Stroke: Fighting Back Against America’s No. 3 Killer
Each year, about 400,000 Americans suffer strokes. About 160,000 die; about half the survivors are seriously disabled. But there are steps you can take to reduce your risk of stroke.

The Growing Use of Irradiation to Preserve Food
Fruits and vegetables join the list of foods that may be irradiated to preserve freshness and kill insects. Labeling information, including a special symbol, will alert shoppers to products that have been processed with this newest form of food preservation.

Through the Bureaucratic Jungle: A Guide for the Confused Consumer
A consumer who’s looking for help with a problem about some product and finds the right government agency on the first try is lucky, indeed. Knowing who does what before you pick up the phone or write a letter can help improve the odds.

Keeping Our Food Safe from Animal Drugs
About four out of five animals raised for food in this country are given drugs, and it’s FDA’s job to help make sure no harmful residues of those drugs end up in our meat, eggs or milk. Dr. Gerald Guest, director of FDA’s Center for Veterinary Medicine, discusses how well the agency is meeting that responsibility.

Electrolytes: The Charge in the Body’s Power System
Immersed in the fluids within our bodies are the electrolytes—electrically charged chemicals that help contract muscles, send nerve impulses, and perform other important body functions. Proper diet and fluid intake are the keys to keeping this “electrical system” humming.

Shopping for the Second 50 Years
Consumers are more and more concerned about choosing foods that will help them live “a second 50 years of healthy, active life,” according to a recent survey. The survey also found shoppers relying mainly on themselves to decide what’s safe to eat.

When you perspire, your body loses more than just water. Sweat contains important minerals known as electrolytes, which help control muscle movements and many other body functions. Excessive perspiration is just one way the body’s electrolyte balance can be thrown out of kilter. For more about electrolytes, turn to page 24.
Updates

‘Safe’ Sunlamps Not So, FDA Study Finds

Tanning salons that claim the lamps they use are “safer than the sun” are deceiving their customers, an FDA study suggests. New laboratory findings provide the first strong indication that radiation from tanning booths and beds marketed in recent years may pose a long-term threat of skin damage such as premature wrinkling and cancer, according to C. David Lytle, acting director of the Division of Life Sciences in FDA’s Center for Devices and Radiological Health.

Speaking before a recent FDA science writers seminar, Lytle said many indoor tanning booths and beds use ultraviolet A, or UVA, a form of radiation just beyond visible light on the radiation spectrum. Its wavelengths are shorter than visible light but longer than UVB, the radiation emitted by older sunlamps. UVB radiation is far more likely to cause burns and is believed to be the most carcinogenic (cancer-causing) component of sunlight. But the new study raises concerns about UVA, as well.

In the study, researchers found that cells taken from mice and exposed to levels of UVA radiation comparable to those from tanning devices showed an increased rate of mutation, indicating the presence of potential carcinogens.

Lytle and his associates said the longer wavelengths in UVA radiation are known to penetrate the skin more deeply than UVB radiation, producing a deeper tan but perhaps long-term damage such as cancer, as well. He also warned that UVA tanning devices can cause serious burns in people who have sensitive skin, are photosensitive because of drugs or food, have cold sores, or have had certain kinds of eye surgery.

(For more on the do's and don’ts of indoor tanning, see “Tanning Beds Are Not Without Drawbacks” in the December 1983-January 1984 FDA Consumer.)

Estrogen Effective Against Osteoporosis

Estrogen can help treat osteoporosis in postmenopausal women, and adding another female hormone, progestin, to estrogen treatment can reduce the risk of a precancerous condition of the lining of the uterus, according to FDA.

In an April 11 Federal Register notice, the agency said short-acting oral estrogens can be labeled and promoted for use in post-menopausal women, and adding evidence of loss or deficiency of bone mass, to retard further bone loss. The labeling should recommend that estrogen be prescribed in the lowest effective dosage range and that it be used with other important measures such as exercise and calcium-rich foods or calcium supplements, the agency said.

FDA concluded that estrogen could prevent bone loss after a review of current studies and recommendations from advisory committees.

Osteoporosis, or loss of bone mass, is a common cause of collapsed vertebrae (“dowager’s hump”) and the leading underlying cause of fractures in older persons. The bones that break most commonly in osteoporosis are those of the spine, arms, and upper legs. While taking estrogens after menopause seems to slow down bone loss, there is not enough evidence to show that it prevents bones from breaking.

Some studies have shown a small increase in the risk of breast cancer with higher doses of estrogens used for a long time, but an FDA advisory committee concluded last year that these studies did not clearly apply to lower doses and that the balance of evidence indicates no link between breast cancer and estrogen replacement treatment.

In a related action, FDA recently said estrogen labeling should note that studies have shown that adding progestin for seven or more days to a cycle of estrogen lowers incidence of endometrial hyperplasia (a precancerous condition of the lining of the uterus). The labeling already says that “while a postmenopausal woman not taking estrogens has one chance in 1,000 each year of getting endometrial cancer, a woman taking estrogens has 5 to 10 chances in 1,000 each year. For this reason it is important to take estrogens only when they are really needed.”

Estrogens are female hormones produced by the ovaries and are important in developing and maintaining the
female reproductive system. Indirectly, they contribute to the shaping of the skeleton and changes in bone formation. Estrogen production declines greatly after menopause. Progestins are another type of female hormone. Estrogens and progestins are also used in birth control pills. The labeling changes do not apply to these drugs.

For more about osteoporosis, see “Osteoporosis, Calcium and Estrogens” in the November 1984 FDA Consumer.

Aspartame Survives Court Challenge

Aspartame survived a legal challenge April 21 when the U.S. Supreme Court refused to hear claims from the Community Nutrition Institute and other consumer groups that the liquid form of the artificial sweetener may cause brain damage in heavy users of low-calorie soft drinks.

The court's action let stand a ruling by the U.S. Circuit Court of Appeals for the District of Columbia, which found last September that FDA followed proper procedures in approving the sweetener, marketed as NutraSweet by the NutraSweet Co., formerly G.D. Searle and Co. of Skokie, III.

The consumer groups said FDA should have held a public hearing on the safety of aspartame before it gave final approval in 1983 and contended that the sweetener could cause adverse health effects, such as behavioral changes, severe headaches, brain damage, and harm to fetuses.

NutraSweet lawyers, however, said the appeals court properly concluded there was insufficient evidence to justify a hearing on aspartame’s safety.

The case involved only liquid aspartame, which is used in almost all diet drinks. Aspartame for use in dry foods was approved by FDA in 1981. (For more information on aspartame and other artificial sweeteners, see “Sweetness Minus Calories = Controversy” in the February 1985 FDA Consumer.)

Drugs, Devices Win First Patent Extensions

Six drugs and two medical devices are the first products to be granted patent extensions under provisions of the Drug Price Competition and Patent Term Restoration Act of 1984. The products and the length of their extensions are:

- Sectral, an anti-arrhythmic/anti-hypertension drug—two years
- Seldane, an antihistamine—two years
- Tornolate, an anti-bronchitis drug—two years
- Promit, a sterile aqueous solution—1.3 years
- Tonocard, an anti-arrhythmic drug—9 years
- New Jersey Knee, an artificial knee implant—.25 years
- Beta 3000, a magnetic resonance imaging device—1.1 years

The patent provisions of the 1984 act restore time lost from the ordinary patent term of 17 years while products are going through FDA's approval process. The new law allows patent protection to be extended up to five years, provided the total of the patent time remaining after FDA approval plus the extension is no more than 14 years.

Options for OTC Drug Labels

Manufacturers of over-the-counter (OTC) drugs will have more flexibility in wording the labels of their products under a new rule issued by FDA.

Previously, FDA's “exclusivity” policy permitted only language approved by the agency to be used on an OTC drug label to describe what the drug is for. Now manufacturers can use their own words as long as they are truthful and mean the same as the official language.

Under the new rule, manufacturers can use:

- the “official” wording for indications that appears in a final OTC drug monograph (this information must appear in a boxed area with the heading “FDA APPROVED USES”),
- other truthful statements, or
- the approved language as above and other truthful terms for the same indications.

The flexibility in the new rule, published in the May 1 Federal Register, applies only to labeling dealing with indicated uses. All other parts of the labeling—warnings and directions, for example—must continue to be stated in the exact language that has been established in a final OTC drug monograph or by a regulation.

(For more information about what's on an OTC drug product label, see “OTC Drug Labels: ‘Must’ Reading,” in the October 1985 FDA Consumer.)

OTC Drugs for Diarrhea

Three ingredients—activated attapulgite, calcium poly-carbophil, and polycarbophil—are safe and effective for use in over-the-counter (OTC) drugs to treat diarrhea,
FDA said in a recently proposed rule. Labels on products containing these ingredients may indicate that they can be used to reduce the number of bowel movements and improve consistency of loose, watery bowel movements. Products containing attapulgite also may claim to relieve cramps accompanying diarrhea.

Antidiarrheal products must be labeled with the warning: "Do not use for more than 2 days, or in the presence of fever, or in children under 3 years of age unless directed by a doctor," according to the proposed rule.

The proposal is part of FDA’s ongoing review of OTC drug products. It represents the agency’s tentative adoption of the conclusions and recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic and Antiemetic Drug Products. The panel of nongovernment experts was one of 17 assisting in the review.

Twenty-five ingredients were evaluated by the panel. FDA agreed with the panel’s recommendation that four were not safe and effective for treating diarrhea: glycine, potassium carbonate, rhubarb fluidextract, and scopola-min hydrobromide. More studies are needed to establish effectiveness of 18 ingredients, including bismuth subsalicylate, activated charcoal, kaolin and pectin.

The proposed rule was published in the April 30 Federal Register. A final standard will be published after FDA reviews comments on this proposal.

**Warning on Painkiller**

U.S. physicians have been asked to prescribe a new painkiller drug, Suprol, with caution and to consider prescribing other drugs instead after FDA received 16 reports of unexpected and puzzling adverse reactions in patients taking the drug.

The adverse reactions—flank and back pain accompanied by evidence of decreased kidney function—developed shortly after the patients had their initial dose. All patients fully recovered, generally within five to 10 days after they stopped taking the drug, but the decreased kidney function is a serious concern.

In a letter to physicians, the manufacturer, McNeil Pharmaceutical Laboratories, asked that the drug be prescribed with caution while the cause, frequency and severity of the reactions are being assessed. The letter also asked that similar reactions be reported immediately.

The current FDA Drug Bulletin, which is mailed to every physician in the United States, also contains a description of the reactions and requests that physicians report such reactions in patients taking Suprol or related drugs. Suprol is one of about a dozen drugs known as non-steroidal anti-inflammatory drugs (NSAIDs), some of which are used for pain and some for arthritis.

Reports of adverse reactions may help determine whether Suprol is the only drug of its class capable of causing the flank pain-kidney failure reaction or just the first in which it has been recognized. Although there has been fairly extensive use of Suprol in several European countries for up to 2½ years, only three similar cases have been reported there.

About 300,000 U.S. patients have received the drug since marketing began early this year. McNeil, located in Spring House, Pa., is voluntarily revising the physician labeling of the drug to include a warning about the reactions.

**Antidote for Heart Drug Overdoses**

The first antidote for digoxin, a heart drug used by some 4 million people but which kills about 175 a year through overdoses, has been approved by FDA. The antidote, Digibind, also is approved to treat overdoses of another widely used heart drug, digitoxin. Both drugs are derived from the poisonous plant digitalis, or foxglove.

The dosages at which digoxin and digitoxin are effective in strengthening the heart’s rate and rhythm are very close to the doses that can cause serious problems.

Although patients taking these drugs are cautioned to watch for early signs of toxicity, about 175 deaths occur each year from accidental overdose and suicide. Use of Digibind may prevent many of these deaths, which account for half of all accidental poisoning deaths among people over 60.

In addition, thousands may require treat-
ment for digoxis intoxication with severe heart arrhythmias or heart block.

Besides overdose problems in adults, each year there are about 1,000 accidental ingestions of heart drugs among children under 6, according to the American Association of Poison Control Centers. These childhood poisonings are rarely fatal, but about half require hospitalization or other medical treatment. In the many cases involving digoxin, Digibind may be used.

Digibind, approved by FDA in May, will be manufactured by the Wellcome Foundation Ltd., Beckenham, England, and distributed by Burroughs Wellcome Co., Research Triangle Park, N.C.

Reprints Available

Reprints are available of “DES Update,” from the April issue of FDA Consumer.

Reprints can be obtained from the Food and Drug Administration, HFI-40, S600 Fishers Lane, Rockville, Md. 20857. Up to 100 copies will be provided. Negatives of reprints are also available for those organizations needing more than 100 copies.

PKU Correction

The article “Enzymes—The Movers and Shakers of Our Body Chemistry” in the April 1986 FDA Consumer incorrectly stated that people who suffer from phenylketonuria (PKU), a deficiency of the enzyme phenylalanine hydroxylase, must omit the amino acid phenylalanine from their diets. In fact, phenylalanine must be provided in carefully controlled quantities to just meet nutritional needs. Amounts in excess of those needs must be avoided.

Consumer Forum

Keeping Oysters

I enjoy your publication both as a consumer and a food professional. In reading the article “The ABC’s of Food Storage” in the March 1986 issue, I came across a statement on page 14 that is incorrect. “Don’t keep oysters more than a day in the refrigerator.”

I recommend to consumers that they be sure that the seafoods they buy are fresh. Oysters in the shell should be alive. Shells should be tightly closed or should close tightly when tapped. Shucked oysters should be plump and creamy colored with clear or slightly opalescent liquid. They should not contain more than 10 percent liquid, and should have a mild odor. Oysters in the shell should be kept moist (cover them with a damp cloth or paper towel) and stored in a container which is leakproof but does not inhibit air flow. Do not store live oysters (in the shell) in a covered, airtight container or submerged in water; oysters will use up the available oxygen and die. The oysters should stay alive for 7 to 10 days in the refrigerator. Shucked oysters, however, should be stored in a covered leakproof container, and the meats should be totally covered with their liquor. Shucked shellfish can be stored for 7 to 10 days in the refrigerator.

Shucked oysters may also be frozen and held for 3–4 months in the freezer at 0°F. If shucking the oysters yourself, save and strain the liquid. Wash the meats in cold water to remove sand and grit. Place the meats in small freezer containers and cover with the saved liquid. Leave at least a ½-inch space between the liquid and the lid to allow for expansion.

Seafood should always be stored in the coldest part of the refrigerator where the temperature is most stable. The best places are the meat and vegetable compartments. Seafood is highly perishable, and quality deteriorates rapidly if the product is mishandled.

Doris T. Hick
Seafood Technology Specialist
Sea Grant Marine Advisory Service
University of Delaware
Newark, Del.

