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FDA CONSUMER

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

• VOL. 27 NO. 4

MAY 1993 •

FOCUS ON FOOD LABELING

READ THE LABEL



SET A HEALTHY TABLE



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Focus on Food Labeling

Good Reading for Good Eating

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Reading food labels will be more rewarding after manufacturers make changes required by new FDA and USDA regulations. An overview of the changes shows why.

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FDA is allowing claims on food about seven nutrient-disease relationships. They may begin appearing on products at your supermarket starting May 8.

'Nutrition Facts' to Help Consumers Eat Smart

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Figuring out the significance of the nutrients listed on packaged food panels used to often require more mathematical skill than many people wanted to use. Now the new panel will give information on calories, fats, sodium, fiber, sugar, and other nutrients in an easier-to-understand format.

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DVs, or Daily Values, are a new way to put food label information in perspective. FDA hopes these values will help consumers use food label information to plan a healthy diet.

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The process of writing the new food regs was sometimes like trying to carefully simmer a stew that persists in boiling over. Some of the "cooks" who stirred the pot provide insights into how a successful recipe emerged from their efforts.

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If this seems like a lot of paperwork, imagine 10 times more—that's how many comments FDA received on NLEA proposals. To find out more about the folks who worked on the proposals, see page 33.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

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Keep Iron Tablets Away from Children

Citing reports that five toddlers in the Los Angeles area died from June 1992 through January 1993 after eating iron supplement tablets, the U.S. Public Health Service warned parents to keep any iron supplements beyond the reach of children. PHS' national Centers for Disease Control and Prevention published a compilation of the reports in its *Morbidity and Mortality Weekly Report* of Feb. 19, 1993.

According to the CDC report, preliminary investigation by Los Angeles County found that:

- A 16-month-old boy died in June 1992 after eating iron tablets contained in a loosely capped container on a table.
- An 18-month-old boy died in September 1992 after eating iron tablets from an uncapped bottle found on a table.
- A 12-month-old boy died in November 1992 after eating iron tablets; no container was available.
- An 11-month-old girl died in December 1992 after a 2-year-old sibling fed her iron tablets from a box on the floor.
- A 13-month-old girl died in January 1993 after eating iron tablets spilled on the floor.

In the four cases where a container was found, all tablets were for use during pregnancy. They were prenatal, 325-milligram ferrous sulfate tablets with an elemental iron content of 60 mg per tablet. All containers had child-resistant safety caps and a warning to keep the medication away from children.

Although three of the deaths were from prescription tablets, 60-mg tablets are

available over-the-counter. As few as five tablets of a high-potency (110 mg) preparation could be fatal to a 22-pound child. Four of the children had eaten 30 tablets or more. Even though many of these tablets are sold over-the-counter and are in nutritional supplements, they are still potentially dangerous.

Iron is the most common cause of pediatric poisoning deaths reported to the U.S. poison control centers, CDC said. In 1991, the centers received reports of 5,144 ingestions of iron supplements, with 11 fatalities.

Hairsprays Flammable

Consumers may be seriously burned if aerosol hairspray products are exposed to



open flame during use or while still wet on the hair, FDA warned Feb. 23.

Recent reports of injuries and deaths from aerosol hairspray-related fires prompted FDA's warning. In many cases, hair ignited after inadvertent exposure of the aerosol hairspray to lit cigarettes,

matches or lighters—either directly or before the hairspray completely dried on the hair. Serious burns to the user's hair and upper body resulted.

Aerosol hairsprays that contain flammable ingredients are labeled with warning statements on proper use (for example: "Flammable. Avoid heat, fire and smoking during use until sprayed hair is fully dry.") Consumers should keep the products away from children.

Hydrocarbon propellants with SD alcohol 40 solvent are what make most aerosol hairsprays highly flammable.

Implantable Defibrillator Combines Three Actions

The first implantable device to combine three actions to help the heart beat regularly was approved by FDA last Feb. 11.

The Medtronic PCD (pacer cardioverter defibrillator) Tachyarrhythmia Control System can be electronically programmed to deliver:

- small, swift, "pacing" electrical impulses to restore regular beating to a heart whose rate is too slow (bradycardia) or too rapid (tachycardia)
- stronger "cardioversion" shocks to restore normal rhythm when pacing doesn't stop the irregularity
- a high-energy "defibrillation" shock to restart the heart when the PCD detects heart fibrillation, or quivering.

The PCD has three main parts: the pulse generator, wire leads, and an external programmer.

The pulse generator, about the size of a cassette tape, is implanted under the skin or muscles of the abdomen. It contains a

computer and battery that monitor the heart rhythm and deliver electrical stimuli when necessary.

Several wire leads, which carry the electrical impulses, connect the pulse generator to the surface of the heart.

The external programmer allows the doctor to fine-tune the pulse generator to the patient's needs. The programmer's memory bank stores facts, such as the number, types and success of heart-rhythm treatments the patient has received and a record of what the heart was doing during the most recent abnormal episode.

The device is intended for patients with chronic, prolonged abnormal heart rhythm, usually caused by coronary artery or heart muscle disease. Many people who have this kind of heart rhythm will have suffered and survived cardiac arrest or a stopped heart. Nearly 400,000 Americans die annually from abnormally fast or irregular heart rhythm.

In a study of 434 patients implanted with the PCD system, 271 patients together had more than 9,700 episodes of abnormal heart rhythm or cardiac arrest. The device corrected nearly 98 percent of these incidents, thus showing it can prevent sudden death in such patients.

Patients receiving the PCD should be closely followed by their doctors. FDA requires that the manufacturer, Medtronic, Inc., Minneapolis, track the patients and look for unexpected problems. The firm must also study certain aspects of performance, such as the lead system's function and fracture rate and the survival rate of PCD patients compared with that of patients implanted with another approved defibrillator.

U.S. First to Approve Single-Treatment Cancer Drug

The United States is the first country to approve a single-treatment intravenous drug for hairy cell leukemia, a rare, often fatal cancer of the blood and bone marrow.

The drug, Leustatin (cladribine), is given to patients in one continuous treatment over a seven-day period. In contrast, other cancer drugs are administered in several separate treatments over a period of months. Also, while most cancer drugs act only on one specific stage of cell activity, Leustatin destroys both dividing cells and cells at rest.

FDA approved the drug on March 2, 1993, after clinical trials showed that 89 percent of patients treated once with Leustatin experienced either complete or partial remission of cancer for eight to 25 months.

Patient follow-up is presently too short to assess the longer-term benefits of the drug. The company will be following patients who took part in the clinical trials and reporting long-term results to FDA.

The most serious side effects associated with Leustatin include fever and a low white blood cell count the first two months after treatment. Because only one treatment is required, patients may not have some of the recurrent side effects frequently associated with multiple treatments of cancer chemotherapy, such as nausea, vomiting, headaches, and rashes.

In early 1992, FDA granted the drug a treatment IND, allowing its expanded use before approval.

Hairy cell leukemia gets its name from the hairy appearance of the cancer cells under the microscope. The disease cur-

rently affects about 3,000 Americans, mostly men. Due to the low incidence of the disease, Leustatin has been designated an "orphan" product, a designation that provides incentives for companies developing products for diseases affecting fewer than 200,000 people in the United States.

Leustatin will be marketed by Ortho Biotech Inc., of Raritan, N.J., an affiliate of Johnson and Johnson.

Second Bioengineered Clotting Factor Licensed

A new genetically engineered clotting factor to treat people with hemophilia A was licensed by FDA last Feb. 28, following the recommendation of the agency's Blood Products Advisory Committee.

The product, antihemophilic factor (recombinant), is for preventing and controlling excessive bleeding and for preparing people with hemophilia A for surgery. Its brand name is Kogenate. Kogenate is the second recombinant DNA-derived clotting factor for people with hemophilia A. The first, Recombinate, was licensed last December. (See "New Treatment for Hemophiliacs" in the Updates section of the March 1993 *FDA Consumer* for more on Recombinate.)

People with hemophilia A, an inherited disorder, cannot form blood clots adequately because they lack or have insufficient blood-clotting protein factor VIII. The unchecked bleeding can be fatal.

Previously, patients were given factor VIII concentrates pooled from thousands of plasma donations. Kogenate is made using baby hamster kidney cells that have

been altered by recombinant DNA technology to produce factor VIII. The resulting factor is highly purified, eliminating any possibility of transmission of virus from plasma.

