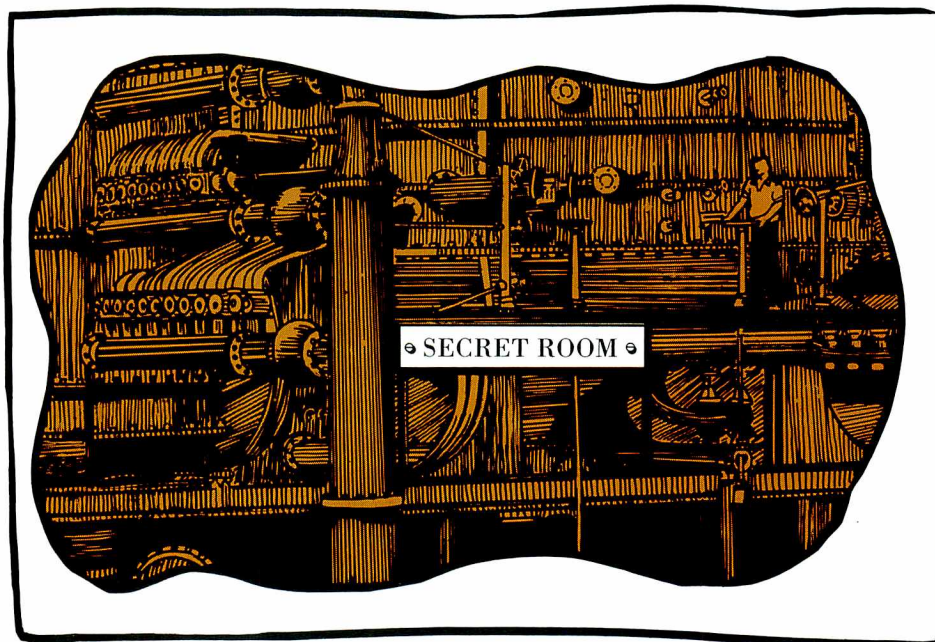
On Oct. 12, 1994, Judge John G. Heyburn of the U.S. District Court in Louisville, Ky., sentenced Patsy J. Mays, former owner, director, and secretary-treasurer of Sun Up Foods Inc. of Benton, Ky., to six years and eight months in prison and imposed a \$100,000 fine.

Her brother-in-law, Samuel W. Mays, former Sun Up vice president and operations manager, received the same prison sentence. He was not fined.

At press time, James V. Mays—Patsy Mays' husband and the acknowledged ringleader of the hoax—awaited sentencing scheduled for Dec. 6, 1994. He is a former owner, director and president of Sun Up.

The previous May 6, James Mays, Patsy Mays and Samuel Mays were convicted on one count of conspiracy and 20 counts of violating the Federal Food, Drug, and Cosmetic Act. James Mays and Patsy Mays also were found guilty of seven and five counts of mail fraud respectively.

The company had been substituting an inexpensive liquid beet sugar for some of the more expensive orange juice con-



centrate, labeling the product unsweetened orange juice concentrate, and selling it to manufacturers and dairies for making juice for retail sales. According to documents obtained by FDA, the scheme allowed Sun Up to increase its sales from almost nothing in 1984—its second year of operation—to more than \$57 million in 1989.

The extent of the conspiracy was discovered in an FDA investigation that included more than 250 interviews with at least 150 former employees, suppliers, builders, customers, and others who did business with Sun Up. Investigators also reviewed an estimated 1 million paper

and computer documents seized by U.S. marshals with help from FDA. The marshals also seized several objects, including an electric control panel that had disguised an entryway, as evidence of Sun Up's efforts to conceal the fraud.

Also sentenced Oct. 12 were:

- James Timothy Mays—son of James and Patsy Mays—Sun Up's vice president of sales and marketing. He pleaded guilty to one count of conspiracy and was sentenced to 20 months in prison.
- Elizabeth Mays Murphy—the Mays' daughter—who, with her husband, Stephen Murphy, owned Candy Base Co., a Sun Up sugar supplier. They pleaded

guilty to nine counts of Food, Drug, and Cosmetic Act violations and were placed on probation for two years.

- John Donald Langness, Sun Up's production and plant manager. He pleaded guilty to one count of conspiracy and was placed on probation for four years.

Frank Farmer, another Sun Up sugar supplier, pleaded guilty to one count of adulteration of orange juice with intent to mislead and defraud. He was fined \$50 and sentenced to three years' probation.

As part of the plea agreements, these five testified against James, Samuel and Patsy Mays during a three-week trial.

Sun Up filed for bankruptcy in September 1990, under Chapter 11 of the Federal Bankruptcy Act. It shut down in May 1992. The plant is now under new ownership.

FDA first learned of possible illegal activities at Sun Up in the late 1980s, when employees of Sun Up and other companies anonymously reported to FDA that Sun Up was substituting sugar for orange juice concentrate and marketing the product as an unsweetened orange juice product.

At that time, Sun Up operated a plant in Louisville, Ky. FDA inspections of the plant found no evidence to support the complaints.