Ms. Hicks is generally correct. However, the statement that “shucked shellfish can be stored for 7 to 10 days in the refrigerator” needs qualification.

A fresh shucked oyster will have a shelf life of a few days to several weeks, depending on many factors, including the initial quality of the oyster. This, in turn, depends upon the season harvested, water quality and temperature, and conditions of handling before shucking (removing the meat from the shell). Unfortunately, consumers cannot be certain how many days of shelf life remain when they purchase shucked oysters. Current industry practices for transportation, processing and distribution require days, and in some instances more than a week, for fresh shucked oysters to reach their market outlets. Therefore, consumers should not keep shucked oysters for more than a few days in the home refrigerator.
Try discussing the subject of stroke with someone who's middle-aged, and the reaction is usually immediate. "If I have to have a stroke, I'd rather die than end up as a cripple or vegetable," he or she is likely to say.

The fear is understandable, because many in this age group are acquainted with the aftermath of strokes in aged parents or other relatives. They have witnessed firsthand the effects of stroke—the inability to speak, the distorted face and useless arm, the loss of control of bodily functions.

The statistics are not reassuring. Each year, about 400,000 Americans suffer from stroke. About 160,000 die immediately or shortly after the stroke's onset. Of every 100 who survive the acute illness, about 10 will be able to return to work virtually without impairment, 40 will be slightly disabled, 40 will be more seriously disabled and require special services, and 10 will need institutional care. Only about 16 percent of the 1.8 million Americans today who have survived stroke are completely independent. What's really discouraging is that after a stroke does its damage, in most cases it's difficult or impossible to reverse its effects. Stroke is the third leading cause of death in this country, behind heart disease and cancer.

Most people have heard about stroke and know it has something to do with the brain, but are not exactly sure what it is. A stroke occurs when an area of brain tissue dies because its blood supply has been cut off or decreased. As brain cells die, the functions they control—speech, muscle movement, understanding—die with them, or are impaired.

Although the brain represents only about 2 percent of the body's weight, it commands a lion's share of the body's oxygen supply—about 25 percent—and about 70 percent of the glucose consumed by the body. It receives 15 percent of the blood pumped by the heart through the arteries. This disproportionate amount is necessary because the brain, unlike other organs, cannot store the energy that it makes from glucose and oxygen in the blood. Brain cells can live only for a few minutes if their blood supply stops, as when the heart stops beating in cardiac arrest. Once they die, they cannot be regenerated.

The old word for stroke—apoplexy—conjures up an image of someone who is felled suddenly by a blow, much as a tree is felled by lightning. Though a major stroke can occur quickly, just like a bolt of lightning, the factors leading to a stroke usually have been building up within the body for a long time.

About two-thirds of all strokes occur because of blockages that gradually form in the arteries that feed the brain. (Strokes from such blockages are called ischemic strokes or infarctions, just as the death of part of the heart muscle is called myocardial infarction.) The blockages are caused by a clot—called a thrombus or embolus, depending on where it's formed.

A thrombotic stroke occurs when an artery in the head or neck becomes either completely clogged or so narrowed that not
enough blood reaches a particular area of the brain. This clogging is usually caused by atherosclerosis, also known as hardening of the arteries. Though this disease is associated with aging, atherosclerosis can begin as early as childhood. Through the years, plaque (consisting of fat-containing material and calcium) builds up on the inner linings of blood vessels, much as mineral deposits build up within a water pipe. The plaque may get so thick it shuts off the blood supply. Or clots may form on the rough surface of the plaque, plugging up the arteries.

Atherosclerosis is also a factor in embolic stroke, which occurs when a clot or piece of a clot breaks away from a diseased artery in another part of the body (in the heart or lungs, most frequently) and is carried along by the bloodstream until it ends up in a smaller artery in the brain.

A hemorrhagic stroke occurs when a blood vessel ruptures in or around the brain. Hemorrhagic strokes are more dangerous than those caused by blockages because not only does the part of the brain served by the blood vessel die, but blood may spurt out so forcefully that surrounding brain tissue is damaged. They occur primarily when a spot in an artery wall that has been weakened by disease—most often atherosclerosis or high blood pressure—breaks suddenly or begins to leak blood. Hemorrhagic stroke can also be caused by a defect called an aneurysm, a section of an artery wall that is so thin that it balloons out under normal blood pressure and may burst under high blood pressure. Hemorrhagic strokes account for about 15 percent of all strokes and are fatal in about 50 percent of cases.

About 10 percent of the time, there is advance warning of an impending stroke in the form of one or more transient ischemic attacks. A TIA is a kind of mini-stroke which signals that the blood flow to the brain has been temporarily interrupted (ischemia)—in most cases from tiny clots (emboli) that have broken loose from plaque in heart or neck arteries. Depending on the part of the brain affected, a TIA can cause blindness in one eye (a “blackout” or “whiteout” of vision, blurring, or something often described as if a shade were being pulled down over the eye), difficulty in speaking or writing, or numbness or weakness of the face, arm, or leg on one side of the body. An attack usually lasts less than 30 minutes, with complete return to normal (thus the word transient).

A TIA is a strong predictor of stroke—about one-third of those who’ve had one can expect to have a stroke within five years. So it’s important to report episodes of this type to a doctor. A doctor can often determine whether atherosclerosis is causing the problem by listening with the stethoscope to the sounds in the carotid arteries, which are located on each side of the neck. If either is partially obstructed, a swishing sound called a bruit (pronounced brew ‘ee) is sometimes heard as the blood is pushed through the narrowed segment of the artery with each heartbeat. (Sometimes people can hear their own bruits.)

When someone has many TIsAs, a test called an arterial angiogram can be performed in the hospital to locate the narrowed blood vessel. A long, thin, flexible tube is inserted into an artery in the arm or leg and is threaded up into a neck artery. After dye is injected into the artery via the tube, X-ray pictures of the head and neck are taken in rapid succession, enabling a doctor to see the movement of blood through the arteries in the brain.

In cases where the blockage looks severe, the doctor may recommend an endarterectomy, in which a surgeon opens the artery and cleans out the blockage. (Texas surgeon Dr. Michael DeBakey performed the first successful carotid endarterectomy in 1953.) Since an endarterectomy carries risks (as does an angiogram), some doctors prefer to treat TIsAs with blood-thinning drugs rather than surgery. Among the drugs used, FDA has approved aspirin—which prevents blood platelets from clumping together—to treat men who have had TIsAs caused by emboli. Studies have not shown that aspirin is as effective in reducing TIsAs in women.

When stroke finally does occur, it may be difficult to diagnose which type it is, because different areas of the brain are affected, producing a variety of symptoms. However, there are some clues.

In thrombotic strokes, symptoms often progress by steps: It may take minutes or even hours for the full damage to be felt. Typically, a victim may experience clumsiness upon getting up in the morning, soon followed by a headache. At breakfast, the right half of the field of vision in both eyes may disappear (sometimes the victim is not aware of this loss). Then, suddenly, the victim may find it difficult or impossible to speak, and ultimately may develop weakness or complete paralysis on the right side of the body, all in a matter of seconds or minutes.

In such cases, a diagnosis of damage to the left side of the brain caused by thrombosis can be made almost with certainty, especially if the victim has a history of one or more TIsAs. (Each side of the brain controls the opposite side of the body, but speech and language are associated with areas in the left, or dominant, hemisphere.) High blood pressure is present in about 60 percent and diabetes in about 24 percent of patients. The peak age for thrombotic stroke is 70.

An embolus, in contrast, plugging one of the brain arteries at random, produces all its damage within a matter of seconds or minutes at the most. There is usually no warning or pain. Though this type of stroke can happen at any time, it comes more frequently during sleep than other strokes, which occur more often in the morning. The symptoms vary depending on the area of the brain involved, but are similar to those of thrombotic strokes.

A hemorrhagic stroke caused by a ruptured aneurysm of an artery to the brain often strikes while the victim is awake and active and produces a sudden, excruciating headache. The sufferer may then complain of a stiff neck, become nauseated, vomit, and finally lapse into unconsciousness. It is thought these aneurysms may be present at birth or may develop after birth at weak points in the arteries. Blood found in the spinal fluid or seen on a CT scan (computed tomography—a form of X-ray exam) would confirm the diagnosis. This type of hemorrhage most commonly occurs between 35 and 65 years of age.

Hemorrhages within the brain (intracerebral) tend to come on abruptly, preceded in half of the victims by a headache. In most cases, the blood pressure is extremely high. Nausea and vomiting are also common. The damage done by this type of stroke progresses gradually over minutes or hours; it doesn’t occur in steps as in thrombotic strokes. Since hemorrhagic strokes generally occur during the day when a person is active, victims may be alert when the stroke begins and quite aware that something terrible is happening to them. As a rule, they deteriorate quickly and often are in a coma upon arrival at the hospital. This type of stroke is fatal in about four of five cases. Those who survive are left with major disabilities.

Correct diagnosis of the type of stroke suffered is important because treatment varies. When strokes are caused by blockages, (Continued on page 11)
When an artery that supplies blood to the brain becomes blocked, a stroke can result. One way such blockage can occur is through atherosclerosis, a condition where fatty material called plaque accumulates on artery walls. Below, a normal artery is shown at left, an artery clogged with plaque at right. The higher the blood pressure and the more cholesterol in the blood, the faster the accumulation. An extreme example of plaque accumulation is shown above.
What’s Your Risk of Stroke?

A number of factors influence stroke risk:
- **Age** — Although stroke may occur at any age, even in newborns, the danger of stroke grows with age. Eighty percent of strokes occur in persons 65 and older.
- **High blood pressure** — Perhaps the greatest stroke risk factor. Strokes occur two to four times more frequently in people with high blood pressure — 160/95 or greater — as in those with normal blood pressure. As blood pressure, especially systolic pressure (the first number), goes up, the chance of stroke goes up, too.
- **History of stroke** — Those who have had one stroke and survived are at greater risk for another stroke. In the Framingham study — a study of 5,000 residents of a Massachusetts town that has been going on since 1949 — it was found that of 198 men and 196 women who had initial strokes, 84 had second strokes and 27 had third strokes. Stroke survivors generally do not have as long a lifespan as the general population.
- **Heart disease** — Clots, which can lead to stroke, don’t form in normal hearts, but they may form occasionally in those with valve defects and after heart attacks and certain bacterial infections, such as rheumatic fever. Heart surgery also often causes emboli to form, as does the artificial heart.
- **Gender** — It helps to be a woman rather than a man, because stroke is more frequent in males until the age of 75. (After 75 the incidence is about the same for men and women.) Men have a 44 percent greater chance of having a first stroke, with a five-year recurrence rate almost double that of women. However, women who use oral contraceptives run a slightly higher chance of stroke than women who do not. Oral contraceptive users above 35 who also smoke and have high blood pressure have a 14 times higher risk of having a stroke than women with none of these risk factors.
- **Diabetes** — People who have too much sugar in the blood run almost double the risk of stroke. One possible explanation currently being explored by researchers is that the excessive blood sugar that results from diabetes not only damages blood vessels, but also appears to interfere with the normal breakdown of fibrin, a plasma protein that holds blood clots together.
- **Race** — Stroke mortality in blacks is almost double that of whites in the 35- to 74-year age group. The greater incidence of high blood pressure among blacks is definitely a factor in adult strokes, while sickle-cell anemia, which occurs almost exclusively in blacks, often causes atherothrombotic strokes, especially in children under 15.
- **“Thick” blood** — In some diseases, such as polycythemia, too many red blood cells are manufactured, causing the blood to become thick and sludge-like. The flow of this “thick” blood to the brain is slowed and the tendency to form clots is increased, both of which may lead to brain infarcts. In people who have this problem, the age-old technique of bleeding (phlebotomy) is used to reduce the number of red blood cells.
- **Heredity** — Some people carry stroke risk in their genes. Stroke victims, more often than others, have a parent or parents who also had strokes. Several studies have shown that high blood pressure and diseases of the blood vessels in the brain are more frequent among identical twins than fraternal twins of the same sex, pointing further to a genetic risk factor, since identical twins have exactly the same genes, while fraternal twins don’t.
- **Smoking** — In the Framingham study, cigarette smoking has been shown to be an apparent risk factor for stroke, but only in men under 65. Other studies have confirmed the relationship between cigarette smoking and stroke in younger age groups. In one study, male college students who smoked 10 or more cigarettes a day were at twice the risk for eventual fatal stroke than those who smoked less than 10 a day or didn’t smoke at all. The evidence that smoking, by itself, is a risk factor for stroke in women is not strong. But smoking is related to other risk factors (alcohol consumption, use of oral contraceptives) and to diseases of other organs, particularly the heart. The good news is that the risk of stroke decreases if the person stops smoking.
- **Alcohol** — People who drink heavily, are obese, and lead sedentary lifestyles are also said to run a greater risk of stroke, but the evidence is strong only for alcohol. Though obesity and high blood pressure often go hand in hand, those who are obese but don’t have high blood pressure or diabetes do not run a significantly greater risk of stroke.
- **Drug abuse** — Stroke can be caused by amphetamines, cocaine, and “Ts and Blues” (pentazocine and tripelennamine). Heroin and LSD are also implicated in stroke.
You Have to Remember to Treat Them with Dignity...

A young nurse tells about her experiences in taking care of stroke victims:

"I remember my first stroke patient very well, an old black lady. She told me what it felt like to have a stroke, how suddenly half of her body began to feel numb, beginning with a tingling feeling on the left side of her face and traveling down the side of her body.

"What frightens me about stroke is how unpredictable it is. To think something can happen so fast and ruin a person's life. What must go through a person's mind when they're having a stroke? They must be scared stiff when they realize they've lost control of their bodies and can't move, can't feel.

"I was kind of uncomfortable about working with stroke patients at first, but after a while I felt better about the whole thing. It was very rewarding, but real hard work, both mentally and physically. In the hospital we see them at their worst, in the acute stage. They need lots of nursing care. They can't do anything for themselves. All the things we take for granted — moving an arm, feeding ourselves — we had to do for them. How horrible it must be for them to sit in a hospital room, waiting for a nurse to come in and help them do the most menial things.

"Stroke patients are dead weight and hard for a small woman like me to handle. You have to watch that their arms and legs don't get caught when they're transferring them from the bed to a wheelchair. You forget that that arm or leg doesn't move and you have to move it for them.

"Some make a good comeback, some don't. I've seen many come in completely helpless, but with occupational and physical therapy they begin to regain their functions. They get physical therapy right away so the muscles don't atrophy.

"Attitude plays a part, too. You've got to be positive and try to make them positive. You must praise everything they do to encourage them. It's a big deal when some of them take a spoonful of food by themselves, but it all takes a long time. They have to learn to be patient. But... if the stroke has destroyed a certain part of the brain and their mind goes, we can't help them no matter what we do.