Kogenate is manufactured by Miles Inc., Elkhart, Ind.

Grand Jury Indicts Two Fruit Juice Manufacturers

As the result of an intensive investigation by FDA's Detroit district office, a federal grand jury, on Feb. 18, returned a 33-count indictment against two fruit juice manufacturers and seven individuals. The indictment charges that the defendants defrauded the public by replacing orange juice with low-cost, inferior ingredients in their orange juice products.

The indictment alleges that between 1979 and 1991, Peninsular Products Company of Lansing, Mich., and Flavor Fresh Foods Corporation of Chicago used beet sugar, citric acid, amino acids, and orange pulp wash in foods they falsely labeled and sold as orange juice from concentrate and concentrated orange juice for manufacturing. By using these ingredients in place of natural orange juice, the firms were able to sell their products at inflated prices, defrauding the public of more than \$10 million between 1984 and 1990 alone.

The two firms also added preservatives, including the antibiotic natamycin, to their products. Although the products containing natamycin do not pose a health risk, the preservative has not been tested for use in beverages and is not approved by FDA for such use. The agency has only approved natamycin for food use on cheeses to prevent mold growth.



Peninsular Products sold the orange juice under the Orchard Grove label. Flavor Fresh was sold under its own brand name. In addition, Peninsular packaged and sold adulterated orange juice under at least 23 other private label brands. The indictment does not allege that other private label distributors had any knowledge that the Peninsular or Flavor Fresh orange juice sold under their labels contained adulterants.

Products were sold in at least 11 states, including Illinois, Indiana, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, Ohio, Pennsylvania, and Tennessee. In addition, they were sold to numerous school districts under the U.S. Department of Agriculture school breakfast program, including Chicago area schools, the St. Louis, Mo., school system, and various Michigan schools, such as those in the Lansing, Grand Rapids, and Detroit areas.

Action Taken Under Program to Prevent Disease Transmission

Under a program to prevent transmission of AIDS, tuberculosis, and other diseases by endoscopes and other medical devices used inside the body, FDA has inspected 30 manufacturers of products used to sterilize devices and analyzed nine sterilant products. As a result, the agency issued seven warning letters, initiated two legal actions to seize products, and requested six recalls.

The agency began its inspections in 1990 with Sporicidin Co., of Rockville, Md., because this firm's sterilants—Sporicidin HD Solution and Sporicidin Cold Sterilizing Solution—were widely used. FDA testing confirmed reports in scientific literature that these products were ineffective.

At FDA's request, the firm's sterilants and its Sporicidin Brand Disinfectant Spray, Sporicidin Brand Disinfectant Solution, and Sporicidin Disinfectant Towelettes were seized in 1991 at three locations—the firm's headquarters in Rockville, a distribution warehouse in Baltimore, and a contract manufacturing site in Jonesborough, Tenn. None had been cleared for marketing by FDA, as the agency requires for such products.

A U.S. district court determined that the products at the Tennessee site were adulterated and ordered their destruction.

Acting with the Environmental Protection Agency and the Federal Trade Commission, which also took action against the firm, FDA ordered Sporicidin Co. to recall its sterilants. Before marketing them again, the firm will need to show FDA

evidence that they are safe and effective.

Last Feb. 12, FDA gave the firm clearance to market its three seized disinfectants for use only with medical devices not used inside the body. FDA is considering additional claims.

The agency is now reviewing general purpose disinfectants, used to disinfect and sanitize noninvasive medical devices such as hospital beds and wheelchairs.

Don't Rush Cataract Surgery, Expert Panel Advises

Physicians and patients should not rush into cataract surgery if glasses or visual aids provide satisfactory vision and the patient's lifestyle is not compromised, a panel of eye and health-care experts announced recently.

Only when patients have conditions such as glaucoma is cataract surgery necessary, according to the panel, whose recommendations were released Feb. 25 by the Agency for Health Care Policy and Research (AHCPR), a part of the U.S. Public Health Service.

The panel's clinical practice guidelines, "Cataract in Adults: Management of Functional Impairment," encourage patients and ophthalmologists to consider stronger glasses, magnifying lenses, pupil dilation, or a delay until the cataract becomes more burdensome.

A cataract, the clouding of the eye's lens, impairs vision, often reducing a person's ability to participate in various activities. Cataract surgery, which involves replacing the clouded lens with a plastic intraocular lens, is the most common surgical procedure among Americans

over 65. Younger people develop cataracts less frequently, but also require surgery at times.

Denis O'Day, M.D., the leader of the panel and chairman of the department of ophthalmology at Vanderbilt University School of Medicine, said, "The operating surgeon and patient should discuss the risks and benefits of cataract surgery, and then weigh them against the degree to which a cataract interferes with daily activities. Ultimately, the decision must be made by the patient."

During its research, the panel reviewed almost 8,000 published studies on cataract care, as well as information provided by consultants, specialty societies, and others. One study, which evaluated the incidence of retinal detachment after YAG-laser capsulotomy (a procedure to correct opaqueness of the remaining lens capsule), found the procedure to be associated with an almost fourfold increase in the risk of retinal detachment. Each year, more than 600,000 patients who previously had cataract surgery undergo this procedure.

The cataract guidelines are endorsed by the American Academy of Ophthalmology, Association of University Professors of Ophthalmology, American College of Surgeons, American Society of Ophthalmic Registered Nurses, National Society to Prevent Blindness, and the Alliance for Aging Research.

Copies of *Management of Cataracts in Adults*, a quick-reference brochure for clinicians based on the guidelines, and a guide for patients, are available free from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907, or by calling (1-800) 358-9295.

(See also "Lifting the Clouds of Cataracts" in the December 1989-January 1990 *FDA Consumer*.)

Early Detection Is Best Asthma Medicine

Parents who recognize the early symptoms of asthma in their children can play an important role in reducing the severity of the disease. This was the finding of a report in the journal *Pediatrics* by William Taylor, M.D., of the national Centers for Disease Control and Prevention and Paul Newacheck, DPH, of the University of California at Berkeley.

According to the report, there were 2.7 million cases of childhood asthma in 1988, the last year for which data are available. The disease causes 10 million missed days of school and 200,000 hospitalizations each year. Black children with asthma had more severe disability and more frequent hospitalizations, possibly, Taylor suggested, because black families were more likely to have inadequate health insurance.

The report found that almost 30 percent of children with asthma had some limitation in activity. However, with the right treatment, Taylor said, most children with asthma can take part in sports and exercise programs.

"While asthma has no cure," he said, "there is much the patient or the patient's caregiver can do to control it, especially if treatment is started when the disease first strikes."

Parents who suspect a child may have asthma should arrange for examination by a doctor, Taylor said. If asthma is diagnosed, the doctor can prescribe specific medicines and discuss ways to manage the

illness. The U.S. Public Health Service does not recommend treating a child's asthma with nonprescription medicines because these provide only temporary relief. The only effective treatments for asthma are those prescribed by a doctor.

Once a child is diagnosed with asthma, parents can help by:

- taking the child regularly to a doctor knowledgeable about the disease
- following whatever treatment plan the doctor advises
- asking family members with colds or flu to take precautions—such as washing hands—to avoid spreading germs
- making sure the child takes prescribed medicine.

The report was based on information from 17,100 households included in the PHS 1988 National Health Interview Survey.

(For more about asthma, see "More Than Snuffles: Childhood Asthma" in the July–August 1990 *FDA Consumer*.)

New Free Publication

"Use Medicine Safely" is a new FDA publication available free to the public. This booklet, geared to people with low-level reading skills, outlines a checklist of things to watch out for and discuss with the doctor to be sure medicines—both prescription and over-the-counter—are taken properly.

Up to 100 copies can be requested by writing to FDA, HFI-40, 5600 Fishers Lane, Rockville, MD 20857, or by faxing your order to (301) 443-9057. Be sure to include the publication number (FDA 93-3201).

Toll-Free Health Info Available

A list of toll-free numbers for health information from national organizations is available from the U.S. Public Health Service. Consumers can call these numbers for recorded data, referrals, printed material, and, in some cases, personal counseling for a variety of health concerns and diseases.