In late 1989, Sun Up moved its operations to a new facility in Benton, Ky. In spring 1990, an East Coast customer of Sun Up recalled an entire shipment of the product it had bought after laboratory

analysis showed contamination with beet sugar. FDA later learned that because of the resulting publicity, Sun Up lost about 90 percent of its business in the first 60 days following the recall. As a result, the company had to lay off employees and reduce salaries by almost half.

In December 1990, Leonard Farr, a compliance officer in FDA's Cincinnati district office, attended a Florida Citrus Commission interview of a former Sun Up employee.

In an affidavit, the employee indicated that at both its facilities, the company had bought large amounts of sugar and had set up secret rooms to hold tanks of liquid beet sugar. The employee also provided copies of purchase records and names of people who would talk about Sun Up's activities.

FDA immediately got a search warrant for the Benton facility. During the search on Dec. 21, 1991, records were seized; however, FDA investigators could not locate the secret room described by the informant.

During the next four months, FDA investigators conducted interviews and, at one of them, learned the location of the secret room. After obtaining a second search warrant on May 8, 1991, and accompanied by U.S. marshals, FDA investigators again searched the facility. This time, they found the hidden room. At FDA's request, U.S. marshals seized a 4-by-2½-foot steel electric control panel, which disguised the only entry to the room. Investigators also

located stainless steel pipes hidden in the walls. The pipeline was linked to the main processing area.

During searches in May and July 1991, FDA investigators identified a similar setup in the abandoned plant. They had to rebuild the pipe system to see if some discarded pipes found on the plant's property fit into the secret setup. They did.

"I never saw anything as sophisticated as this," Farr said. "These pipes were really well-hidden."

Farr said the pipes were set up to look like part of the sewage system, and during a government inspection, the line carrying the sugar could be shut off and the outside pipe closed to conceal the sugar line inside.

Additional evidence showed that Sun Up:

- ran its illegal activities from at least 1985 to late 1990
- secretly received under cover of night up to 20 million pounds of beet sugar
- used Candy Base Co., of Louisville, Ky., and Murray, Ky., and Frank Farmer, in Jackson, Tenn., as fronts for buying sugar. Both billed Sun Up to make it look like they bought "orange concentrate" instead of sugar.
- cheated consumers out of \$10 million to \$20 million in fake orange juice.

FDA received no reports of deaths or illness from the "sugar-sweetened" juice concentrate.

Paula Kurtzweil is a member of FDA's public affairs staff.

Plasma Center Owner Sentenced

The owner of a Cincinnati plasma center has been sentenced for illegally shipping source plasma used in manufacturing *in vitro* reagents for testing blood groups.

Victor Torbeck, owner of Cincinnati-based Worldwide Biologicals, Inc., was sentenced Sept. 23, 1994, in the U.S. District Court for the Southern District of Ohio, Western Division, to six months' home confinement and three years' supervised probation. He was also fined \$5,500

and assessed a \$200 court fee.

Torbeck pleaded guilty April 29 to two counts of introducing into interstate commerce a misbranded medical device with the intent to defraud and mislead, one count of misbranding a medical device after receipt from interstate commerce and

while held for sale, and one count of making a false representation to FDA.

As part of his plea agreement, Torbeck surrendered the United States license for his plasma center and is barred for life from working in the blood or plasma business.

In vitro reagents are considered medical devices under the Food, Drug, and Cosmetic Act. Source plasma centers that ship their products in interstate commerce are required to be licensed by FDA.

A routine inspection of Torbeck's Cincinnati laboratory July 18, 1991, by FDA's Cincinnati district revealed violations of the agency's good manufacturing practice (GMP) regulations. Investigators found that the laboratory was not adequately testing blood products it received from all four of Torbeck's collection centers—two in Cincinnati, including the firm's corporate headquarters, one in Fayetteville, N.C., and one in Nashville, Tenn. As a result of the GMP violations, FDA suspended the license of the Cincinnati laboratory on Oct. 1.

"We asked that [Torbeck] select another lab, which FDA had to approve, to test the materials that he collected," said compliance officer Eric Batchelor.

Concurrently, FDA investigators in Raleigh, N.C., found that the Fayetteville Center also had GMP violations and its license was also suspended Oct. 1.

The following month, FDA allowed the Fayetteville Center to resume collecting plasma for purposes of a reinspection. In March 1992, the center was permitted to ship the products collected in Fayetteville to Torbeck's corporate headquarters solely for storage. However, he was not permitted to sell any plasma that had been collected at the Fayetteville Center.

On July 15, 1992, FDA learned from a confidential informant that Torbeck had illegally sold and shipped from the center in Cincinnati plasma that had been collected in Fayetteville.

On Sept. 20, 1992, FDA investigators, along with U.S. marshals, seized the records from Torbeck's Cincinnati corporate headquarters facility.

From records, investigators learned that Torbeck had received from his Fayetteville center 12 bottles of plasma containing the valuable antibody to the red blood cell Rh antigen E, which is the primary component of Anti-E blood grouping reagent.