"The real sick ones are fed through their nose — it's called nasogastric feeding. Many of them are incontinent. They feel humiliated. It's like they're babies and they need to be taken care of like babies. But you have to remember to treat them with dignity, because you can hurt their feelings and make them feel worse. The families are hard to deal with, too. They're full of anger. They're angry about the stroke and what it's done to the one they love.

"Aphasic stroke [loss of speech] is devastating. The patients can think straight but can't express themselves. People treat them as if they're stupid, but their minds are functioning. They become very depressed. In fact, stroke patients are mostly depressed. You'd be depressed, too, if you suddenly found that half of your body had gone dead."

Evelyn Zamula is a member of FDA's public affairs staff.
The Growing Use of Irradiation to Preserve Food

by Chris W. Lecos

After more than two years of deliberation and the review of thousands of written comments from proponents and opponents, the Food and Drug Administration has given the green light for the expanded uses of irradiation in the U.S. food supply. Food irradiation, at the levels approved, will provide industry with another way to extend the shelf life of food and to protect it against insects without creating any health hazards to consumers, the agency stressed.

A regulation published by FDA in the Federal Register April 18, 1986, allows for the first time the use of radiation on fruits and vegetables and increases the level of radiation allowed for dried herbs, spices, and vegetable seasonings. The regulation is the result of a proposal published in 1984 that elicited more than 5,000 public comments, and follows a July 22, 1985, approval by the agency for the use of radiation on pork.

Besides setting maximum radiation levels, the regulation also spells out labeling requirements for irradiated food for the next two years. Labels of packaged foods sold at the retail level will have to clearly state that the products have been treated with radiation. They also must have a logo, or symbol, to inform shoppers that the products have been irradiated. Also, supermarkets and grocery stores will have to identify fresh fruits and vegetables that have been treated with radiation. FDA said this can be done in various ways, such as counter signs, cards and other displays near the produce bins. Irradiated foods sold on the wholesale market that might be reprocessed must have labeling that advises not to irradiate the product again.

FDA's regulation makes it clear that it expects the food industry to use only as much radiation as is needed to accomplish the "intended technical effect" on a particular food product. A manufacturer is expected to use a dosage lower than the allowable maximum if that is all that is needed to kill insects or microbial contaminants, or retard the ripening of fruit.

Although the idea of food irradiation is new to most consumers, the latest regulation is the result of more than 40 years of research into the process, much of it by the federal government. America's astronauts have been eating irradiated foods almost from the beginning of the space program. (And FDA long ago authorized the use of radiation to sterilize hospital equipment; the use of X-rays and gamma rays to inspect food; and the use of ultraviolet radiation to control the growth of surface microorganisms and to sterilize water used in food production.)

The first approved use of radiation on food occurred when FDA permitted it to kill insects in wheat and wheat products in 1963 and to slow the development of sprouts in potatoes in 1964. However, the process was never adopted by industry for these foods because cheaper methods of preservation were available.

Earlier this year, the U.S. Department of Agriculture approved irradiation of fresh pork—at limits set last year by FDA—to control the parasite that can cause trichinosis. (The permitted levels of radiation—between 300 gray and 1 kilogray—will eliminate the risk of trichinosis, but will not necessarily kill bacteria that can cause food poisoning. Careful handling—with clean hands and utensils—and thorough cooking of pork are still necessary. For a discussion of radiation terms, see the boxed insert.)

First used in the Netherlands, the international logo that will now appear on irradiated foods in the United States consists of a solid circle, representing an energy source, above two petals, which represent the food. The five breaks in the outer circle depict rays from the energy source. The logo used overseas is green; FDA did not specify any particular color for the U.S. version.

Expanding the uses of irradiation to include fruits and vegetables and increasing the radiation levels for dried herbs, spices and dehydrated foods was proposed by FDA on Feb. 14, 1984 (see "Irradiation Proposed to Treat Food," May 1984 issue of FDA Consumer). The regulation published April 18 is the result of that proposal. Specifically, the regulation:

- Permits manufacturers to use up to 1 kilogray of radiation on fresh fruits and vegetables to inhibit ripening and kill insects, spiders, mites and other pests that commonly infest these foods. One kilogray is considered a low level for irradiating foods.
- Increases the previously permitted irradiation level for spices, herbs and other dried or dehydrated aromatic foods from plants from 10 kilogray to 30 kilogray. This is regarded as a high dosage level.
- Requires that labels of irradiated foods sold at the retail level state that they were "treated with radiation" or "treated by irradiation." This is the wording that will be in effect for two years. Similar language would have to be used on packaged wholesale foods, along with the warning that the product should not be irradiated again. A special logo also must be on the label of irradiated foods sold at retail but is optional for wholesale foods.
- Establishes record-keeping and other general requirements for manufacturers.

Also, facilities that are used for food irradiation must comply with plant and worker safety requirements of the Nuclear
Regulatory Commission and the Occupational Safety and Health Administration.

FDA started paving the way for its recent regulation in 1981, when it announced that it was considering how to ensure the safety of irradiated foods. Under provisions of the federal Food, Drug, and Cosmetic Act, a food additive—including a source of radiation used to process food—must be shown to be safe “under the proposed conditions of use” before FDA can approve it.

Any safety assessments of irradiated foods, a committee of FDA scientists said, should be based on projected levels of human consumption of those foods; estimates of the “identity, amount, and potential toxicity of new chemical constituents generated in the food” by the irradiation process; and use of the most up-to-date methods of toxicity testing. The committee estimated that “as much as 40 percent of the total diet” theoretically could consist of irradiated foods. However, it estimated that actual consumption probably would not exceed 10 percent of the diet.

The committee reported that food irradiated at doses up to 1 kilogram “is wholesome and safe for human consumption, even where the food that is irradiated may constitute a substantial portion of the diet.” The committee added that foods “comprising no more than .01 percent of the daily diet [such as spices] and irradiated at 50 kilogram or less also can be considered safe for human consumption without toxicological testing.” In effect, the FDA committee stated, there was such an “adequate margin of safety” that toxicological testing wasn’t necessary to establish the safety of irradiated foods. In its April regulation, FDA concurs that the irradiation levels it is allowing are safe.

When food is irradiated, most of the radiation passes through the food without being absorbed. The small amount that is absorbed is what kills any insects, extends shelf life, and prevents fruits or vegetables from ripening too fast.

Unlike chemical pesticides, irradiation leaves no residue in food. Exposing food to gamma rays, electron beams, or X-rays—the common irradiation methods—does not make the food radioactive, nor does it pose any radioactivity danger to consumers. Consumers are not exposed to radiation.

Like other methods of processing, the agency said in the April Federal Register notice, irradiation does cause small chemical changes in the food. These changes produce new substances called radiolytic products. The agency noted that experiments have shown that “very few of these radiolytic products are unique to irradiated foods; approximately 90 percent of the radiolytic products . . . are known to be natural components of food.” The remaining 10 percent are chemically similar to natural food components.

Responding to contentions that radiolytic products are toxic, FDA said that it disagreed that toxic substances would be produced in food in unsafe amounts under the radiation levels approved. “The agency has no evidence to cause it to change its position that the chemical differences between foods irradiated at the doses allowed by this regulation and non-irradiated foods are too small to cause concern about the safety of the irradiated foods.”

Irradiation also can affect the flavor, texture and, to some extent, even the nutrient content of food. But these changes also occur when food is cooked, canned or frozen. The scientific literature, FDA said, indicates that there are no nutritional differences between food that is not irradiated and food irradiated at levels below 1 kilogram. Although higher levels of radiation are

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### Measuring Irradiation

To the layman, the scientific terms used to describe the amount of absorbed radiation can be confusing. In the past, the term “rad” was in common use. It stands for “radiation absorbed dose.” Currently, the term “gray” (abbreviated Gy) is used, instead. FDA’s regulation describes radiation levels in terms of “kilogram” (kGy).

One gray is equal to 100 rads. The prefix “kilo” stands for 1,000. Thus, 1 kilogram equals 1,000 gray, which equals 100,000 rads. One kilogram is the maximum level FDA has set for treating fresh fruits and vegetables.

The terms kilorad (krad) and megarad (Mrad) also are used. One kilorad equals 1,000 rads. The prefix “mega” means 1 million. Thus, 1 megarad equals 1 million rads or 10 kilogram.

### FOODS APPROVED BY FDA FOR IRRADIATION TREATMENT

<table>
<thead>
<tr>
<th>Food</th>
<th>Purpose</th>
<th>Dose Limit</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruits and vegetables</td>
<td>To slow growth and ripening and to control insects</td>
<td>Up to 1 kilogram (kGy)</td>
<td>April 18, 1986</td>
</tr>
<tr>
<td>Dry or dehydrated herbs, spices, seeds, teas, vegetable seasonings</td>
<td>To kill insects and control microorganisms</td>
<td>Up to 30 kGy</td>
<td>April 18, 1986</td>
</tr>
<tr>
<td>Pork</td>
<td>To control Trichinella spiralis (the parasite that causes trichinosis)</td>
<td>Minimum 0.3 kGy to maximum of 1 kGy</td>
<td>July 22, 1985</td>
</tr>
<tr>
<td>White potatoes</td>
<td>To inhibit sprout development</td>
<td>50 to 150 gray</td>
<td>Aug. 8, 1964</td>
</tr>
<tr>
<td>Wheat, wheat flour</td>
<td>To control insects</td>
<td>200 to 500 gray</td>
<td>Aug. 21, 1963</td>
</tr>
</tbody>
</table>
IRRADIATION FACILITY

Main Chamber
Concrete Walls 6½' Thick

Irradiation Source
(Usually Cobalt-60)

Packaged Food Loaded on Conveyor

Unprocessed Products

14 / July-August 1986 / FDA Consumer
This diagram portrays one type of food irradiation facility (not drawn to scale). Packaged food travels on a conveyor between six-and-a-half-foot-thick concrete walls to a chamber where it is exposed to gamma rays from a radiation source. The chamber is about 4,000 square feet. The radiation source consists of a number of "pencils" of a radioactive isotope, in this case cobalt-60. Each pencil is about 18 inches long and three-eighths of an inch in diameter. A computer controls conveyor speed and radiation dose.

Source: Radiation Technology, Inc., Rockaway, N.J.

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allowed for spices and herbs, these minor ingredients are not sources of nutrients. FDA concluded that the “destruction of nutrients [from irradiation] is not an issue in this rulemaking.”

Half of the comments that FDA received focused on the retail labeling issue, and more than 80 percent of them urged that retail labeling be mandatory to prevent consumer deception. Further support also was given to labeling of wholesale packages of food.

FDA's labeling requirements are almost the same as those for foods it had approved in the past for irradiation. The logo to identify irradiated foods, however, is a new feature. FDA hopes that consumers will become so familiar with it that eventually it can be used by itself, without any text about irradiation on the label. Under the regulation adopted in April, the present labeling language will be dropped in two years unless FDA issues a new proposal to extend the present language requirement. If not extended, only the logo will be required.

In addition to requiring a label statement that a food has been "treated with radiation" or "treated by irradiation," FDA is encouraging manufacturers to state, on the labels of wholesale and retail products, the purpose and the type of the irradiation. For example, the label might say "treated with radiation to control spoilage," "treated with radiation to extend shelf life," or "treated with radiation to inhibit maturation." A label also could state that a product was treated with X-rays, gamma radiation or electron beams.

As FDA put it: "The agency recognizes that, because this is a new technology, manufacturers may want to use additional labeling statements as part of a consumer education effort. For example, in addition to the required language, the firm may wish to state that 'this treatment does not induce radioactivity.' The agency will permit such educational statements if they are truthful and not misleading to consumers."

Some food processors opposed the use of such words as irradiation and radiation because of potential consumer sensitivity to any mention of radiation. Some favored substitute language—such as "picowave treatment" and "ionizing energy." FDA rejected these because consumers might misunderstand and be confused by such language. FDA said it gave careful consideration to the term "picowave treatment," but rejected the suggestion because it was "not in common use in the industry nor in the scientific community and would be neither more informative to the consumers than the label statement [approved in the new regulation] nor more understood by those in the food-processing industry."

"The agency does recognize that some population groups may harbor a prejudice against anything treated with radiation," the notice added, "but is of the opinion that with the labeling flexibilities provided in this regulation, manufacturers will be able to overcome these prejudices as consumers become more educated about the process and the advantages this technology has over alternatives existing in the industry."

In responding to some of irradiation's critics, FDA agreed that other methods were available for insect control (such as pesticides) and for inhibiting the ripening of fresh fruits and vegetables. "However," the agency said, "the existence of such methods is not a reason to prohibit equally safe alternatives, nor does the [Food, Drug, and Cosmetic Act] authorize FDA to arbitrarily limit the safe alternatives that are to be allowed. The agency believes that the marketplace should determine which alternative method is used when safety is not an issue."

Chris W. Lecos is a member of FDA's public affairs staff.
Pizza. Italian in origin but most definitely an all-American food. And, like all food sold in interstate commerce, pizza is regulated by the federal government. It’s not that federal inspectors stand around and make sure that the dough flippers in your local pizza parlor toss the rolled-out crust to the right height. Rather, the federal people are checking to see that the pizza manufacturing plants are making products that are fit to eat and that live up to the ingredients listed on their labels. In other words, the feds are there to assure consumers that their pizzas are safe and wholesome.

But which federal agency does that job? If pizza lovers get a bad pizza, who do they complain to besides the seller? Well, in many cases, the complaint should go to the Food and Drug Administration. But not always. If it’s a pepperoni pizza (or any pizza that contains meat), then the U.S. Department of Agriculture is the party to talk to. Of course, FDA or USDA are to be consulted only if the pizza was sold in interstate commerce. A locally made pizza is the concern of local food and health authorities.

There are many cases where the public gets confused about who is responsible for what when it comes to consumer products. And there are a number of times when, for perfectly logical reasons, agencies have overlapping responsibilities. Here’s a rundown of who watches over what.

• **Drugs:** The majority of drug regulation belongs to FDA. New drugs—both prescription and over-the-counter—must be approved by FDA before being marketed. FDA is responsible for ensuring the safety and effectiveness of drugs and overseeing their manufacture. These responsibilities are carried out under the Federal Food, Drug, and Cosmetic Act.

  Because some medically accepted, FDA-approved drugs have a potential for abuse (for example, amphetamines, barbiturates, and morphine), limits have been set on the amount that can be manufactured each year. The Drug Enforcement Administration sets these limits and registers everyone who handles these drugs, from manufacturers and distributors to pharmacists.

  Illegal drugs with no approved medical uses, such as heroin and LSD, are the sole responsibility of DEA. Responsibility for methadone treatment programs for heroin addicts is shared by FDA, DEA, the National Institute on Drug Abuse, and the states.