Some frequently called hot lines are:

- *National AIDS Hotline*
(800) 342-AIDS; 8 a.m. to 2 a.m.
Spanish language: (800) 344-7432
- *Alcoholism and Drug Addiction Treatment Center*
(800) 382-4357; 24 hours
- *Alzheimer's Disease and Related Disorders Association*
(800) 621-0370; 9 a.m. to 5 p.m.
In Illinois: (800) 572-6037
- *Asthma and Allergy Foundation of America*
(800) 7-ASTHMA; 9 a.m. to 5 p.m.
- *Arthritis Foundation Information Line*
(800) 283-7800; 9 a.m. to 7 p.m.
- *American Council of the Blind*
(800) 424-8666; 9 a.m. to 5:30 p.m.
In Washington, D.C.: (202) 467-5081
- *Cancer Information Service*
(800) 4-CANCER

In Alaska: (800) 638-6070;

In Oahu, Hawaii: (800) 524-1234;

9 a.m. to 10 p.m. weekdays; 10 a.m. to 6 p.m. Saturdays. (A service of the National Cancer Institute.)

- *National Child Abuse Hotline*
(800) 422-4453; operates 24 hours
- *American Diabetes Association*
(800) ADA-DISC; 8:30 a.m. to 5 p.m.
In Virginia and District of Columbia metro areas: (703) 549-1500
- *Dial a Hearing Screening Test*
(800) 222-EARS; 9 a.m. to 5 p.m.
In Pennsylvania: (800) 345-EARS
- *National Kidney Foundation*
(800) 622-9010; 9 a.m. to 5 p.m.
- *National Safety Council Lead Poisoning Hotline*
(800) 532-3394; operates 24 hours
- *Meat and Poultry Hotline*
(800) 535-4555; 10 a.m. to 4 p.m.
- *STD (Sexually Transmitted Diseases) Hotline*
(800) 227-8922; 8 a.m. to 8 p.m.

All times are Eastern for weekdays unless otherwise specified.

For a complete list of toll-free health information lines, telephone (800) 336-4797 between 9 a.m. and 5 p.m. (Eastern time) or write to: The Office of Disease Prevention and Health Promotion, National Health Information Center, P.O. Box 1133, Washington, DC 20013-1133. (An optional number, especially if the caller already knows the name of the national organization, is 800-555-1212.)

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

Good Reading For Good Eating

by Paula Kurtzweil

It may not have the power of a Pulitzer prize-winning novel or the luridness of a checkout counter tabloid, but the new food label still promises to make for good reading.

New regulations from FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture see to that. They ensure that:

- nutrition information will appear in the labeling of almost all foods
- labels will provide information on how the food fits into an overall daily diet
- labels will include information on the amount per serving of saturated fat, cholesterol, dietary fiber, and other nutrients of health concern to today's consumers
- terms used to describe a food's nutrient content—"light," "fat-free," and "low-calorie," for example—will meet government definitions so that they mean the same for any product on which they appear
- health claims about the relationship between a nutrient or food and a disease that



“The new food label is an unusual opportunity to help millions of Americans make more informed, healthier food choices.”

—David Kessler, M.D., Commissioner of Food and Drugs

are supported by scientific evidence will be allowed for the first time

- serving sizes:
 - are more consistent across product lines to make comparison shopping easier
 - are expressed in common household and metric measures
 - better reflect the amounts people really eat.

There will be many more products with labels to read because the regulations, for the first time, make nutrition labeling mandatory for almost all processed foods. Also, uniform point-of-purchase nutrition information will accompany many fresh foods, such as fruits and vegetables and raw fish, meat and poultry.

The new food label is reading that can be put to good use, too, because it's designed to help clear up much of the confusion that has prevailed on supermarket shelves. It also can help consumers choose more healthful diets. And it can serve as an incentive to food companies to improve the nutritional qualities of their products.

“[This isn't] just another government program,” said FDA Commissioner David Kessler, M.D. “The new food label is an unusual opportunity to help millions of Americans make more informed, healthier food choices.”

“We expect the labels also will provide more food companies with an incentive to improve the nutritional quality of their products,” said H. Russell Cross, Ph.D., FSIS administrator.

The new labels will start to appear on products this year, although manufacturers

have until May 8, 1994, to comply with most of FDA's new labeling requirements and until July 6, 1994, to comply with FSIS', which cover processed meat and poultry products. (FDA regulates labeling of most food products, except for meat and poultry products, which fall under FSIS' jurisdiction.)

FSIS' voluntary point-of-purchase nutrition information program for raw meat and poultry goes into effect then, too. Point-of-purchase information for fresh produce and raw fish has been available in some grocery stores since November 1991. (See “Nutrition Info Available for Raw Fruits, Vegetables, Fish” in the January-February 1993 *FDA Consumer*.)

Advertising is not covered by NLEA; however, the Federal Trade Commission has indicated it may apply the same criteria to advertising that FDA and FSIS do to labels.

A Look Back

The changes will mark the first extensive renovation of the food label since 1974, when FDA and USDA established voluntary nutrition labeling and began requiring nutrition information on labels of products that contain added nutrients or that carry nutrition claims. Other than adding sodium as a mandatory and potassium as a voluntary component to the list of nutrients allowed in voluntary nutrition labeling in 1984, the nutrition label has remained essentially the same all that time.

Nutrition labeling wasn't ignored during the interim, though, as Congress, regulators, and consumer and industry groups

put forth ideas to overhaul it. Their efforts intensified as consumers became more interested in nutrition, and food marketing strategies began to focus on that interest.

That marketing trend represented a departure from usual practice, according to Ed Scarbrough, Ph.D., director of the Office of Food Labeling in FDA's Center for Food Safety and Applied Nutrition.

“The line from industry used to be: ‘Nutrition won't sell food. It's price, taste and convenience,’ ” he said. “By the time we got into the 1980s, nutrition clearly was selling products. Industry recognized this and started making claims about the food.”

That was both good and bad, Scarbrough said. On the one hand, it gave consumers more information about nutrition. But on the other, claims got pushed to their outer limits as manufacturers scrambled to gain a competitive edge for their products.

“Consumers reacted to that,” he said. “They couldn't believe many of the claims being made.”

At about the same time, the Surgeon General of the U.S. Public Health Service and the National Academy of Sciences' National Research Council released two reports that lent strong support to development of a new food label. These reports—the 1988 *Surgeon General's Report on Nutrition and Health*, and the 1989 *National Research Council's Diet and Health: Implications for Reducing Chronic Disease Risk*—concluded that evidence substantiates an association between diet and risk of chronic disease and recommended similar dietary changes.

There will be many more products with labels to read because the regulations, for the first time, make nutrition labeling mandatory for almost all processed foods.

Those recommendations reflected what many public health experts had been saying for years: for example, that Americans should reduce their intake of fat (especially saturated fat), cholesterol and sodium; maintain appropriate body weight; and consume adequate amounts of calcium and fiber. The National Research Council's report went so far as to recommend quantitative amounts for certain nutrients.

It soon became apparent, however, that the current food label did not offer enough information to help consumers follow those guidelines. That, coupled with often questionable marketing practices, led to the first serious effort to revamp the food label.

Developing a New Label

The effort got under way in 1989, when FDA published an advance notice of proposed rule-making and, with FSIS, held nationwide hearings to find out what consumers, food manufacturers, and health professionals wanted on the food label.

Early in 1990, FDA began publishing proposals for new food labeling regulations that would, among other things, mandate nutrition labeling for almost all processed foods, limit health claims, establish reference Daily Values for certain nutrients, and define serving sizes.

Later that year, the Nutrition Labeling and Education Act (NLEA) became law, mandating numerous changes in food labeling. (The law does not cover meat and poultry products.)

NLEA resembles FDA's 1990 propos-

als in many ways. For example, it mandates nutrition labeling for almost all processed foods regulated by FDA and authorizes appropriate health claims on the labels of such products. It goes one step further by calling for activities to educate consumers about nutrition information on the label and the importance of using that information in maintaining healthful dietary practices.

According to John Vanderveen, Ph.D., director of FDA's Office of Plant and Dairy Foods and Beverages, the law makes the United States the first country in the world to have mandatory nutrition labeling and to allow health claims on food labels. "We've been pioneers," he said.

In November 1991, FDA announced proposals to implement many of the law's provisions. At the same time, FSIS issued parallel proposed regulations for meat and poultry.