They found that on May 11, 1992, Torbeck illegally shipped to Frankfurt, Germany, three bottles of plasma containing Anti-E and on May 22, he shipped one bottle of misbranded plasma containing Anti-E to Conroe, Texas. Torbeck had no license to make either of these shipments.

Agency investigators also learned that Torbeck falsely labeled bottles of plasma as containing Anti-E to hide the fact that he had illegally shipped the four bottles of plasma drawn from the Fayetteville center.

During an FDA inspection on June 26, Torbeck told agency investigators that 12 bottles of plasma contained Anti-E, as the labels stated, and were drawn from his Fayetteville center. The investigators knew these statements were false.

In November 1992, FDA asked the district court to issue subpoenas to major U.S. manufacturers of medical devices using blood products, requesting shipping and receiving information concerning blood products received from Worldwide Biologicals. During the next 16 months, agency investigator Marianne Allen evaluated the manufacturers' records to try to determine when and to whom Torbeck had shipped plasma.

Based on FDA's evidence, Torbeck pleaded guilty to all counts on April 29, 1994, rather than proceed with a grand jury indictment. As a result, Torbeck transferred ownership of his Cincinnati

corporate headquarters to his son. The three remaining collection centers, in Cincinnati, Nashville and Fayetteville, have all since closed.

—Kevin L. Ropp

Sorry, Wrong Label

As a result of reporting to FDA a tomato can labeled "rejected due to rust," a consumer in Lindhurst, N.Y., received an apology and gift certificate from the California manufacturer who mistakenly left the test label under a regular label after reconditioning the can.

The consumer discovered the test label while preparing cans for recycling last spring and was concerned that food was possibly being marketed in rusty cans. Fortunately, this was not the case, and the manufacturer promised FDA it would try to keep its employees "on their toes."

Consumer safety officer Rochelle Globus, of FDA's Long Island resident



post, in the New York district, investigated the complaint on June 21, 1994. Globus collected copies of the label and reported the incident to FDA's San Francisco district office, which has jurisdiction over the manufacturer, Tri-Valley Growers plant no. 7, in Modesto, Calif.

On July 20, Robert Howell, of the San Francisco district's Stockton resident post, visited the plant and showed George Bishop, the plant's distribution quality control manager, photocopies of both labels. Bishop identified the can as having been manufactured at his plant in 1991.

Howell learned that Tri-Valley destroyed badly rusted cans, but that it was not uncommon for the firm to recondition cans with only minor rust. As interpreted by Bishop, the coding on the test label indicated the can had undergone such reconditioning, completing the process May 4, 1992.

"Bishop insisted that before redistributing the products, can integrity and appearance is always checked," Howell says. "He said he would use my visit and the example to reinforce standing policy and insure test labels would be removed. He said that while these types of slip-ups are uncommon, they do happen, and that he would try to keep his people on their toes."

—Dixie Farley

Huge Cache of Frozen Foods Destroyed

Eleven vendors storing 58 tons of frozen vegetables and seafood in a Washington state warehouse voluntarily destroyed the food after a ruptured refrigerant line severely contaminated the goods with ammonia gas.

Seattle-based Olympic Cold Storage Service Inc., which has since gone out of business, had housed the foods in its 90-year-old facility. The disposed goods were worth "several hundred thousand



dollars," according to FDA documents.

On Feb. 24, 1994, a forklift operator ran the lift into an ammonia line on the third floor of the four-story facility. Ammonia gas seeped from the damaged line into the third-floor storage area and penetrated the packaging of frozen foods stored there, says Tom Piekarski, compliance officer in FDA's Seattle district.

"The company repaired the leak and tried to vent the gas with fans," Piekarski says. "But from what we could determine, the damage had already been done." Only food stored on the third floor was contaminated.

In mid-March, during a routine inspection of the facility, a U.S. Department of Agriculture official noticed a strong ammonia smell and notified FDA, which sent an investigator and an analyst to inspect the warehouse March 22.

On site, the FDA investigator was nearly overcome by the strong ammonia odor. He choked and his eyes burned, yet he was able to collect several food samples for testing. The analyst stayed outside the facility.

That same day, a Washington state inspector placed a 30-day embargo on

food stored on the facility's third floor. An FDA laboratory analysis of the samples confirmed that ammonia contamination had rendered the goods unfit for human consumption.

When the state's embargo expired, the 11 owners of the damaged food agreed voluntarily not to distribute the goods. Meanwhile, FDA began the process of filing for seizure of the food.

But by mid-May, Olympic Cold Storage had decided to go out of business. With no storage space and with the possibility of seizure, the food owners agreed to destroy all the contaminated goods.

From May 25 to 31, the food was taken to a local transfer station for final transport to a waste management facility in Arlington, Ore., where it was buried in a landfill.

By not having to seize, store and dispose of the goods, the federal government saved "thousands of dollars," Piekarski says.

—John Henkel

Summaries of Court Actions will not appear in this issue of FDA Consumer, but will return in future issues.

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