• **Advertising:** While consumers take many drugs, even over-the-counter products, on their physician’s advice, advertising can play a big role when deciding which brand to buy. Responsibility for drug advertising is shared by FDA and the Federal Trade Commission. FDA has primary responsibility for prescription drug ads; FTC for nonprescription ads.

  Advertising for other FDA-regulated products, such as foods, is FTC’s responsibility, too. But if the information or claims are on the product’s label, rather than in an ad, FDA is responsible.

  Claims made in advertisements for mail-order products also come under U.S. Postal Service regulations.

• **Packaging:** Tamper-resistant packages for drugs have become an important part of FDA’s responsibilities. But another special form of packaging—child-resistant caps to help prevent poisonings—is regulated by the Consumer Product Safety Commission. CPSC has this function because it regulates other consumer goods—such as cleaning products—on which the safety caps also are required.

  Sometimes the deciding factor as to which agency regulates a product is how the product is used. An example of just how complicated this shared jurisdiction can be is rubber nipples. If the nipple is part of a baby bottle, it belongs to FDA because it comes in contact with food. If it is part of a pacifier, then it is CPSC’s responsibility.

• **Pesticides:** While it is all right for things such as bottle nipples to come in contact with food, a worm in an apple or a spider in a bunch of bananas can be pretty upsetting. Pesticides can help
prevent those unpleasant occurrences and other damage and destruction of crops. But overuse of these chemicals can cause potentially harmful residues on food. Air, water and soil can be contaminated, too, if pesticide users don't follow the regulations.

FDA, USDA, and the Environmental Protection Agency share the responsibility for regulating pesticides. EPA determines safety and effectiveness and establishes tolerance levels for residues on feed crops and raw and processed foods. These tolerance levels (the amount of pesticide allowed to remain on a crop after harvesting) are normally set 100 times below the level that might cause harm to people or the environment. To ensure that pesticide residues do not exceed the allowable levels, FDA tests all foods except meat and poultry. USDA's Food Safety and Inspection Service enforces EPA's regulations for those foods.

In fact, the Food Safety and Inspection Service has complete responsibility for meat and poultry. Well, not exactly complete. The animal byproduct gelatin and meat from wild game fall under FDA regulations.

- **Seafood:** FDA also makes sure that lobster, shrimp, flounder and other delicacies from the sea are safe to eat. FDA regulations cover quality, labeling and identification of fresh, frozen and canned seafood. Raw shellfish, which if not properly harvested and handled may transmit gastrointestinal diseases such as hepatitis A or carry natural or chemical toxins, must meet the requirements of state health agencies in addition to FDA requirements.

To help seafood processors prepare better quality products and meet FDA regulations, the Department of Commerce's National Marine Fisheries Service runs a voluntary inspection program. While Department of Commerce inspectors look for many of the same things that FDA investigators do, it is FDA that has the authority to enforce the regulations.

- **Veterinary Products:** Products for animals—such as feeds, pet foods, and veterinary drugs and devices—come under FDA's jurisdiction. However, USDA's Animal and Plant Health Inspection Service tests and licenses all animal vaccines and serums.

- **Water:** Depending on how it gets to consumers, water is regulated by either FDA or the Environmental Protection Agency. If the water comes through the tap, it must meet EPA's national standards for drinking water. However, bottled water is FDA's responsibility. FDA defines bottled water as "water that is sealed in bottles or other containers and intended for human consumption," not including mineral water or soda water. (Other FDA regulations cover those.) FDA's bottled water standards are compatible with EPA's standards for drinking water.

- **Alcohol:** Although FDA regulates bottled water and other thirst quenchers, alcoholic drinks belong to the Treasury Department's Bureau of Alcohol, Tobacco, and Firearms. ATF works very closely with FDA on health issues that affect both agencies' products. For example, sulfites (preservatives found in some foods, beer and wine) can cause severe reactions in people sensitive to them. The level of sulfites ATF allows in wine is based on the levels FDA sets for foods.

- **Radiation:** In addition to chemical preservatives such as sulfites, FDA also regulates one of the newest methods to keep food from spoiling—irradiation. (See "The Growing Use of
Where to Get Help

Here are the addresses and phone numbers of government agencies that can help with consumer problems and questions. These are for Washington offices. Local offices are listed in the phone book under U.S. Government.

Food and Drug Administration
Office of Consumer Affairs (HFE-88)
5600 Fishers Lane
Rockville, Md. 20857
301-443-3170

Food Safety and Inspection Service
U.S. Department of Agriculture
Meat and Poultry Hotline
Room 1163S
Washington, D.C. 20250
1-800-535-4555

Animal and Plant Health Inspection Service (Animal vaccines)
U.S. Department of Agriculture
Washington, D.C. 20250
202-436-8633

Federal Trade Commission
6th St. and Pennsylvania Ave., N.W.
Washington, D.C. 20580
202-523-3598

Bureau of Alcohol, Tobacco, and Firearms
Room 4402
Ariel Rios Federal Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20226
202-566-7135

Consumer Product Safety Commission
Washington, D.C. 20207
800-638-CPSC (2772)

Drug Enforcement Administration
U.S. Department of Justice
1405 Eye St., N.W.
Washington, D.C. 20537
202-633-1000

National Institute on Drug Abuse
5600 Fishers Lane
Room 10443
Rockville, Md. 20857
301-443-6500

Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460
202-829-3535

Nuclear Regulatory Commission
Office of Public Affairs
Washington, D.C. 20555
202-492-7715

National Marine Fisheries Service
U.S. Department of Commerce
Washington, D.C. 20235
202-634-7111

Irradiation to Preserve Food* in this issue.) And ensuring that electronic products such as microwave ovens, television sets, and X-ray equipment don’t expose consumers to unnecessary radiation is also FDA’s responsibility. But FDA isn’t the only agency with responsibilities for radiation.

EPA monitors radiation in the environment and, along with FDA, developed guidelines for other federal agencies on the use of X-rays in medicine. Licensing and regulation of the nuclear industry is the Nuclear Regulatory Commission’s responsibility. NRC also ensures that the public is safeguarded from hazards arising from the possession and use of nuclear materials in power reactors, hospitals, research laboratories, or other commercial facilities.

Although the sun’s radiation isn’t regulated, sun-tan parlors come under the jurisdiction of several agencies. Sun-tanning lamps, booths and beds, which under the law are both radiation-emitting devices and medical devices, are regulated by FDA. FTC regulates advertising for tanning booths, beds and parlors, and several states and local jurisdictions also have statutes covering these establishments and devices.

* State Responsibilities: In fact, because the federal government only regulates products that are shipped in interstate commerce, the states enforce many of the same regulations federal agencies do on products that never cross a state’s borders. Consumers with questions or complaints about those products should contact their state government.

The states, not the federal government, are responsible for licensing physicians, pharmacists and other health professionals.

And state and local governments inspect and regulate such establishments as restaurants and health spas.

Responsibility for new products often requires cooperation from more than one agency. For example, cordless phones are regulated by three agencies—FDA, CPSC and the Federal Communications Commission. CPSC has primary responsibility for the safety of cordless phones, and FCC ensures that the transmissions from these phones don’t interfere with other radio transmissions. When it was discovered that the sound levels produced by the ringers in some models could damage hearing, it was decided that FDA has responsibility concerning the safety of the ringing sound produced by the phones, because sound is a form of radiation. (The problem with the ringers has been corrected. See “Free Fix for Unsafe Cordless Phones” in the Updates section of the November 1985 FDA Consumer.)

Consumers can also contact manufacturers with questions and complaints about products. Many manufacturers encourage this communication. Toll-free numbers and company addresses are included on the labels of many foods and nonprescription drugs.

Even with toll-free numbers and other guidance, getting answers may still take more than one phone call. Which agency will regulate a new product isn’t always clear-cut. New regulations and even new government agencies can cause responsibilities to change hands. But, by knowing the general responsibilities of consumer agencies, getting an answer on the first call shouldn’t require quite as much luck.

Dori Stehlin is a member of FDA’s public affairs staff.
Besides being responsible for ensuring the safety and effectiveness of human drugs, FDA has a similar, although less well-known, responsibility for veterinary drugs. To a great degree, this involves the safety of these drugs not only for animals but also for people, because of the widespread use of drugs in animals raised for food.

To get a better understanding of how FDA protects the public health from unsafe residues of veterinary drugs in meat, eggs, and milk, FDA Consumer editor Bill Rados interviewed Dr. Gerald Guest, acting director of FDA's Center for Veterinary Medicine.

Q. Dr. Guest, both you and FDA Commissioner Frank Young have been widely quoted in the press as saying that America's food supply "is the safest in the world." What do you base that on?

A. Let me talk a little about the responsibilities of the Center for Veterinary Medicine and what we're all about. I think then you'll understand why I believe our country's food supply is so safe. The Food and Drug Administration, through this center, is responsible for assuring that animal drugs and medicated feeds are safe and effective and that food from treated animals is safe to eat.

Prior to approval, a new animal drug must undergo extensive testing. The drug sponsor—usually that means the manufacturer—must conduct laboratory and clinical investigations that establish the safety and effectiveness of the substance. The sponsor must also demonstrate that any drug residues remaining in a food-producing animal at slaughter pose no threat to human health.

Once the drug is approved, based on all these data, a monitoring/investigating system takes over. The U.S. Department of Agriculture's Food Safety and Inspection Service obtains samples of body tissue from slaughtered animals and analyzes those samples. Their findings are sent to FDA field offices for follow-up by our field investigators. Regulatory action is taken against those responsible for drug residues above the legal limit, and those animal carcasses found to have dangerous residues are kept from the marketplace.

Taking all of these activities into account—from extensive pre-clearance requirements through rigorous surveillance, monitoring and enforcement activities—I do indeed believe that Americans have the safest food supply in the world.

Q. How much are drugs used in livestock?

A. About four out of five food animals are given drugs during their lifetime. Some receive medication to treat specific illnesses. Often, however, drugs are given to entire herds or flocks—usually in their feed—to prevent disease outbreaks and to help the animals grow faster on less feed. About 30 percent of the chickens, 80 percent of veal calves and pigs, and 60 percent of the beef cattle raised for food in the United States are routinely given medicated feeds.

Q. How many different drugs are used? Are they all really necessary?

A. About 750 drug products are approved for use in food animals. That's about 100 different basic drugs. Virtually all of these drugs are needed to insure the continued availability of safe, wholesome and affordable animal-derived foods to the American public.

Q. What percentage of the animals that USDA checks are found to have illegal residues?

A. Residues above the legal limits are found in approximately .2 percent of poultry samples; for livestock, the rate is 1 percent.

Q. How is this checked? Does USDA check every animal for every drug?

A. USDA collects samples for routine meat inspection. They refer any violative samples to FDA for subsequent enforcement actions.

Perhaps I should explain here that FDA establishes the allowable conditions of drug use and establishes the allowable tolerances or action levels for residues of those drugs.

Each sample cannot be tested for every drug, nor is there reason to do so. Veterinary drugs are each approved for use in a particular animal species. Test methods are developed for detection and analysis of residues in that species.

USDA actually has two parts to its residue sampling program. First, they randomly check a certain number of animals at a slaughterhouse for certain drugs—or pesticides—without regard to the condition or appearance of the animals. The second type of sampling is more directed: Any animal that appears to have had any kind of an illness or that has a visible mark where a drug was injected or that comes under suspicion for some other reason is tested.

On the whole, the program is set up on a statistical basis so that, even though the
number of animals checked is only a small percentage of all the animals that are slaughtered, we can be confident that what we are seeing reflects what’s going on throughout the marketplace.

Q. How do you decide what residue levels are safe?
A. A drug sponsor is required to furnish the scientific information necessary to demonstrate that the residues are safe in edible animal tissues—that is, meat, eggs and milk.

This scientific information includes toxicological studies, to see how hazardous the drug is. It also includes metabolism studies, to see how the animal breaks down the drug in its body. There are depletion studies, to find out how long it takes for the drug and its byproducts to clear out of the animal’s meat, milk or eggs. For drugs whose early tests indicate they could be carcinogenic [cancer causing], we require lifetime feeding studies in mice and rats to accurately determine the true risk. Finally, the agency, after reviewing all the research data, establishes a tolerance level for tissue residues. Or, in some cases, a zero tolerance will be set, and no residue level will be acceptable.

Q. Are all residues harmful or potentially harmful? Have people ever actually been injured, or gotten cancer, because of drug residues in meat, eggs or milk, or is this just a theoretical risk?
A. One potentially serious risk of excessive drug residues is allergic reactions, which can range from a mild case of hives to severe, life-threatening anaphylactic shock.

Evidence of this actually having occurred in people from eating meat, eggs or milk with excessive drug residues, however, is rare, indeed. In fact, our surveillance has never found any actual cases of such allergic reactions caused by drug residues. There are three or four citations of residue-induced reactions in the scientific literature, but even those aren’t all from the United States. One case involved a person who ate raw sausage and had a reaction. The sausage was checked and was found to contain residues of penicillin.

So it’s an extremely rare occurrence, but you can’t be sure how often it happens because it may go unreported, or the relationship between an allergic reaction and residues in food may not be discovered. It’s important to keep in mind that we build a 1,000-fold or 2,000-fold safety factor into our tolerances. This helps to avoid ill effects even when a residue occurs that slightly exceeds the legal limit.

The same holds true for the potential risk of cancer from residues of carcinogenic drugs. We aren’t aware of any cases of cancer that can be linked to drug residues in food. Of course, such an association would be almost impossible to establish, given the many potential causes of cancer—viruses, radiation, environmental carcinogens, and so forth.

Nevertheless, you don’t need, nor do you want, actual victims to make the case that the food supply must be kept free of cancer-causing residues. And, given our surveillance and enforcement programs, I’m confident it is.

Q. The drug DES, widely used for many years as a growth promoter in livestock and poultry, was completely banned by FDA in 1979 because of evidence it causes cancer. Yet we later found widespread disregard for that ban. Is there evidence that the drug is still being used?
A. Diethylstilbestrol (DES) had been used since 1954 in animal feeds and as implants in various species of animals. The use of the drug in livestock was banned in 1979 because of questions about the safety of its residues and because an adequate analytical method to detect those residues had not been developed.

In early 1980, we discovered that some implants that had been manufactured before the ban were still being used. In 1983, we discovered a small number of veal calves in New York that had been treated with DES. In that case, the drug had been brought into the United States from Europe. In both instances, regulatory actions were taken, and the courts backed the government’s position.

There are now no approved veterinary drugs containing DES in the United States or in any country that I am aware of.
Illegal use of veterinary drugs can be an even greater threat to the public health than the illegal use of human drugs.