Both agencies reviewed tens of thousands of public comments on the proposals before publishing the final regulations in the Jan. 6, 1993, *Federal Register*.

As allowed under NLEA, FDA delayed the date by which manufacturers must comply with the nutrition labeling and nutrient content claims provisions of NLEA by one year from the statutory effective date of May 8, 1993. FDA found that the earlier date would cause "undue economic hardship" on industry. FSIS postponed implementation of its regulations until July 1994 for the same reason.

However, consumers may start to see new labels this year, if, as expected,

manufacturers seek to make their products among the first with the new food label.

Briefly, here is what consumers can expect to see:

Mandatory Nutrition Labeling

About 90 percent of processed food will carry nutrition information. Among the exemptions will be plain coffee and tea; some spices, flavorings and other foods that contain no significant amounts of nutrients; ready-to-eat food prepared primarily on site, such as deli and bakery items; restaurant food; bulk food that is not resold; and food produced by small businesses. (As required under NLEA, FDA defines a small business as one with food sales of less than \$50,000 a year or total sales of less than \$500,000. FSIS defines a small business as one that employs 500 or fewer people and produces no more than a certain poundage of product.)

Foods in small packages (generally those no larger than a package of Life Savers, or meat and poultry products less than a half ounce) do not have to have nutrition information on their labels unless they make a nutrition claim. However, FDA-regulated products must carry a telephone number or address consumers can use to get required nutrition information.

Nutrition information is voluntary for many raw foods: the 20 most frequently eaten raw fruits, vegetables and fish, under FDA's voluntary point-of-purchase nutrition information program, and the 45 major cuts of meat and poultry, under USDA's voluntary point-of-purchase program.

MILESTONES IN U.S. FOOD LABELING

1906 The Federal Food and Drugs Act and the Federal Meat Inspection Act authorize the federal government to regulate the safety and quality of food. The responsibility falls to the U.S. Department of Agriculture and its Bureau of Chemistry, FDA's predecessor.

1913 The Gould Amendment requires food packages to state the quantity of contents.

1924 In *U.S. v. 95 Barrels Alleged Apple Cider Vinegar*, the Supreme Court rules that the Food and Drugs Act condemns every statement, design or device which may mislead, misdirect or deceive, even if technically true.

1938 The Federal Food, Drug, and Cosmetic Act replaces the 1906 Food and Drugs Act. Among other things, it requires the label of every processed, packaged food to contain the name of the food, its net weight, and the name and address of the manufacturer or distributor. A list of ingredients also is required on certain products. The law also prohibits statements in food labeling that are false or misleading.

1950 The Oleomargarine Act requires prominent labeling of colored oleomargarine to distinguish it from butter.

1957 The Poultry Products Inspection Act authorizes USDA to regulate, among other things, the labeling of poultry products.

1966 The Fair Packaging and Labeling Act requires all consumer products in interstate commerce to contain accurate information and to facilitate value comparisons.

1969 The White House Conference on Food, Nutrition, and Health addresses deficiencies in the U.S. diet. It recommends that the federal government consider developing a system for identifying the nutritional qualities of food.

1973 FDA issues regulations requiring nutrition labeling on food containing one or more added nutrients or whose label or advertising includes claims about the food's nutritional properties or its usefulness in the daily diet. Nutrition labeling is voluntary for almost all other foods.

1975 Voluntary nutrition labeling, postponed from its originally planned 1974 date, goes into effect.

1984 FDA adds sodium to the list of required, and potassium to the list of optional, nutrients on the nutrition panel. Effective in 1985, the new regulation also defines terms, such as "low sodium," that may be used on labels to make sodium-content claims.

1988 Surgeon General C. Everett Koop releases *The Surgeon General's Report on Nutrition and Health*, the federal government's first formal recognition of the role of diet in certain chronic diseases.

1989 The National Research Council of the National Academy of Sciences issues *Diet and Health: Implications for Reducing Chronic Disease Risk*, which presents additional evidence of the growing acceptance of diet as a factor in the development of chronic diseases, such as coronary heart disease and cancer.

Under contract with FDA and USDA's Food Safety and Inspection Service (FSIS), the Food and Nutrition Board of the National Academy of Sciences convenes a committee to consider how food labels could be improved to help consumers adopt or adhere to healthy diets. Its

recommendations are presented in *Nutrition Labeling: Issues and Directions for the 1990s*.

FDA publishes an advance notice of proposed rule-making on food labeling and, with FSIS participating, holds a series of four public hearings around the country.

1990 FDA proposes extensive food labeling changes, which include mandatory nutrition labeling for most foods, standardized serving sizes, and uniform use of health claims.

The Nutrition Labeling and Education Act reaffirms the legal basis for FDA's labeling initiative and establishes an explicit timetable.

1991 FDA issues more than 20 proposals to implement NLEA. In addition, the agency issues a final rule that sets up a voluntary point-of-purchase nutrition information program for raw produce and fish. FSIS unveils its proposals for mandatory nutrition labeling of processed meat and poultry and voluntary point-of-purchase nutrition information for raw meat and poultry.

1992 FDA's voluntary point-of-purchase nutrition information program for fresh produce and raw fish goes into effect.

1993 FDA issues the final regulations implementing NLEA. Regulations covering health claims become effective May 8, 1993. Those pertaining to nutrition labeling and nutrient content claims are effective May 8, 1994.

FSIS issues regulations for nutrition labeling of meat and poultry, effective July 6, 1994.

—P.K.



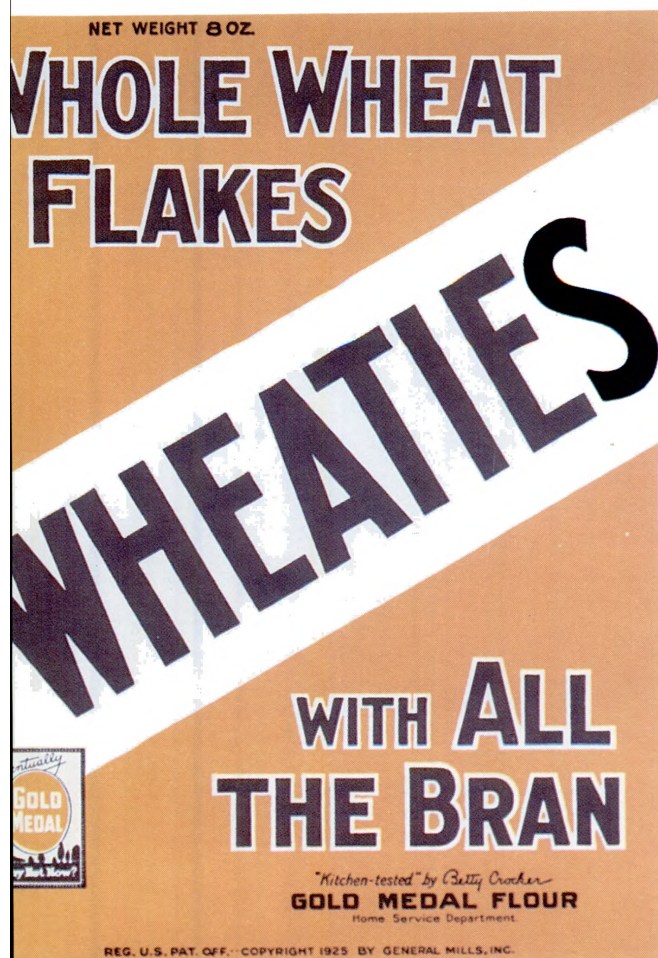
The 1938 law cracked down on many of the abuses shown in this label from the early 1900s, such as using a foreign language to give apparently mandatory information, omitting the name of the product and the quantity of contents, giving an apparently incomplete list of ingredients, and not specifically stating the manufacturer or distributor's name and place of business. (Photo No. 93-1759)



Under the 1906 Act, there was nothing to prevent manufacturers from making claims, such as the one on the far right of this label, implying that a food was certified or approved by FDA. The 1938 Federal Food, Drug, and Cosmetic Act outlawed these and other false and misleading claims, and they remain illegal today. (Photo No. 1758)

Until 1906, food labels were not required to give any information—so this one didn't. (Photo No. 1760)

The changes will mark the first extensive renovation of the food label since 1974.



WHEATIES (WHOLE WHEAT FLAKES) READY TO EAT

HERE—at last—is the right way to right weight for children and grown ups. Nature's way to normal health and energy.

WHEATIES are delicious breakfast flakes of whole wheat—with all the body building vitamins and natural mineral salts—in the perfectly balanced form that whole wheat yields.

Cereals should yield more than just energy and should contain the elements for growth.

WHEATIES bring you this wealth of food material in crisp appetizing flakes that are good to eat.

Wheaties Contain

VITAMINS A & B—which tend to promote growth, improved appetite, and resistance to disease.

PHOSPHATES—in a form valuable for regulating body functions.

LIME—for good bones and teeth.

IRON—for good red blood.

CARBOHYDRATES—in a digestible form to furnish energy.

WHEATIES contain all the natural bran of the wheat which aids in the elimination processes.

A bowlful of WHEATIES with milk or cream is an ideal breakfast or supper.

For recipes write to

Betty Crocker

Home Service Department
GOLD MEDAL FLOUR

Washburn Crosby Co., Inc.
Minneapolis, Minn.

Although voluntary, the programs for raw produce, meat, fish, and poultry carry strong incentives for retailers to participate. Guidelines state that if voluntary compliance is found to be insufficient, the agencies may move to make it mandatory.

Nutrition Panel

A revised list of nutrients—selected because of their relationship to current health concerns—will appear on the nutrition panel. (See “‘Nutrition Facts’ to Help Consumers Eat Smart” on page 22.) Some of the nutrients are carryovers from the previous label: calories, total fat, total carbohydrate, protein, sodium, vitamins A and C, calcium, and iron. The new ones are calories from fat, saturated fat, cholesterol, sugars, and dietary fiber. No longer required are thiamin, riboflavin and niacin because deficiencies of these vitamins are no longer considered significant public health problems. However, manufacturers may list these and other nutrients if they choose, subject to certain conditions.

Serving sizes specified on labels now will be more uniform across all product lines so that consumers can more easily compare the nutritional qualities of similar products. They also will be closer to the amounts people actually eat.

The amount of certain nutrients will be expressed not only in terms of the amount per serving but also in terms of a percent of a new dietary reference value, called the Daily Value. The “percent Daily Values” will be based on a 2,000-calorie diet.

Although health claims proliferated in the 1980s, they've been around for years, as the right panel of this 1925 label for Wheaties shows.

(Photo courtesy of General Mills Inc.)

Serving sizes specified on labels now will be more uniform across all product lines so that consumers can more easily compare the nutritional qualities of similar products.

(See “‘Daily Values’ Encourage Healthy Diet” on page 28.)

Requiring nutrients to be declared as a percent of the Daily Value is intended to help consumers understand the role of individual foods in the context of the total daily diet.

Nutrient Content Claims

Any term used to describe the nutrient content of a food will mean the same on every product on which it appears. Also, the list of acceptable claims now includes such descriptors as “free,” “low,” “light” (or “lite”), “reduced,” “less,” and “high.” “Lean” and “extra lean” also have been defined and will apply specifically to the fat content of meat, including game meat, poultry, and fish.

Health Claims

Claims linking a nutrient or a food to the risk of a disease or health-related condition now will be allowed only under certain circumstances on FDA-regulated products. FDA will allow statements about the relationships between:

- calcium and osteoporosis
- fat and cancer
- saturated fat and cholesterol and coronary heart disease (CHD)
- fiber-containing grain products, fruits and vegetables and cancer
- fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and CHD
- sodium and hypertension

- fruits and vegetables and cancer.

There are strict requirements about when and how these claims can be used. (See “Starting This Month, Look for ‘Legit’ Health Claims on Foods” on page 14.)

Ingredient Labeling

Full ingredient labeling will appear on all processed, packaged foods, including standardized foods such as mayonnaise, macaroni and bread, which previously were exempt.

Also, for the first time, the ingredient list will include, when appropriate:

- FDA-certified color additives, such as FD&C Yellow No. 6, by name
- sources of protein hydrolysates, which are used in many foods as flavor enhancers
- declaration of caseinate as a milk derivative in foods that claim to be nondairy, such as coffee whiteners.

In addition, beverages that claim to contain juices must declare the total percentage of juice on the information panel. (See “Ingredient Labeling: What’s in a Food?” in the April 1993 *FDA Consumer*.)

Economic Impact

It is estimated that the new food label will cost FDA-regulated food processors between \$1.4 billion and \$2.3 billion over the next 20 years. However, the benefits to public health—measured in monetary terms—are estimated to well exceed the costs. Potential benefits include decreased

rates of coronary heart disease, cancer, osteoporosis, obesity, high blood pressure, and allergic reactions to food.

Public Education

To help consumers get the most from the new food label, FDA and USDA have embarked on a multi-year food labeling education campaign. The campaign involves participation by consumer, trade and health groups, as well as by other government agencies. Its purpose is to increase consumers’ knowledge and effective use of the new food label and assist them in making accurate and sound dietary choices in accordance with the Dietary Guidelines for Americans.

“The food label of the future will have more information and be more complicated,” FDA’s Scarbrough said. “Its usefulness will be diminished unless consumers are taught what to do with the information.”

Fred Shank, Ph.D., director of FDA’s Center for Food Safety and Applied Nutrition, and other nutrition experts acknowledge that the task of teaching consumers how to use the new label will be formidable.

“It’s been a long haul,” Shank said about efforts to revamp the label. “But the greatest challenge lies ahead—in educating consumers.” ■

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



STARTING THIS MONTH

Look For 'LEGIT' Health Claims On Foods

by Dixie Farley

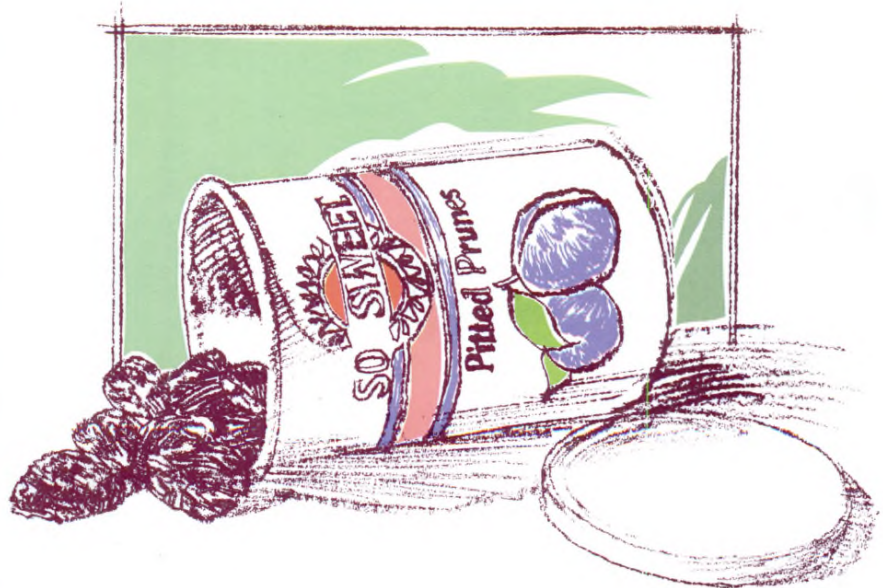
Planning a healthy diet will soon be easier. Beginning this May 8, food labels may provide not only the nutrient content of products but also claims about certain relationships between diet and disease.

As mandated by the Nutrition Labeling and Education Act of 1990, the Food and Drug Administration has issued final food labeling rules for health claims. (See accompanying summary.) The rules, published in the Jan. 6, 1993, *Federal Register*, allow claims about seven relationships:

- calcium and a reduced risk of osteoporosis (a condition of lowered bone mass)
- sodium and an increased risk of hypertension (high blood pressure)
- dietary saturated fat and cholesterol and an increased risk of coronary heart disease
- dietary fat and an increased risk of cancer
- fiber-containing grain products, fruits, and vegetables and a reduced risk of cancer
- fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and a reduced risk of coronary heart disease
- fruits and vegetables and a reduced risk of cancer.

"These rules allow information on food labels that can help to educate the public about recognized diet-disease relationships," says Elizabeth Yetley, Ph.D., acting director of FDA's Office of Special Nutritionals. "Authorized claims must meet requirements to prevent label information that would be false or misleading." Yetley coordinated the agency's health claims evaluation.

Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.



Health claims became a hot issue in the 1980s, when food marketing strategies began reflecting increased recognition of the role of nutrition in promoting health. A 1984 ad campaign by the Kellogg Company for All Bran cereal advised consumers to maintain proper weight and eat a well-balanced diet including low-fat, high-fiber foods, fresh fruits, and vegetables. Stating the National Cancer Institute “believes eating the right foods may reduce your risk of some kinds of cancer,” the health message was both attributed to and approved by NCI.

According to an FDA survey by Alan Levy, Ph.D., and Raymond Stokes, Ph.D., sales of high-fiber cereals increased 37 percent within a year as consumers apparently discriminated between high- and low-fiber products.

Under the provisions of the Federal Food, Drug, and Cosmetic Act in effect at that time, FDA took the position that information about a disease on a food label implied that eating the food could beneficially affect the course of the disease. The agency considered such statements to be drug claims.

In 1987, however, in response to developing scientific data on the relationship between diet and disease, FDA proposed changing its policy to permit appropriate health messages on food labels. The agency noted that the rapid increase in in-

formation and of public interest in nutrition “argues for recognition and dissemination of such new knowledge, and food labels offer one appropriate vehicle for this dissemination.”

Soon, many claims appeared on foods—often only partly meeting FDA’s proposed criteria. For this reason and because of widely divergent comments on the proposal, FDA solicited additional comments and held a public hearing. The agency withdrew the 1987 proposal and repropose regulations in February 1990 to more narrowly define health claims and more clearly state its criteria for claims.

Scientific support for diet-disease relationships and public interest in health continued to grow, encouraging Congress in the fall of 1990 to pass the Nutrition Labeling and Education Act. The new law confirmed FDA’s authority to regulate health claims on food. Among other things, it required that the agency determine whether health claims were appropriate for 10 relationships:

- calcium and osteoporosis
- sodium and hypertension
- lipids (fats and fat-like substances) and cardiovascular (heart and blood vessel) disease
- lipids and cancer
- dietary fiber and cardiovascular disease
- dietary fiber and cancer
- folic acid and neural tube defects

- antioxidant vitamins and cancer (antioxidants inhibit or prevent oxidation—a chemical reaction whose effect in the body is not well-understood)
- zinc and immune function in the elderly
- omega-3 fatty acids and heart disease.

FDA evaluated the scientific evidence and published its tentative findings in the Nov. 27, 1991, *Federal Register* food labeling proposal. The health claims proposals garnered more than 6,000 letters. To reach its final decisions about health claims, FDA reviewed more than 1,400 scientific studies and authoritative reports.

Definitions, Restrictions

According to the final rule, a “health claim” is any claim on the package label or other labeling (such as an ad) of a food, including fish and game meats, that characterizes the relationship of any nutrient or other substance in the food to a disease or health-related condition.

An example of a health claim is, “Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.” This claim associates the two necessary components: a specific nutrient or food substance and a specific health problem.

Health claims include implied claims, which indirectly assert a relationship. Implied claims may appear as third-party references, such as “The National Cancer In-

Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.



stitute recommends a high-fiber diet." Brand names (such as "Heart Smart"), symbols (such as heart-shaped logos), and vignettes (descriptions), when used with specific nutrient information, may within the context of the label result in a health claim.

In contrast, claims about general health or food classes are not health claims. Some examples: the Food Guide Pyramid logo (a pyramid-shaped depiction of the Dietary Guidelines for Americans), valentine candy in a heart-shaped box, and "Eat five servings of fruits and vegetables a day for good health." FDA would consider those examples health claims if a specific nutrient and disease were introduced—the term "low fat" and a heart logo, for instance. Context is the key.

The definition does not cover nutrient-deficiency diseases—such as scurvy, caused by lack of vitamin C. Such diseases, which are no longer of major public health significance in the United States, are adequately regulated under other portions of the FD&C Act. Thus, FDA believes it would be inappropriate to subject these relationships to the health claims rules.

Finally, health claims do not apply to:

- exempt infant formulas
- foods intended for children under 2 years
- medical foods, which are foods formu-

lated for dietary management of diseases or other medical conditions

- foods regulated as drugs.

To qualify for labeling with a health claim, foods must contain:

- a nutrient (such as calcium) whose consumption at a specified level as part of an appropriate diet will have a positive effect on the risk of disease or
- a nutrient of concern (such as fat) below a specified level.

The foods must contribute nutrition to the diet by containing at least 10 percent of the Daily Value (DV) of one or more of the nutrients vitamin A, vitamin C, iron, calcium, protein, and fiber. These nutrients must occur naturally in the food at least at 10 percent of the DV.

The Nutrition Labeling and Education Act specifies that foods bearing health claims must not contain any nutrient or food substance in an amount that increases the risk of a disease or health condition. Because dietary guidance calls for people to limit intake of fat, saturated fat, cholesterol, and sodium, FDA identified these substances as risk nutrients and set disqualifying levels for them per serving and per reference amount and, when a food has a small reference amount (30 grams or two tablespoons or less), per 50 g of the food. (As stated in FDA's new rule, the "reference amount" is the amount customarily consumed on an eating occasion. The

serving size will be close, but not necessarily identical, to the reference amount.) Foods bearing health claims, then, must contain 20 percent or less of the DV of: fat (13 g), saturated fat (4 g), cholesterol (60 milligrams), and sodium (480 mg).

Thus, whole milk, which is high in calcium, may not bear a calcium-osteoporosis claim because its fat content exceeds the disqualifying levels, and excess fat increases the risk of cancer and heart disease. Skim, 1 percent, and 2 percent milks and milk products generally qualify for calcium-osteoporosis health claims.

Main dish products (6 ounces or more with not less than 40 g of two foods from two or more of the four food groups) and meal products (10 ounces or more with not less than 40 g of three or more foods from two or more food groups) may not bear claims if they contain, respectively, 30 or 40 percent or more of the DV for a disqualifying nutrient. FDA may by regulation permit a claim on food that contains a nutrient in amounts that exceed the disqualifying level if the agency finds that the claim will help consumers maintain a healthy diet, and the labeling discloses the presence of the nutrient at that level. No such exceptions have yet been made.

Every statement, phrase or symbol on a food label (health claim or not) must be truthful and not misleading. Because many factors affect disease development, it

About Supplements. . .

The Dietary Supplement Act, Title II of the Prescription Drug User Fee Act of 1992, prohibits FDA until at least Dec. 15, 1993, from making final labeling rules for supplements and from taking action against supplements for unauthorized health claims. The legislation became law Oct. 30, 1992.

As with conventional food, however, a supplement component may qualify for a health claim under the Nutrition Labeling and Education Act of 1990 if it confers a health benefit due to its nutritive value and meets other FDA health claims criteria.

"If a nutrient is shown to provide the benefit, then it's the nutrient content that's important, not its source," says Elizabeth Yetley, Ph.D., of FDA's Center for Food Safety and Applied Nutrition, who coordinated the agency's review of health claims.

Dietary supplements include products providing nutrition, such as vitamins, minerals, amino acids, and fatty acids. They also include substances such as herbs and bee pollen.

Under the Nutrition Labeling and Education Act, even when a supplement contains a nutrient in an amount in excess of that found in conventional food, the rule doesn't necessarily prevent a health claim. For example, a calcium-osteoporosis health claim would be permitted in supplements containing calcium in higher potencies than those found naturally in foods such as dairy products, provided the supplement meets the claim's other criteria. If the potency exceeds 400 milligrams a day, however, the labeling must state there's no known benefit from taking more than 2,000 mg a day.

Meanwhile, the new supplements act requires that, during 1993, the General Accounting Office study FDA's management of dietary supplements, and the Office of Technology Assessment study the relationship between supplements regulation (in other countries as well as the United States) and health outcomes. Under the act, FDA is to publish proposed rules (by June 15) and final rules (by Dec. 31, but no earlier than Dec. 15) that are responsive to the Nutrition Labeling and Education Act regarding supplements. ■

—D.F.

would be misleading to overemphasize the role of the food substance in a claim, such as indicating it will prevent the disease. Claims that a substance will prevent a disease are drug claims. Thus, in discussing the diet-disease relationship, health claims may only say the substance "may" or "might" reduce the risk. Claims must indicate the disease depends on many factors and may be required to mention other factors that affect the benefit—such as regular exercise, in calcium-osteoporosis claims.