Q. If a drug is found to cause cancer, is it supposed to be automatically banned from use in food-producing animals?
A. No, not necessarily. A provision of the Delaney anti-cancer clause of the Food, Drug, and Cosmetic Act stipulates that a carcinogenic compound can be used in food-producing animals if the drug will not harm the animals and if "no residue" of the compound will be found in any edible tissues of the animal when tested by the approved methods.

But as analytical methods have become more sensitive over the years, this exception has become unworkable. Levels of residues that were so low they were previously undetectable can now be detected. So we have proposed procedures and criteria to permit these exceedingly low levels of residues that present an insignificant risk of cancer to the public.

Q. What is this insignificant-risk level?
A. One in 1 million. This doesn't mean that one in every million people will contract cancer as a result of this regulation. Rather, it represents a one in 1 million increase in risk over the normal risk of cancer over a lifetime. This is considered an insignificant level of risk.

Q. Recently, some supermarkets have been advertising meat from animals raised without drugs. Is this safer for consumers?
A. Since our residue monitoring program effectively protects the public from any potentially unsafe residues of animal drugs in meat, eggs and milk, I see no health advantage in buying these special meats.

Q. Dr. Sanford Miller, director of FDA's Center for Food Safety and Applied Nutrition, has said that microbiological contamination of food, which can cause outbreaks of food poisoning, is a bigger problem than chemical contamination. Do you agree?
A. Yes, I agree with Dr. Miller's assessment. Microbiological contamination can be a problem. Illegal drug residues could conceivably be eliminated; the risk of microbiological contamination is virtually impossible to eliminate. The contamination can occur at any point in the farm-to-consumer chain—on the farm, through the processing and distribution systems, and in the American kitchen.

When you consider the potential for contamination at each of the links in this chain, you have to tip your hat, I think, to the federal, state and local governments and the food industry for the remarkable job they do in safeguarding the food supply.

Q. Former CVM director Lester Crawford has said that the illegal sale of veterinary drugs could have more serious public health consequences than any problem with human drugs. Do you agree?
A. I believe Dr. Crawford was referring to situations of extreme misuse of veterinary drugs. In those cases, I agree that illegal use of veterinary drugs can be an even greater threat to the public health than the illegal use of human drugs. What puts a different light on this issue is that use of illegal human drugs generally involves the consent of the persons involved. But the consumer of meat, milk and eggs has no way of knowing if hazardous substances are present in those foods, and no way of knowing if unapproved drugs have been used on the animals.

The illegal import of veterinary drugs is an insidious practice that also threatens the public health. The DES episode of 1983 happened because the drug was brought from Europe through Canada and into the United States. The U.S. Customs inspectors look for and deny entry of illegal drugs when they are identified, but just as human drugs are successfully smuggled into the country, so are animal drugs.

Q. Is the animal drug industry as well regulated as the human drug industry? Isn't there a pretty widespread problem with uncontrolled sale of prescription animal drugs?
A. In general, we believe that animal drugs are as well regulated as human drugs, although there are chronic problems that we are always watching.

One of these problems is the illegal sale of prescription drugs. In 1985 we took 73 regulatory actions against those firms and individuals found to be violating the law in such cases. We’ve also encouraged state boards of pharmacy and state boards of veterinary licensing to take more active roles in regulating distribution of veterinary prescription drugs. The states have been very effective in regulating human prescription drugs; we hope that veterinary drugs can be just as well-regulated.

Through a more active surveillance program and some special initiatives in several states last year, we do know which drugs make up the bulk of the illegal market. We’re continuing the fight, and we’re winning some significant battles.

Q. What happens to farmers whose animals are found to have illegal residues?

A. Two things. First, carcasses found with unsafe drug residues are removed from the slaughterhouse, and USDA will sample the next five animals from that farm. Second, FDA will send a regulatory letter to the farmer, outlining the violation and warning of more stringent legal action if steps are not taken to correct the problem. It is in the farmer’s best interest to correct these problems early, to avoid the possibility of more severe legal action, such as an injunction or prosecution.

It’s important to remember that at least 99 percent of the livestock producers use drugs properly. We know this from the low rate of illegal residues that we find through our surveillance.

Q. Do you feel like you are walking a regulatory tightrope—on the one hand trying to protect consumers from unsafe food and on the other trying to avoid putting unnecessary constraints on livestock producers’ ability to provide a plentiful supply of inexpensive food?

A. Yes, definitely. However, when you’ve got a hard decision to make, you make the choice on the side of protecting the public’s health.

Q. There has been a long-running controversy over the use of antibiotics in livestock. Some believe that the use cuts down on their effectiveness in humans. Is the use of antibiotics in livestock and poultry decreasing as consumers become more concerned about this issue?

A. In November of 1984, the Natural Resources Defense Council petitioned the secretary of health and human services to ban the routine use of penicillin and tetracyclines in animal feeds as an imminent health hazard. After a legislative hearing on the issue and review of contract reports and the published literature, the secretary denied the petition in November 1985.

We believe that over the past year the industry has decreased the routine use of penicillin and tetracyclines in animal feeds. For example, in April 1985, the National Cattlemen’s Association recommended that its members suspend the use of tetracycline in beef cattle. [Editor’s note: The beef cattle industry does not use penicillin in feeds.] I would rather not speculate further on this question since the agency’s still reviewing the issue. However, I will say that as more alternative drugs become available, the industry will have a number of drugs that are not used for treating disease, but are reserved for food production purposes.

Q. Given recent and pending budget cuts, does FDA, and particularly your center, have adequate resources to protect the public from unsafe residues?

A. The budget cuts will have an effect on our activities. However, protection of the public health will, of course, continue to be our top priority. Our cuts in personnel and budget will be taken from areas that have little direct impact on public health. In fact, even with the cuts, we are reprogramming resources in order to increase field activities in areas of prevention of illegal residues and prevention of the illegal sale of veterinary prescription drugs.
Maintaining normal body functions is the job of a number of interrelated organ systems, among them the cardiovascular, the respiratory, the nervous, and the digestive systems. All of these systems largely function without our conscious input.

Essential to their functioning is another system of sorts, which might be thought of as the body’s electrical system. This system is found in the fluids that bathe all the body’s cells and in the fluid of the cells themselves. It consists of chemical compounds called electrolytes that, when dissolved in the fluids, separate into electrically charged particles called ions. It is the electrical charge held by these ions that enables them to play their indispensable roles in transmitting nerve impulses, contracting muscles, keeping a proper level of fluids in the body, and controlling the acid-alkaline balance in these fluids.

Some of the electrolytes have a positive charge; they are called cations (pronounced kat’ i uns). Others are negatively charged and are called anions (an’ i uns). The major cations are potassium, magnesium, sodium, and calcium. Chloride is a major anion.

Electrolytes are distributed unevenly between the intracellular fluid (within the cells) and the extracellular fluid (outside the cells, including the blood). Potassium and magnesium, for example, are found mainly within cells; sodium and chloride predominate in the fluid outside the cells.

Electrolytes come from the food we eat. They are absorbed by the intestines, and after they have served their purpose they are excreted by the kidneys. The amount that leaves the body daily is about equal to that taken in; some electrolytes are lost by other means, such as through exhaled air and perspiration. The kidneys are able to reabsorb electrolytes as needed—thus they play an important role in keeping just the right level of electrolytes for the body’s needs. But this delicate balance can be upset in a number of ways, interfering with the essential work of the electrolytes.

For example, when a person is stricken by any of a number of diseases, or becomes dehydrated through diarrhea, excessive perspiration, or vomiting, it is often noted that among the complications is an electrolyte imbalance. Even though this term is frequently used, it takes a bit of explaining—what electrolytes are, what they do, and how they get out of kilter—to understand.
Patients who have kidney problems should avoid laxatives containing magnesium.

the importance of the body’s “electrical system.”

Potassium
As the principal cation in the intracellular fluid, potassium has many important functions, including activating enzymes, processing and storing carbohydrates, and helping to transmit nerve impulses to the heart and skeletal muscles. Deficits of potassium thus can have major consequences.

A most important cause of potassium loss is the use of potent diuretics such as the thiazides. These drugs, used widely to treat hypertension and heart disease, rid the body of excess water and sodium. Unfortunately, this causes increased excretion of potassium as well.

Potassium can also be lost through excessive perspiration, repeated enemas, trauma (such as severe burns), uncontrolled diabetes, and diseases of the intestinal tract, as well as operations to correct them. Even a form of kidney disease caused by the use of outdated tetracycline or eating too much licorice can result in loss of this important substance.

People who suffer from poor nutrition, those using very low-calorie diet products, and victims of anorexia nervosa or acute alcoholism also may have low potassium levels because they are not taking in enough of the mineral.

Symptoms of potassium loss include a weak pulse, faint heart sounds, falling blood pressure, and generalized weakness. Severe loss of potassium can lead to death.

Too much potassium is not a good thing, either. An excess may cause diarrhea, irritability, muscle cramps and pain. High levels of potassium can be brought on by kidney failure or consuming excessive amounts in food. (See “Potassium: Keeping a Delicate Balance” in the February 1983 FDA Consumer.)

Magnesium
Like potassium, magnesium is found mainly in the intracellular fluid and is also involved in muscle contraction and nerve transmission. It stimulates the activity of many enzymes involved in the processing of fats, proteins and carbohydrates.

Magnesium deficiencies may occur as a result of dietary insufficiency, diarrhea, steatorrhea (an excess of fat in the stool), chronic alcoholism, diabetes, pancreatitis, kidney damage, and use of diuretics. When magnesium levels are low, levels of potas-sium and calcium are often low, too.

An excess of magnesium is usually due to impaired kidney function. Patients who have kidney problems should avoid laxatives or antacids containing magnesium since their use may lead to serious complications that are associated with excess magnesium, including depressed reflexes, muscle paralysis, and respiratory depression.

Sodium
The principal cation in the extracellular fluid is sodium, which is a major factor in maintaining proper fluid balance in the body. Too little sodium is often associated with dehydration: too much can lead to edema (swelling).

A low sodium level in the body may result from excessive sweating, the use of certain diuretics, or diarrhea. Fatigue, muscle weakness, apprehension, and convulsions are among the symptoms of excessive sodium loss.

Sodium concentrations can increase when a person doesn’t drink enough water, especially in hot weather, or if kidney function is impaired. Dry, sticky mucous membranes, flushed skin, elevated body temperature, lack of tears, and thirst are among the symptoms of sodium excess. Too much sodium in the diet is also linked to the development of high blood pressure in susceptible individuals.

Chloride
Chloride, the principal anion of the extracellular fluid is usually paired with sodium. (Salt is sodium chloride.) Chloride is also important for muscle contraction, balancing the fluid levels inside and outside the cells, and maintaining the acid-base balance of the extracellular fluid. An adequate supply of chloride is necessary to prevent bicarbonate, the second most prevalent anion, from tipping the acid-base balance to the alkaline side.

In 1979, a lack of chloride in one brand of infant formula caused a condition called metabolic alkalosis in babies who had been fed that formula exclusively. As a result of this episode, Congress passed the Infant Formula Act of 1980, which spells out the nutrients that must be in formulas and establishes quality control procedures for the manufacture of these infant foods.
Eating a well-balanced diet and drinking plenty of water in hot weather should provide most people with all the fluid and electrolytes they need.

**Calcium**

The extracellular fluid also contains calcium, another cation essential for normal nerve impulse transmission, muscle contraction, and blood clotting. Only a small amount of calcium is ionized. Most of the calcium in the body is in a nonionized state in the bones and teeth.

The ionized form of calcium may be decreased as a result of pancreatitis (inflammation of the pancreas), chronic kidney disease, and sprue (a disease involving malabsorption of certain foods in the intestines). Calcium loss may also be associated with surgical removal of parathyroid tissue. The parathyroids, small glands located near the thyroid, contain a substance that helps control normal calcium levels. Abdominal and muscle cramps, tingling of the finger tips, numbness, and overactive reflexes are signs of calcium loss.

Excess calcium, on the other hand, may result in loss of appetite, nausea, weight loss, kidney stones, and deep body pain. Eating too much calcium, taking too much vitamin D, prolonged immobilization (as in bedrest or space flight), an overactive parathyroid gland, and kidney disease all are factors that may contribute to calcium excess.

**Restoring Balance**

Bringing electrolytes back into balance involves replacing what has been lost, eliminating those substances that are creating an excess, or correcting the underlying problem causing the imbalance, such as kidney disease.

In mild cases of electrolyte loss, such as that experienced by an athlete after a hot, sweaty game, all that is needed is plenty of water to replace fluids. Any sodium that is lost usually can be replaced by adding salt to food before and after exercise. In general, salt tablets should not be used to replace minor sodium loss. There are a number of sports drinks on the market that provide extra electrolytes. However, these preparations can cause intestinal cramps because the fluid tends to be retained in the stomach and intestines.

Other electrolytes that are lost during exercise—potassium and magnesium—also can be replaced through dietary sources. Bananas are often mentioned as a good source of potassium, but they are not the only one. Apricots, dates, figs, oranges, avocados, prunes and raisins also rank high among potassium-rich foods. Many salt substitutes contain potassium chloride, a source of two electrolytes. Green leafy vegetables and whole grains are good sources of magnesium and potassium.

For those taking diuretics, a diet high in potassium, or potassium in tablet or capsule form, or a diuretic that does not cause the excretion of potassium (called “potassium-sparing”) may be prescribed.

Under an FDA regulation, tablets or capsules with less than 100 milligrams of potassium and liquid preparations with less than 20 milligrams in a milliliter (about a quarter teaspoon) are considered dietary supplements. However, preparations with higher levels of potassium are considered drugs and must carry a warning label stating that the product can cause small bowel lesions.

Milk and other dairy products and canned sardines or salmon with bones are good dietary sources of calcium. Calcium is also available as a dietary supplement. High levels of calcium in the body may be relieved by decreasing intakes of this mineral or of vitamin D.

When sodium intake is too high, the solution is to cut back on the amount that’s eaten. Many processed foods are labeled as to salt (or sodium) content. In addition, some products are available in low-sodium varieties and are so identified on the labels.

For severe cases of electrolyte loss, there are a number of replacement fluids containing various amounts of different electrolytes. Since they are given intravenously, such fluids are administered in a hospital. Electrolyte replacement solutions are regulated by FDA as drugs and must be manufactured according to good manufacturing regulations.

Most people will never have to face electrolyte replacement. Eating a well-balanced diet and drinking plenty of water in hot weather or when undertaking strenuous exercise should provide most people with all the fluid and electrolytes they need.

Occasionally, however, even healthy people think they need extra vitamins or minerals. Because each person’s dietary needs are different, it is always a good idea to check with a doctor before taking any kind of dietary supplement.

Annabel Hecht is a member of FDA’s public affairs staff.
Consumers' preference for healthful foods is taking a new tack, according to a recent survey. Health-conscious shoppers are shifting their main concern away from avoiding foods and ingredients viewed as harmful to choosing foods that they feel will increase fitness and energy and add years to their lives, even "a second 50 years of healthy active life," according to a survey spokesman.

The survey also found that, when it comes to deciding what is safe to eat, most consumers prefer to rely on themselves first and the federal government next. Fewer shoppers are relying on consumer groups and manufacturers to make food safety choices for them.

These are some of the findings reported by the Food Marketing Institute (FMI) of Washington, D.C., in its annual survey of consumer attitudes toward nutrition. FMI, an organization of food retailers and wholesalers, includes most of the large chain and independent supermarkets. The survey, based on 1,004 telephone interviews by Louis Harris and Associates, Inc., a New York City survey firm, was conducted last January.

In a speech at the FMI-sponsored National Food Policy Conference last March, Tim Hammonds, senior vice president for research and education at FMI, said the latest survey showed how consumers' food choices were being influenced by a growing desire to promote their own and their family's general well-being.

Consumers have become "increasingly knowledgeable, increasingly sophisticated," Hammonds said. "I believe we are seeing a very important transition of attitude." Consumers are less concerned with what they should avoid as harmful and are placing a greater priority on "dietary changes designed to produce a positive result of increased fitness, energy or longevity," he said.

"I don't mean to say people will stop avoiding certain substances such as fat or cholesterol," he added. "What I mean to say is that they will avoid fat and cholesterol less out of fear of disease and more out of desire for the positive aspects of a more active, healthier and longer life that a healthier diet can bring. . . . Along with
Shoppers' Biggest Nutrition Concerns

Listed below are the most frequent answers in 1986 to the question: "What is it about the nutritional content of what you eat that concerns you and your family the most? What else concerns you?"

Vitamin/mineral content
Salt
Sugar
Fat
Additives
Preservatives

Percent of Respondents
(Totals more than 100 percent because of multiple answers)

Source: Food Marketing Institute

Largest Declines in Shoppers' Nutrition Concerns
The concerns that declined the most among surveyed shoppers between 1983 and 1986:

<table>
<thead>
<tr>
<th>Percent of Respondents</th>
<th>1983</th>
<th>1986</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural foods</td>
<td>12</td>
<td>3</td>
</tr>
<tr>
<td>Preservatives</td>
<td>22</td>
<td>15</td>
</tr>
<tr>
<td>Chemical additives</td>
<td>27</td>
<td>16</td>
</tr>
</tbody>
</table>

Source: Food Marketing Institute

Largest Increases in Shoppers' Nutrition Concerns
The concerns that increased the most among surveyed shoppers between 1983 and 1986:

<table>
<thead>
<tr>
<th>Percent of Respondents</th>
<th>1983</th>
<th>1986</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat content</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Calories</td>
<td>6</td>
<td>11</td>
</tr>
</tbody>
</table>

Source: Food Marketing Institute

this change in attitude as to why certain things are avoided comes a much broader range of related activity such as physical exercise, weight control, and a pursuit of physical well-being in its broadest context."

When the shoppers were asked specifically whether they were concerned about nutritional content, 58 percent replied that they were "very concerned"—about the same as was reported in 1985 but down from the 64 percent reported in 1983. Those figures, Hammonds said, point not to an overall decline in interest in nutrition but a replacement of the vague, general concerns with more specific issues.

"Over the last two years," Hammonds explained, "we have probed deeper by exploring specific nutrition-related behaviors such as 'selecting recipes for nutritional content,' 'serving nutritional snacks,' and 'selecting foods to balance the family diet.' Of seven of these behaviors, the frequency in 1986 increased for six and remained the same for one. None went down."

Consumer interest increased the most between 1983 and 1986 toward fat, cholesterol and calories. Seventeen percent of those surveyed this year said they were concerned about the fat content of foods, compared to only 9 percent three years ago; 13 percent singled out cholesterol content as a serious concern today, compared to 5 percent in 1983; and 11 percent voiced their calorie-consciousness in this
year’s survey, compared to 6 percent in 1983.

“The biggest gainers [in increased consumer concerns] tend to be meat related,” Hammonds noted. He pointed out that the U.S. Department of Agriculture’s data show a declining trend in beef and red meat consumption in the United States and a sharp increase in poultry and fish consumption. (See “Special Report: America’s Changing Diet,” in the October 1985 FDA Consumer.) Poultry consumption is rapidly approaching that of beef in the United States.

Consumer self-reliance in deciding which products are safe to buy continues a trend that has been reflected in previous FMI surveys. Forty-eight percent of those interviewed this year said they relied on themselves first to make such judgments. In 1979, only 39 percent listed themselves first. Only 18 percent listed the federal government first seven years ago, compared to 29 percent this year. This year’s finding is 2 percent below that of last year, however.

“Reliance on themselves as the ultimate guarantor of food safety is in first place by a wide margin, as it has been for the last four years,” Hammonds said. “Safety, of course, would be a combination of the obvious—checking packaging for signs of tampering, for example, and the more complex, such as avoiding foods perceived to be harmful in the diet.”

Although Americans have made significant changes in their diets, Hammonds said changes in food purchasing patterns have been “glacial in comparison to their attitudinal changes.” Not all the changes in attitude, however, are based on a well-informed understanding of nutrition. There are many myths and misperceptions among consumers even though important strides in knowledge have occurred, he asserted.

FMI’s survey continued to reflect public uncertainty and skepticism over conflicting and often complex scientific opinion on health issues. There is “a widespread feeling that many—but certainly not all—diet and food safety recommendations are themselves the subject of scientific controversy. At one time or another, all of us must have felt while listening to the ‘experts’ that for every Ph.D. there is an equal and opposite Ph.D.,” Hammonds said.

“We are subject to too many claims, counterclaims, and subtleties, too many reversals of earlier findings,” he said. “In fact, my definition of a ‘dietary law’ is a ‘half-truth stated so as to cause maximum irritation to those who believe in the other half.’”

Because of this complexity and confusion, Hammonds contended that nutrition experts need to place a greater emphasis on broader health goals. For example, there is a need for “hard, believable, understanding research, providing the attainable behavior changes actually do some good. The emphasis here has to be on lack of ambiguity, simplicity of communication, and on attainable change [that is] well within the reach of mainstream America,” he said.

Hammonds declared that the present generation of Americans was “the first... in history that could realistically look forward to a second 50 years of healthy, active life.” If consumers become more convinced that good nutrition can help improve their lifespan, he said, “then it will be possible to make more people conscious of nutrition and of the dietary changes needed to promote their general feeling of well-being.”

—Chris W. Lecos

Who Ensures Your Food is Safe?

As far as you personally are concerned, whom do you rely on most to be sure that the products you buy are safe—the federal government, the state government, consumer organizations, manufacturers, retailers, or yourself as an individual?

<table>
<thead>
<tr>
<th>Who Ensures Your Food is Safe?</th>
<th>Percent of Respondents</th>
<th>1979</th>
<th>1986</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yourself as an individual</td>
<td></td>
<td>39</td>
<td>48</td>
</tr>
<tr>
<td>Federal government</td>
<td></td>
<td>18</td>
<td>29</td>
</tr>
<tr>
<td>Consumer organizations</td>
<td></td>
<td>19</td>
<td>9</td>
</tr>
<tr>
<td>Manufacturers</td>
<td></td>
<td>17</td>
<td>8</td>
</tr>
<tr>
<td>State government</td>
<td></td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Retailers</td>
<td></td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

Source: Food Marketing Institute
The Notebook

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 large public libraries.

- Sales of performance-enhancing drugs are “staggering” in potential and could become a $1 billion segment of the psychotropic drug market after 1990, according to “Psychotropic Drugs in the U.S.,” a new report by Frost & Sullivan. Such drugs could be used to treat Alzheimer’s disease and other forms of mental deterioration in the aged. Overall, sales of psychotropic drugs, which exert an effect on the mind, will reach $1.9 billion in 1986 and nearly $2.8 billion by 1990, the report by the New York-based market research firm says.

- Magazine advertising for the Potato Board said potatoes are packed with vitamin C, iron, fiber and vitamin B₆, but the National Advertising Division of the Council of Better Business Bureaus, Inc., questioned whether the iron level (4 percent to 6 percent of the U.S. Recommended Daily Allowance) was significant. The ad agency agreed that it was not and said future ads would not present potatoes as a good source of iron.

- Medical devices recently granted pre-market approval by FDA:
  - The Orthopak Bone Growth Stimulator System, manufactured by Biolectron, Inc., Hackensack, N.J., and the Physio-Stim Osteogenesis Therapy System, made by American Medical Electronics, Inc., Dallas, Texas, both for the treatment of fractures that haven’t healed after nine months (FR April 9 and 18).
  - AB COREK (radio-immunoassay for antibody to hepatitis B core antigen in serum or plasma) to aid in hepatitis diagnosis, manufactured by Sorin Biomedica, S.p.A., New York, N.Y.; and TANDEM-R PSA Immunoradiometric Assay for the Quantitative Measurement of Prostate-Specific Antigen (PSA) in Serum, to aid in prostate cancer treatment, manufactured by Hybritech, Inc., San Diego, Calif. (FR April 10 and 9).
  - The spherical ALGES Bifocal Contact Lens produced by University Optical Products Co., Largo, Fla. (FR April 28).

- Statement of identity requirements for over-the-counter (OTC) drugs will apply to both single active ingredients and combinations of active ingredients under a proposed change in FDA labeling regulations. Applicable OTC monographs will be indicated as the source of identity information (FR April 17).

- The narcotic drug alfentanil would be moved from Schedule I to Schedule II of the Controlled Substances Act under a Drug Enforcement Administration proposal. FDA has advised that the drug, though it has a high potential for abuse, will be approved for medical use in the near future (FR April 17).

- The Public Health Service is proposing that private firms be charged user fees for reference biological standards or biological preparations for comparative performance tests, distributed by the Centers for Disease Control in Atlanta, Ga. (FR April 29).

- Consumers spent over $20 billion on diet foods and beverages in 1985, and sales of those products will reach at least $28.8 billion in 1990, according to a Business Communications Company, Inc., study of the diet foods industry. The market research firm, based in Stamford, Conn., says the maturing of the populace and increased longevity are increasing the market potential for diet foods. For the period 1985 to 1990, the study forecast sales increases of 10.4 percent for reduced-sugar products, 9.5 percent for calorie-controlled foods, 3.8 percent for reduced-fat foods, and 7.4 percent for reduced-sodium products. Caffeine-free beverage sales will go up by 5.3 percent, and reduced-calorie and reduced-alcohol beverages will jump 8.6 percent, the firm predicts.

- The National Institute on Alcohol Abuse and Alcoholism is funding grants to study the role of heavy alcohol consumption in lowering resistance to infectious diseases and as a potential co-factor in the development of AIDS (FR April 30).

- FDA has denied a petition by the Pet Food Institute, Washington, D.C., asking that class and collective names be allowed as an alternative to common or usual names for listing ingredients in pet food labeling. The agency said the petition did not show that the use of common or usual names is impractical or results in deception or unfair competition (FR April 3).
The Trial of the Blue-Green Algae Eaters

by Carol Ballentine

During a trial earlier this year in a federal courtroom in Portland, Ore., people were wearing—with obvious pride—buttons that read: "I EAT ALGAE." In fact, this odd dietary proclamation told only part of the story; these people not only ate the aquatic plants, they profited by them, too. They were distributors of a line of products made of blue-green algae by one of the defendants in the trial, K. C. Laboratories of Klamath Falls, Ore.

At issue in the courtroom was the status of the products. The firm and its distributors insisted that the products were food supplements and needed no FDA approval to be marketed. But FDA contended that the products were drugs because the firm claimed that the algae could be used to treat an array of maladies ranging from Alzheimer's disease to herpes. If the products were drugs, they would have to be approved by FDA as safe and effective before they could be sold.

In the end, the judge in the case agreed with FDA that the products should not be allowed on the market, but the path to that decision was as slippery as the contested water weed itself.

Investigators from FDA's Seattle district office first inspected K.C. Laboratories in 1983 when it was just starting operations. The firm was owned by Victor Kollman. Kollman explained to the investigators that K.C. Laboratories was harvesting blue-green algae from Klamath Lake to be freeze-dried, bottled and sold as a food supplement.

The algae was harvested from the lake when the species Aphanizomenon flos-aquae was predominant. Aphanizomenon flos-aquae has been found to produce a toxin that is a powerful neuromuscular blocking agent. In laboratory studies it has caused animals to stop breathing. The algae produces the toxin during its most active growth state, which is also when it is most likely to be harvested. The district office recommended to FDA headquarters that the products be seized. Legal documents were subsequently filed with the federal court, and a deputy U.S. marshal was instructed to seize the goods.

When the marshal and an FDA investigator arrived at the firm, Kollman met them with undisguised hostility. While the marshal was phoning for assistance, Kollman and his wife locked themselves inside the plant. When they refused to open the doors, the marshal, assisted by several Klamath County sheriffs, shattered the glass entry door with a sledgehammer and entered. They arrested the Kollmans, charging that they had interfered with federal officials, and placed under seizure about $120,000 worth of blue-green algae products, which they took by truck to a public warehouse.

Undaunted, Kollman continued to harvest and process blue-green algae, which he sold under the name Blue-Green Manna. Specialized forms of Blue-Green Manna were advertised in the company's newsletter, The Klamath Courier, including Mannacol (recommended for "metabolic dysfunctions"), Mannamist (for allergies), Mannapep (to enhance mental and physical performance), Mannastat (for cuts and burns), and Mannazen (to "establish a balance between physical, intellectual, and spiritual biorhythms").

The products were sold through some 2,500 distributors involved in a multi-level marketing plan. FDA made follow-up inspections at some of these distributors, including an undercover inspection of one such distributor in Everett, Wash. Posing as a potential distributor, a Seattle district investigator found an impressive stack of literature that was to be given out with the...
algae products. Blue-Green Manna, the literature said, could repair damage to the brain and restore the ability of the body to resist disease. Because the algae itself did not age or get sick, it could act as a "natural healer." One printed sheet called Blue-Green Manna "God's gift to modern man" and claimed it could treat high blood pressure, stomach distress, menstrual discomfort, headaches, skin rashes, blindness, leukemia, sickle-cell anemia, and herpes. Video and audio cassette tapes were also available which extolled the benefits of Blue-Green Manna products.

The proprietor of the establishment explained to the investigator the wondrous powers of Blue-Green Manna. He said it had cured his arthritis and his wife's tonsillitis. He also said that Dr. Kollman had used the product to cure 100 lepers in India in 90 days. This was a story Seattle district staff had heard before—but the statistics had changed.