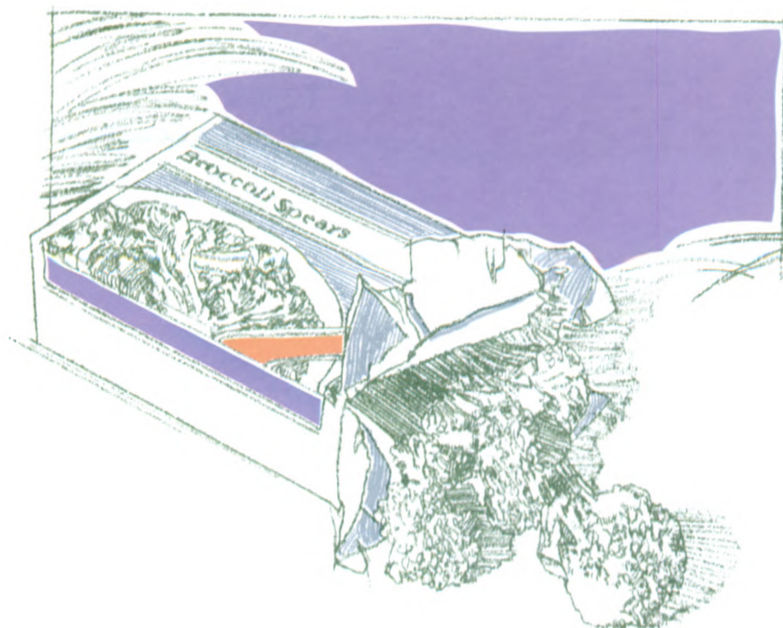
Health claims cannot substitute a disease risk indicator for the disease itself, unless authorized. Claims for fat and heart disease, for instance, may optionally include the link of lowering blood cholesterol—as in, "Development of heart disease depends upon many factors. A healthful diet low in saturated fat and cholesterol may lower blood cholesterol levels and may reduce the risk of heart disease."

Many claims will be consistent with certain recognized dietary guidelines and may state them. A sodium-hypertension health claim, for instance, may say it is consistent with dietary guidelines to "use salt and sodium in moderation." Some other optional information is allowed, such as the number of people affected by the disease.

New Claims

When petitioned, FDA will authorize new claims if specific requirements are met.

While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.



First, the nutrient or food substance must be related to a disease or health condition for which most people or a specific group of people, such as the elderly, are at risk.

Second, for a claim to be valid, the rules require significant agreement among qualified experts that the claim is supported by the "totality of publicly available scientific evidence." This evidence must include data from well-designed studies conducted with recognized scientific procedures and principles.

OTC Drugs with Food Health Claims

Over-the-counter drugs that are also foods present complicating concerns for FDA. One such case is calcium antacids, which have been used as dietary supplements as well.

As drugs, such products are labeled for short-term problems, which, if persistent, may indicate a more serious condition, such as an underlying ulcer. Consequently, the drug labeling directs users to see a doctor if symptoms persist. As food supplements, however, these products are labeled for long-term use at lower levels consistent with daily dietary guidelines. The labeling usually provides no directions to seek medical help and places no time limits on use.

Even though the label may separate such dual directions, FDA is concerned a person may incorrectly assume the medical dosage is safe for dietary usage.

"If firms want to market products with both food and drug instructions or with health claims," says FDA's Yetley, "they may need to provide data to show the agency that the labeling won't confuse consumers, that consumers can differentiate between drug instructions and food or health claim instructions, and that, therefore, the product won't be misused."

Guidelines for Using Health Claims

In labeling with approved health claims, all statements about the diet-disease relationship must be consistent with FDA conclusions. Claims must enable consumers to understand the relationship and the nutrient or food substance's importance in the relationship in terms of a total daily diet.

Required information must be of one type size and in one place, without intervening material. The main panel may refer to a claim located elsewhere, as in an attached pamphlet.

When a health-claim graphic, such as a heart symbol, is used, the claim or a reference to its location must be nearby.

The food label must list the content of the nutrient for which a health claim is made.

If a claim is about reduced levels of a nutrient, such as cholesterol, the content must be low enough to qualify for the approved claim or must meet the FDA definition for "low."

If a claim is made about a nutrient at in-

creased levels, the content must be in an appropriate form and high enough to justify the claim. If a definition exists for the nutrient, the content must meet that definition's "high," unless the approved health claim specifies an alternative level.

Denied Claims

FDA denied a claim for omega-3 fatty acids in reducing the risk of coronary heart disease. Omega-3s are found in oily fish and sea mammals. John Wallingford, Ph.D., who led FDA's review of this claim, noted, "Results of studies relating fish intake and risk of coronary heart disease were conflicting and inconsistent. The most compelling evidence was a well-controlled study that showed fish consumption may reduce the chance of death from a second heart attack. However, these studies did not establish that the effects were due specifically to omega-3 fatty acids."

Data revealed that omega-3s may raise the blood LDL-cholesterol (the bad type) of people with high blood fats and may interfere with blood glucose control in diabetics.

FDA also denied a claim about zinc (an essential trace mineral) and immune function in the elderly. Some studies had suggested that older people consume less zinc than recommended and that intake declines as people age. FDA concluded the evidence did not support the theory that increased dietary zinc would improve the

Claim Specifics

Calcium and osteoporosis. Low calcium intake is one risk factor for osteoporosis, a condition of lowered bone mass, or density. Lifelong adequate calcium intake helps maintain bone health by increasing as much as genetically possible the amount of bone formed in the teens and early adult life and by helping to slow the rate of bone loss that occurs later in life.

Typical foods. Low-fat and skim milks, yogurts, tofu, calcium-fortified citrus drinks, and some calcium supplements.

Requirements. A food or supplement must be "high" in calcium (at least 200 milligrams of assimilable calcium per reference amount or per daily dose of a calcium supplement; a "reference amount" is the amount customarily consumed on an eating occasion). It must not contain more phosphorus than calcium. Claims must cite other risk factors, such as a person's gender, race and age; state the need for regular exercise and a healthful diet; explain that the way adequate calcium intake early in life helps reduce fracture risk later in life is by increasing as much as genetically possible a person's peak bone mass; and indicate that those at greatest risk of developing osteoporosis later in life are white and Asian teenage and young adult women, who are in their bone-forming years. Claims for foods or supplements with more than 400 mg of calcium per reference amount or daily dose must state that a daily intake over 2,000 mg offers no added known benefit to bone health.

Sodium and hypertension (high blood pressure). Hypertension is a risk factor for coronary heart disease and stroke deaths. The most common source of sodium is table salt. Diets low in sodium may help lower blood pressure and related risks in many people. Guidelines recommend daily sodium intakes of not more than 2,400 mg. Typical U.S. intakes are 3,000 to 6,000 mg.

Typical foods. Unsalted tuna, salmon, fruits and vegetables, and low-fat milks, low-fat yogurts, cottage cheeses, sherbets, ice milk, cereal, flour, and pastas (not egg pastas).

Requirements. Foods must meet criteria for "low sodium" (140 mg or less of sodium per reference amount and, when a food has a small reference amount of 30 g or 2 tablespoons or less, per 50 g of the food). Claims must use "sodium" and "high blood pressure" in discussing the nutrient-disease link.

Dietary fat and cancer. Diets high in fat increase the risk of some types of cancer, such as cancers of the breast, colon and prostate. While scientists don't know how total fat intake affects cancer development, low-fat diets reduce the risk. Experts recommend that Americans consume 30 percent or less of daily calories as fat. Typical U.S. intakes are 37 percent.

Typical foods. Fruits, vegetables, reduced-fat milk products, cereals, pastas, flours, and sherbets.

Requirements. Foods must meet criteria for "low fat" (3 g or less of fat per reference amount and, when a food has a small reference amount, per 50 g of the food). Fish and game meats must meet criteria for "extra lean." Claims may not mention specific types of fats and must use "total fat" or "fat" and "some types of cancer" or "some cancers" in discussing the nutrient-disease link.

Dietary saturated fat and cholesterol and risk of coronary heart disease. Diets high in saturated fat and cholesterol increase total and low-density (bad) blood cholesterol levels and, thus, the risk of coronary heart disease. Diets low in saturated fat and cholesterol decrease the risk. Guidelines recommend that American diets contain less than 10 percent of calories from saturated fat and less than 300 mg cholesterol daily.