In July 1984, FDA requested the U.S. Attorney's Office to conduct a second seizure of blue-green algae products, this time those in possession of the Everett distributor. The government alleged that the products were drugs because of the way in which they were promoted, but they had not been shown to be safe and effective. Unfortunately, when the deputy U.S. marshal and a Seattle district investigator got to the Everett firm, there were no blue-green algae products and no literature. The proprietor told them that "a little bird" had told him he had better remove the products from sale or he would lose them. He refused to tell the deputy marshal what he did with the algae products.

In the meantime, however, FDA made another move, requesting an injunction against Kollman, his firm, and other companies that contributed to the manufacture and distribution of the blue-green algae products. These other companies were: Manna International Company; K.C. Laboratories Marketing, Inc.; K.C. Laboratories Production, Inc.; Wynetta Spencer-Kollman and her firm, Klamath Publishing Co., which produced promotional materials for the products and sold them to K.C. Laboratories Marketing; D. Raymond Schmidt, head of Schmidt Food Processing Co. (which freeze-dried the algae); Susan E. Davis, vice president of K.C. Laboratories Marketing; and APG Company, Inc., which held a lease from the state permitting it to harvest the algae from upper Klamath Lake.

FDA charged that the defendants were making medical claims for their blue-green algae products, which put them legally in the drug category; however, the firm had not done the necessary studies to prove that the products were safe and effective for these uses. Kollman denied that he had made therapeutic claims for the products and said they were intended as foods, not drugs.

In November 1985, in the U.S. District Court for the District of Oregon, Judge Gus Solomon granted a preliminary injunction against the firms and individuals, barring the manufacture and distribution of blue-green algae products. The injunction had little effect on the distributors, who continued to distribute the products that they had stockpiled or that they had received from a new firm, Multi-Cellular Biologiks, which purchased the assets and liabilities of the Kollman firms.

In December 1985, the government sought and was granted a temporary restraining order against Multi-Cellular Biologiks preventing them, too, from manufacturing and distributing blue-green algae products. In February 1986, Judge Solomon made the injunction permanent against K.C. Laboratories.

In doing so, the judge said, "Since I issued the preliminary injunction, I have received hundreds of letters from distributors and others who say they have purchased and used the products. . . . They repeat the claims made to the court by Kollman that this is a food and not a drug and they go on to say it has cured them or members of their families of such conditions as Alzheimer's disease, heart trouble, skin disturbances, allergies, prostate problems, lack of sex drive, emotional problems, and alcoholism. . . . All of these actions merely confirm my strong belief that the claims which defendants have made for their products and the publicity given such claims are believed by many people."

Judge Solomon said that in fact the recommended dosage of the product provided little nutritional value and at a price one would scarcely expect to pay for a food—over $300 a pound. He also added that Kollman had not been honest about his credentials since there was no evidence that he had a doctorate or was entitled to be called doctor, as he claimed.

The defendants were permanently enjoined from manufacturing and marketing any products that contain blue-green algae. The judge also enjoined the production or distribution of literature related to blue-green algae products and ordered Victor Kollman and K.C. Laboratories to recall all blue-green algae products and raw and processed algae produced since Nov. 29, 1985. An order of permanent injunction against Multi-Cellular Biologiks was granted in April 1986.

Carol Ballentine is a member of FDA's public affairs staff.

Cat and Mouse Game

The New Eastern Food Company could have used a cat like T. S. Eliot's Gumbie Cat who was "deeply concerned with the ways of mice." The felines kept by the Philadelphia warehouse, allegedly for rodent control, lacked Gumbie's dedication.

The failure of the cats to do their jobs was evident to investigators from FDA's Philadelphia office during an extensive inspection of the firm, which distributed rice, flour, canned goods, fresh vegetables, red meat, poultry and other foods to Oriental restaurants in Pennsylvania, New Jersey and Delaware. Because of the rodents and other filthy conditions found by FDA, a U.S. District Court judge closed down the warehouse.

FDA discovered this situation when one of the agency's import inspectors visited New Eastern to examine cans of imported Koon Chun Thick Soy Sauce. What he saw prompted a recommendation that the agency make a thorough inspection of the warehouse. When investigators followed up this information, they learned that the import inspector's report had not been exaggerated. They found both live and
dead insects, insect larvae, and insect holes and trails in bagged and spilled food. A live mouse was seen near bags of rice in a single-story annex attached to the main warehouse, and a dead one was seen on the second floor of the three-story building.

Hundreds of rodent pellets were seen on the floor in the annex and on the first two floors of the main building. Rodent excreta pellets, urine stains, and gnawed holes were observed on or in containers of various lots of food. Many cans of food were swollen and covered with insect material and rodent excreta. (Subsequent laboratory tests revealed that the cans contained decomposing or decomposed material.) Rodent pellets were even found on cabbages in the cooler.

When asked what kind of rodent control he had, the firm’s president replied that he had cats. And indeed he did. The FDA investigators found four cats in the warehouse, along with evidence of their presence—feces and a strong odor of cat urine. The office served as a nursery for a mother and her kittens. One cat was even seen eating from a box of chicken parts that had been left on a loading dock.

Advised that he would have to clean up his act, the owner voluntarily destroyed what could be used. Instead of sweating in the heat of the summer sun, some people head indoors to a tanning salon. There they can lie on a bed of plastic with a row of sunlamps above and below and darken to the desired shade. But tanning beds, unlike the sun, come under the scrutiny of FDA investigators.

An FDA Brooklyn district investigator, making a routine inspection at Tantalizing Tanning Salons, Inc., in Oceanside, N.Y., found several tanning beds that could have given customers more than just a tan. Two beds had inaccurate timers, which could have resulted in burns. Another had no “panic button”—a button the customer can press to shut the machine off manually. That bed also had no user instructions, required by FDA performance standards for sunlamp products. Instructions must cover proper use and warnings about hazards, (for example, that failure to wear safety goggles can cause eye damage).

The Brooklyn office sent a letter to the president of the firm requesting that these problems be corrected. He agreed, and a follow-up inspection found that the corrections had been made.

Schoolchildren Injured by Contaminated Milk

Milk is so important to growing children that it’s a “given” in school nutrition programs. On Oct. 30, 1985, however, the milk served at Berlin, Wisconsin’s Clay-Lamberton Elementary School was important for another reason: Thirty-two children who drank it complained of burning or irritated lips, mouth and throat. Why such adverse effects? Hazardous ammonia refrigerant had leaked into the milk during storage at the Morning Glory Farms bottling plant in DePere. Quick action by two inspectors from the Wisconsin Department of Agriculture, Trade and Consumer Protection brought a prompt recall, and no one suffered permanent injury.

While Clay-Lamberton’s milk break began regularly that day, it was soon apparent that something was wrong. One by one, as the children began to drink, they complained of pain in the mouth and throat. A few vomited. The school nurse examined the children and determined that not enough milk had been consumed to warrant medical treatment, although two children did go home in the afternoon. School administrators reported the situation to the Madison Poison Control Center, which notified the agriculture department’s Green Bay regional office and alerted FDA’s Minneapolis district office as well.

State food and dairy inspector Edgar Salisbury visited the school immediately. He collected 12 opened and 30 unopened half-pint cartons of milk and took them to the department’s Bureau of Laboratory Services for testing. In 10 of the 12 opened cartons, ammonia levels ranged from 90 parts per million (ppm) to 1,524 ppm. The milk in the cartons also had a pH—a measure of the acid-base level—of 7.1 to 10.0 (a normal pH range is 6.7 to 6.9). Milk in many of the unopened cartons also tested in the above-normal ranges for ammonia and pH.

Salisbury determined that, since the delivery truck and the school both used Freon gas rather than ammonia in their refrigeration units, the ammonia leak didn’t occur there.

Meanwhile, state agriculture specialist Donald Hasse investigated Morning Glory Farms. He learned that a ruptured ammonia line had been discovered several days earlier and dairy products had been moved to other coolers in the warehouse and onto a delivery truck so that repairs could be made. Unfortunately, when the quality assurance staff began tracking down and destroying the products exposed to the ammonia, they missed those in the truck. Thus, an undetermined quantity of contaminated milk in half-pint cartons went out with the Oct. 30 shipment to the schools.

Hasse checked all the plant’s coolers and found no additional leaks; he also checked the coolers’ other dairy products that were farther from the rupture and...
found that they contained no ammonia.

While some cartons in the contaminated lot had been distributed to school districts in Michigan as well as Wisconsin, only the milk at Clay-Lamberton and a Berlin middle school—which reported four complaints—resulted in ammonia-induced injuries. Fortunately, the injuries were minor and no one was hospitalized. The firm recalled and destroyed the entire lot of milk cartons. FDA's Minneapolis office monitored the recall.

On Feb. 28, 1986, in a Brown County Circuit Court, Morning Glory Farms pleaded no contest to three counts of storing improperly labeled, contaminated food (Wisconsin regulations require that such food be branded as not for sale or for use by humans) and agreed to pay a fine of $2,885, which included court costs.

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**The Smell of Spoiled Shrimp**

The odor of decomposed seafood is unmistakable. So when the aroma emanating from the Georgia Cold Storage Facility in Savannah became unmistakably strong one day in January 1985, it prompted an anonymous call to FDA and, in the end, the dumping of some $120,000 worth of spoiled, frozen shrimp.

After the telephone tip, an investigator from the agency's Savannah office visited the storage facility. He learned that the source of the scent was 1,600 cases of shrimp, part of an entry of 3,242 cases of frozen peeled Brazilian shrimp initially imported into the United States through Gloucester, Mass., for Sylvan Foods, Westport, Conn. The cargo had been shipped from Massachusetts by truck in June 1984 to the Savannah facility, where the cases sat for more than half a year. The cartons were marked to show the month they had been processed—March, April and May 1984.

The FDA investigator also learned that Sylvan Foods knew that the product had begun to decompose. According to the foreman of the storage facility, the firm had ordered the shrimp segregated by month of production after determining that the shrimp packed in April were in the worst condition. However, only 70 cases from the April lot remained.

Samples of all three months' production from the remaining 1,600 cases were collected, and decomposition was confirmed by organoleptic examination (smelling) at FDA's regional laboratory in Atlanta and New Orleans district laboratory.

Since any foods that consist "in whole or in part of any filthy, putrid, or decomposed substance" are considered adulterated under the Food, Drug, and Cosmetic Act, the Atlanta office filed a complaint on March 22, 1985, in the U.S. District Court in Savannah, Ga., for forfeiture of the goods. A U.S. marshal seized the shrimp three days later.

The firm agreed to destroy the shrimp, and on July 30 the decomposed shellfish were bulldozed into a Savannah landfill.

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"This small sample of reports from the field was prepared by Annabel Hecht, Carol Ballentine, Dixie Farley, Carolyn Hommel and Herman Janiger."
Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against goods alleged to be in violation, and criminal and injunction proceedings are against firms or individuals charged to be responsible for violations. The cases generally involve foods, drugs, devices or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce.

Summaries of Court Actions are prepared by Food and Drug Division, Office of the General Counsel, HHS. Published by direction of the Secretary of Health and Human Services.

SEIZURE ACTIONS

Foods/Poisonous and Deleterious Substances


CHARGED 9-4-79 and amended on or about 1-7-80: When shipped from Matamoros, Mexico, or from other places outside of Texas, the articles, which bore a variety of labels (e.g., “Ravi Club Frozen Shrimp . . . Ravi Fisheries . . . Bombay . . . India,” “Sampaguita Fresh Frozen Shrimps . . . Santero Trading Co., Inc. Makati . . . Philippines,” and “Frozen Shrimp . . . Aresti Corp., Brownsville, Texas . . . Origin: India”), contained (some lots) the poisonous or deleterious substance *Salmonella* microorganisms; some lots of the articles contained insect filth or decomposed substances; and all lots of the articles were unfit for food—402(a)(1), 402(a)(3).

DISPOSITION: Notices of Appearance were filed by a number of firms for the articles, which consisted of more than 600,000 pounds of imported frozen shrimp at two different cold storage warehouses and which comprised both the shrimp on hand at the warehouses when the four complaints were filed and the shrimp received within 30 days thereafter. Specific lots of the articles were claimed by a number of New York importers (i.e., Waldco Enterprises, Inc., Robert Hayman Corp., Ocean Wide Products, Zalloom Brothers of N.J., Inc., and Far Port International, Inc.). Other lots of the articles were claimed by Weinstein International Enterprises, Inc., Robert Hayman Corp., Ocean Wide Products, Zalloom Brothers of N.J., Inc., and Far Port International, Inc. (Aresti Corp., Brownsville, Texas; Civil No. H85-1385; S. No. 260031 et al.; S.J. No. 1).

The parties agreed that certain lots of shrimp had been inadvertently seized, since they had been “block-listed” and had been refused entry into the United States. It was understood that such lots should be released from the seizure, that FDA would not issue any transportation and export permits for such shrimp, and that such shrimp would be allowed to be re-exported only from the Port of Brownsville. Accordingly, the specified lots of block-listed shrimp were ordered released for export. (A subsequent order authorized export from either the Port of Brownsville or the Port of Houston.)

Upon claimants’ motion, the court authorized post-seizure sampling. The parties served a number of interrogatories and requests for admissions. Some of the parties entered into a consent decree of condemnation authorizing release for salvaging. The claimants also filed an amended answer and moved for summary judgment. The court had already found that both the shrimp which had been issued transportation and exportation permits and were held at Brownsville and the shrimp which had been returned from Mexico to Brownsville and offered for import were “in interstate commerce.”

The claimants contended that they had the absolute right under Section 381 of the FD&C Act to export articles of food no matter how many times they had been denied entry into the United States, regardless of FDA’s findings of adulteration. The court noted the following: For seven years, the claimants had reprocessed, and re-offered for import, foods that had been denied admission to the United States, and there was a significant danger that if this shrimp was allowed to be exported it would again be offered for import at some port of entry of the United States. In view of congressional concern in this area, FDA did not abuse its discretion in revoking the import-export privilege of the claimants. Accordingly, the claimants’ motion for summary judgment was denied. Ultimately, consent decrees of condemnation authorized release of the remaining shrimp for salvaging. (F.D.C. Nos. 62409 and 62410; S. No. 260031 et al.; S.J. No. 1)

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: Corn husks, at Dallas, N. Dist. Texas; Civil No. 3-83-1218-G.

CHARGED 7-14-83: When imported from Mexico, the article contained moldy corn husks—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64050; S. No. 83-331-360; S. J. No. 2)

PRODUCT: Flour, all-purpose, at Brunswick, Dist. Md.; Civil No. 84-2192.

CHARGED 5-29-85: When shipped by Piedmont Mills, Inc., Lynchburg, Va., the article contained insect filth—402(a)(3).

DISPOSITION: Consent—authorized release to the shipper for salvaging. (F.D.C. No. 64282; S. No. 84-361-182; S. J. No. 3)

PRODUCT: Noodles, vermicelli, batter mix, and other food stocks, at Houston, S. Dist. Texas; Civil No. H85-1385.

CHARGED 3-21-85: While held by East Asia Corp., Houston, Texas, the articles had been held under insanitary conditions, and
some of the articles contained insect filth—402(a)(3), 402(a)(4). DISPOSITION: The articles were claimed by the dealer, who denied the charges. Subsequently, upon their unopposed motion, the Hong Kong Bank International and Hong Kong Bankcorp., Inc., Houston, Texas, creditors of the claimant, were authorized to intervene. Ultimately, all three claimants moved to withdraw their claims and moved for a default decree. Default decree ordered destruction. (F.D.C. No. 64533; S. No. 85-330-649 et al.; S.J. No. 4)

PRODUCT: *Rice flour*, at La Crosse, Dist. Wis.; Civil No. 85-C-677-S.
CHARGED 7-22-85: While held by Frank J. Italiano, Inc., La Crosse, Wis., the article contained insect filth and had been held under insanitary conditions—402(a)(3), 402(a)(4).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64646; S. No. 85-499-218; S.J. No. 5)

PRODUCT: *Sardines, canned, Beach Cliff, and fish steaks, canned, Beach Cliff*, at Boston, Dist. Mass.; Civil No. 85-0558-C.
CHARGED 2-5-85: When shipped by Stinson Canning Co., Prospect Harbor, Maine, the articles had been packed and held under insanitary conditions (i.e., an excessive number of can seam defects that could result in leakage)—402(a)(4).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64505; S. No. 85-389-051 et al.; S.J. No. 6)

PRODUCT: *Soy sauce, canned, and canned plum sauce*, at Houston, S. Dist. Texas; Civil No. H-85-1601.
CHARGED 4-2-85: When shipped from Hong Kong, China, the articles (labeled “Koon Chun Sauce Factory Thick Soy Sauce [or "Plum Sauce"]...Hong Kong”) were unfit for food due to their swollen containers—402(a)(3).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64520; S. Nos. 85-330-429/30; S.J. No. 7)

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64676; S. No. 85-384-924 et al.; S.J. No. 8)

**Foods/Economic and Labeling Violations**

PRODUCT: “Cane” table syrup, at St. Louis, E. Dist. Mo.; Civil No. 85-1649-C-5.
CHARGED 7-23-85: When shipped by Minton Produce, Marion, Ill., the article (labeled “Anthone’s Ribbon Cane Table Syrup Made By Oliver Anthony, Philadelphia, Mississippi”) had another sweetener substituted for cane syrup—402(b)(2); the article's labeling was false and misleading, since the article contained little or no cane syrup—402(a)(1); the food was offered for sale under the name of another food—402(b); and the article failed to conform to the definition and standard of identity for cane syrup, since the article consisted wholly or in large part of a syrup derived from sources other than the juice of sugar cane—403(g)(1).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64669; S. No. 85-495-796; S.J. No. 9)

CHARGED 7-3-85: When shipped by Bodine’s Inc. Food Products, Chicago, Ill., the article had had grapefruit solids substituted in part for orange juice—402(b)(2); the article had had grapefruit solids added, so as to increase the article’s bulk or weight and to reduce its quality—402(b)(4); and the article failed to conform to the definition and standard of identity for frozen concentrated orange juice, since the article contained grapefruit solids—403(g)(1).
DISPOSITION: Consent—authorized release to the shipper for salvaging. (F.D.C. No. 64662; S. No. 85-308-037 et al.; S.J. No. 10)

**Drugs/Human Use**

PRODUCT: Caffeine & ephedrine sulfate tablets and capsules, and caffeine & phenylpropanolamine tablets, at Cleveland, N. Dist. Ohio; Civil No. C-84-987.
CHARGED 3-22-84: When shipped by Midwest Pharmaceutical, Omaha, Neb., and/or Akers Pharmaceutical, Lewistown, Pa., the articles were new drugs without effective approved New Drug Applications—505(a); and the articles’ labeling lacked adequate directions for use, and the articles were not exempt due to their new drug status—502(f)(1).
DISPOSITION: The possessor of the articles, Airway Distributing, Inc., Cleveland, Ohio, denied the charges and filed a counterclaim for $50,000 against the government. The government moved to dismiss the counterclaim.

The court ruled for the government based on the government’s sovereign immunity and because the two possible statutes permitting such claims (i.e., the Tucker Act and the Federal Tort Claims Act) were not applicable to this case. The Tucker Act was not applicable because it is limited to claims not exceeding $10,000 and Airway Distributing Inc. requested $50,000. The Federal Tort Claims Act did not apply because of an exception for “any claim in respect...the detention of any goods or merchandise by an officer of customs or excise or any other law enforcement officer.” In addition, even if the court had jurisdiction of the counterclaim, the Federal Food, Drug, and Cosmetic Act provided that upon condemnation the owner lost property rights in the condemned goods and the value of the condemned articles could not be recovered. Ultimately, a consent decree ordered the articles destroyed. (F.D.C. No. 64218; S. No. 84-308-421/4; S.J. No. 11)

CHARGED 7-10-85: While held by Holloway Pharmaceuticals, Inc., Birmingham, Ala., who manufactured the article using inter-
state hydrocodone bitartrate and acetaminophen, the article was a new drug without an effective approved New Drug Application; and the article's labeling lacked adequate directions for use, and the article was not exempt due to its new drug status—505(a), 502(f)(1).

DISPOSITION: The article was claimed by the manufacturer. However, since no answer was filed and there was no denial of the charges, the government moved for judgment on the pleadings. The court granted judgment for the government on the pleadings and ordered the article destroyed. (F.D.C. No. 64643; S. No. 85-481-967; S.J. No. 12)

PRODUCT: Procaine HCl combination products, amygdalin products, and pangamic acid (B12) products; at Fort Worth, N. Dist. Texas; Civil No. 4-84-359-E.

CHARGED 8-27-84: When shipped from outside the state of Texas, and while held for sale, the articles' labeling lacked adequate directions for use by laymen—502(f)(1); the pangamic acid products (which were labeled “American Biologics True-15 Parenteral Pangamic Acid Sterile . . . Manufactured for American Biologics, San Francisco, Calif.”, “Sterile Pangamic Acid Vitamin B-15 Injection . . . Distributed by Star Pharmacal Co., San Ysidro, Ca.”, and “Capsules of Provitamin B-15 . . . Krebs Laboratories . . . San Francisco, Calif.”) contained the nonconforming food additive pangamic acid—402(a)(2)(C); and the articles containing procaine HCl (e.g., “Aslavital Produs Original Prof. S.A. Aslan . . . Procaine hydrochloride,” “Zell H . . . Procaine H3 nach Prof. Aslan . . . Registriert Beim Bundesgesundheitsamt Berlin”) were new drugs without effective approved New Drug Applications—505(a).

DISPOSITION: Default—ordered destroyed by FDA and that FDA may maintain samples for official use and destroy such samples after such official use. (F.D.C. No. 64323; S. No. 84-349-702 et al.; S.J. No. 13)

PRODUCT: Steroidal hormone tablets for dieting, at Pompano Beach, S. Dist. Fla.; Civil No. 85-6588.

CHARGED 7-31-85: When shipped in bulk by Tishcon Corp., Pompano Beach, S. Dist. Fla.; Civil No. 84-398-713 et al.; S.J. No. 14)


DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64604; S. Nos. 85-378-478 and 85-378-480; S.J. No. 15)

Drugs/Veterinary

PRODUCT: Chloramphenicol combination drugs for aquarium use, at Inglewood, C. Dist. Calif.; Civil No. CV-85-4608-ER(Kx).

CHARGED 7-15-85: While held by Universal Aquarium Systems, Inc., t/a Aquatronics, Inglewood, Calif., who was manufacturing or repackaging the articles, the articles were new animal drugs, and no approval of any New Animal Drug Application was in effect with respect to the articles' use and intended use—501(a)(5); and the articles' labeling lacked adequate directions for use—502(f)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64634; S. No. 85-324-421 et al.; S.J. No. 16)

PRODUCT: Sodium selenite solutions for injection, at Omaha, Dist. Neb.; Civil No. 84-0-474.

CHARGED 7-25-84: When shipped by Quality Plus Products Co., Inc., Fort Dodge, Iowa, the articles (labeled “Se-Sol-5 [or “Se-Sol-l’] . . . sterile, aqueous solution . . . sodium selenite . . . Distributed By Transworld Laboratories, Inc., Piedmont, CA.”) were new animal drugs, and no approval of New Animal Drug Applications was in effect with respect to their use or intended use—501(a)(5).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64324; S. No. 84-398-829 et al.; S.J. No. 17)

Medical Devices


CHARGED 8-24-84: The article, which had been shipped by Marine & Travellers Agents, Sausalito, Calif., and which was labeled “Acu-Pulse Band—The Acupressure Band—Aids In The Relief Of Nausea Tension—Morning Sickness—Discomforts Of The Chest And Abdomen Naturally—Without Drugs,” had false and misleading labeling claims for nausea, tension, motion sickness, morning sickness, hangovers, discomforts of the chest and abdomen, sea sickness, nausea associated with chemotherapy, heartburn, insomnia, and hiccoughs—502(a); the labeling of the article lacked adequate directions for use, and neither adequate directions for use for the article's intended purposes nor adequate information for use by licensed practitioners for such purposes could be furnished—502(f)(1); the article was from an unregistered establishment and was not the subject of, or included in, a required device list—
502(o); and the article was a Class III medical device and there was no approved pre-market Medical Device Application in effect—501(f).

**DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 64342; S. No. 84-365-834; S.J. No. 18)

**PRODUCT:** Urine test kit, “Gender Test,” at Fountain Valley, C. Dist. Calif.; Civil No. 84-6550-AHS(Px).

**CHARGED 8-31-84 and amended 9-14-84:** While held by Walker Laboratories, Inc., t/a Walker Marketing and Page Testing Laboratories, Fountain Alley, Calif., who manufactured and promoted the article for determining the sex of infants before birth, the article’s labeling contained the false and misleading claim for determining fetal sex with 98.9 percent accuracy, when the article had not been shown to be adequate and effective for such purposes—502(a); the article’s labeling lacked adequate directions for use for the article’s intended purposes—502(f)(1); the article had been manufactured, prepared and processed in an unregistered establishment, was not listed as required, and had not been the subject of a pre-market notification—502(o)(1, 2, and 3); and the article was a Class II device lacking an effective approved pre-market application—501(f)(1)(B).

**DISPOSITION:** The manufacturer claimed the article and denied the charges. The government served written interrogatories and a request for the production of documents on the claimant. The claimant served written interrogatories on the government. Subsequently, the claimant served a second set of interrogatories on the government and served requests for admission. The government moved for summary judgment; and the claimant moved for summary judgment, claiming that the article was not a “device.” The court granted the government’s motion for summary judgment and ordered the article destroyed. The claimant filed a notice of appeal, but failed to perfect the appeal. (F.D.C. No. 64366; S. No. 84-354-781; S.J. No. 19)

**CRIMINAL ACTIONS**

**DEFENDANTS:** S. N. Long Warehouses, Inc., and Gary P. Reeve, president, and Raymond B. Laidet Jr., vice president, St. Louis, E. Dist. Mo.; Criminal No. 84-00212.

**CHARGED 6-10-83 in a complaint for injunction:** That FDA found a number of violations at the defendants’ plant, which made and distributed bakery products for retail sale. (S.J. No. 22)

**DISPOSITION:** Pursuant to stipulation of the parties, the court granted the government’s motion for summary judgment and ordered the article destroyed. The claimant filed a notice of appeal, but failed to perfect the appeal. (F.D.C. No. 64366; S. No. 84-354-781; S.J. No. 19)

**INJUNCTION ACTIONS**

**DEFENDANTS:** Barnhardt Manufacturing Co., Inc. (t/a Carolina Absorbent Cotton Co.), its subsidiary Richmond Dental Cotton Co., and Thomas M. Barnhardt III, president of the corporation and treasurer of the subsidiary, Charlotte, W. Dist. N.C.; Civil No. C-C-83-311P.

**CHARGED 5-27-83 in a complaint for injunction:** That the defendants, at their plant in Charlotte, N.C., manufactured, packed, labeled and distributed in interstate commerce various medical devices (e.g., sterile surgical dressings, gauze sponges, pads, and dental gauze); that the circumstances used for the manufacturing, packing and storing of such devices failed to conform with good manufacturing practice (GMP) regulations; that FDA inspections disclosed a number of deviations from good manufacturing practice; that samples of the defendants’ sterile gauze sponges were found by FDA to contain defective packages having visible openings and pinholes that might compromise the sterility of the sponges; that the firm had also recalled a number of its products because of package defects; and that the defendants were well aware that their activities were in violation of the law—501(h).

**DISPOSITION:** A consent decree of permanent injunction perpetually enjoined the defendants from doing a number of specified acts, including the following: enjoining them from shipping any device which had been produced or held under circumstances that failed to conform with current good manufacturing practice, or which fell below the device’s purported quality or purity; and enjoining production at the defendants’ plant unless and until the circumstances used for production of devices were in conformity with current good manufacturing practice regulations, and unless and until the defendants provided FDA with copies of validation studies of the defendants’ sterilizer equipment, with a report of GMP compliance actions, and with a certificate from a qualified plant inspector reporting that the defendants’ plant met the specified requirements. (Inj. No. 1017; S. Nos. 82-237-550/6; S.J. No. 21)

**DEFENDANTS:** Orlando Baking Co., Nicholas C. Orlando, president, and John C. Orlando, vice president, Cleveland, N. Dist. Ohio; Civil No. C-83-2429.

**CHARGED 6-10-83 in a complaint for injunction:** That FDA found a number of violations at the defendants’ Grand Avenue plant, which made and distributed bakery products for retail sale. (S.J. No. 21)

**DISPOSITION:** Pursuant to stipulation of the parties, the complaint was placed under seal of the court; and a consent decree of permanent injunction was filed in the normal course and was not placed under seal. The consent decree perpetually enjoined the defendants from preparing, packing or holding (at the defendants’ plant at Grand Avenue, Cleveland, Ohio) any interstate food so as to result in the food being prepared, packed or held under insanitary conditions—402(a)(3); and/or so as to result in the food containing insect, rodent or other filth—402(a)(4); and/or so as to result in the food being prepared, packed or held under insanitary conditions—402(a)(4). The decree also ordered the defendants to establish methods, facilities and controls to ensure that food was not contaminated at the defendants’ plant, ordered that the defendants arrange for an expert to certify that their plant had met specified requirements, and ordered that all food on hand which examination or analysis showed to be contaminated with filth be destroyed or otherwise brought into compliance with the law. (Inj. No. 1037; S. Nos. 82-237-550/6; S.J. No. 21)
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