The average American adult diet has 13 percent saturated fat and 300 to 400 mg cholesterol a day.

Typical foods. Fruits, vegetables, skim and low-fat milks, cereals, whole-grain products, and pastas (not egg pastas).

Requirements. Foods must meet criteria for "low saturated fat" (1 g or less of saturated fat per reference amount and 15 percent or less of calories from saturated fat); "low cholesterol" (20 mg or less of cholesterol per reference amount and, when a food has a small reference amount, per 50 g of the food); and "low fat." Fish and game meats must meet criteria for "extra lean." Claims must use "saturated fat and cholesterol" and "coronary heart disease" or "heart disease" in discussing the nutrient-disease link.

Fiber-containing grain products, fruits, and vegetables and cancer. Diets low in fat and rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer. The exact role of total dietary fiber, fiber components, and other nutrients and substances in these foods is not fully understood.

Typical foods. Whole-grain breads and cereals, fruits, and vegetables.

Requirements. Foods must meet criteria for "low fat" and, without fortification, be a "good source" of dietary fiber. Claims must not specify types of fiber and must use "fiber," "dietary fiber," or "total dietary fiber" and "some types of cancer" or "some cancers" in discussing the nutrient-disease link.

Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, may reduce the risk of coronary heart disease. (It is impossible to ad-

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

equately distinguish the effects of fiber, including soluble fiber, from those of other food components.)

Typical foods. Fruits, vegetables, and whole-grain breads and cereals.

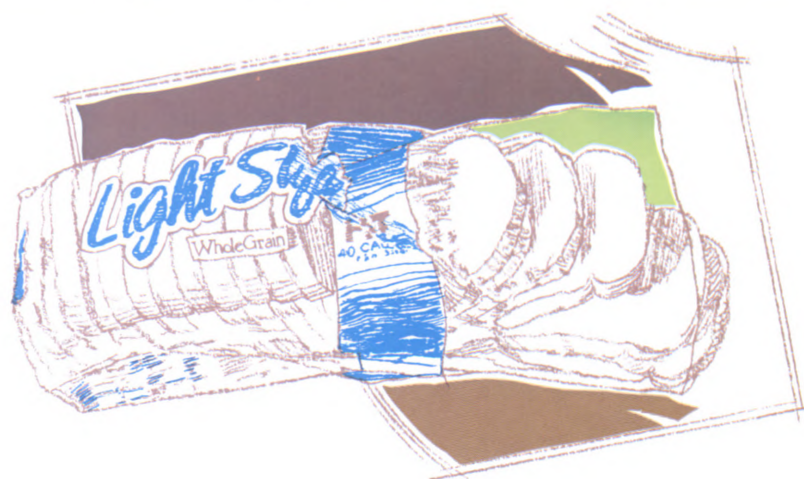
Requirements. Foods must meet criteria for "low saturated fat," "low fat," and "low cholesterol." They must contain, without fortification, at least 0.6 g of soluble fiber per reference amount, and the soluble fiber content must be listed. Claims must use "fiber," "dietary fiber," "some types of dietary fiber," "some dietary fibers," or "some fibers" and "coronary heart disease" or "heart disease" in discussing the nutrient-disease link. The term "soluble fiber" may be added.

Fruits and vegetables and cancer. Diets low in fat and rich in fruits and vegetables may reduce the risk of some cancers. Fruits and vegetables are low-fat foods and may contain fiber or vitamin A (as beta-carotene) and vitamin C. (The effects of these vitamins cannot be adequately distinguished from those of other fruit or vegetable components.)

Typical foods. Fruits and vegetables.

Requirements. Foods must meet criteria for "low fat" and, without fortification, be a "good source" of fiber, vitamin A, or vitamin C. Claims must characterize fruits and vegetables as foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C; characterize the food itself as a "good source" of one or more of these nutrients, which must be listed; refrain from specifying types of fatty acids; and use "total fat" or "fat," "some types of cancer" or "some cancers," and "fiber," "dietary fiber," or "total dietary fiber" in discussing the nutrient-disease link. ■

—D.F.



immune function in older Americans.

Some studies appeared to show zinc supplements improved immunity to disease in older people. But the number of study participants was limited, many studies were flawed, and reported improvements were small. In larger, well-designed studies in which older patients received either zinc or placebos (inert pills) in addition to multi-vitamin and mineral preparations, the greatest immune function improvements were among those taking placebos. Zinc supplementation not only did not improve immune system function in the elderly, at 100 mg or more a day, it actually suppressed immunity.

FDA denied a claim for folic acid and neural tube birth defects. The agency continues, however, to consider this issue. Neural tube defects occur within the first six weeks after conception, often before the pregnancy is known. Adequate daily folic acid intake (at least 0.4 mg, or 400 micrograms, but not more than 1 mg) has been recommended for women from puberty through menopause to reduce the risks of having a baby with these severe birth defects.

The agency convened an advisory committee of outside experts to resolve the remaining issues. "We are proceeding as

quickly as possible to evaluate several potential safety issues," Yetley explains. "We don't want to have a health claim if it might cause harm."

FDA denied claims for fiber and cancer, fiber and cardiovascular disease, and antioxidant vitamins and cancer because the scientific evidence was inconclusive. It is impossible to adequately distinguish effects of fiber or antioxidants from those of other food components, the agency said.

Nevertheless, in approving the claim for fruits and vegetables and cancer, FDA incorporated information on vitamin A (as beta-carotene) and vitamin C. These nutrients are found in fruits and vegetables whose use as part of total dietary patterns is associated with reduced cancer risks.

As stated in the 1991 proposal, FDA considers a health claim on a food label "a promise to consumers that including the food in a diet . . . will be helpful in attaining the claimed benefit and will not introduce a risk of another disease or health-related condition." ■

Dixie Farley is a staff writer for FDA Consumer. Ellen Anderson, Ph.D., a research chemist in FDA's Center for Food Safety and Applied Nutrition, also contributed to this article.

'NUTRITION FACTS'

To Help Consumers Eat Smart

by Paula Kurtzweil

Susan Thom, of Parma, Ohio, knows how important it is for people to know the number of calories from fat they eat each day.

As a registered dietitian, she counsels patients on the need to limit fat consumption to 30 percent or less of total daily calories. As a person with diabetes, and thus at increased risk for heart disease, she strives to do the same for herself.

But, in the past, obtaining that information from the food label has required some mathematical skill—namely, multiplying the total grams (g) of fat in a serving by 9, since 1 g of fat contains 9 calories.

"It does take time," Thom said. "But if you want to feed yourself well, you have to look at the label."

Help is on the way. For Thom and millions of other Americans who seek to restrict their fat intake to recommended levels, a new dietary component is being added to the food label—"calories from fat."

It's just one of many new items of diet-related information manufacturers are required to offer on their food products by 1994. There also will be information on saturated fat, cholesterol, dietary fiber, and other nutrients that relate to today's health concerns, such as heart disease, cancer, and other diseases linked, at least in part, to diet.

There will be more complete nutrient content information because almost all the required nutrients will have to be listed as a percent of the Daily Value. There will be more uniform serving sizes, too, which will make nutritional comparisons between foods easier. And, because nutrition labeling is now mandatory for almost all processed foods, there will be a lot more products with this important information.

"The new information is going to be very helpful for consumers," said Virginia Wilkening, a registered dietitian in FDA's Office of Food Labeling.

"Some of the nutrients—saturated fat and cholesterol—have been allowed on the label before but on a voluntary basis," she said. "Dietary fiber and sugars were not allowed in the nutrition label. With the new label, consumers will soon have information about these and other nutrients, which can help them choose their foods more wisely."

The new requirements for nutrition labeling are spelled out in regulations issued in January 1993 by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). FDA's regulations meet the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), which, among other things, re-

quires FDA to make nutrition labeling mandatory for almost all processed foods. FSIS' regulations, which cover meat and poultry products, largely parallel FDA's. (Meat and poultry products were not covered by NLEA.)

FDA has set May 8, 1994, as the date by which food manufacturers must comply with the new nutrition labeling regulations. FSIS requires meat and poultry processors to relabel their products by July 6, 1994. However, some newly labeled products may begin appearing in grocery stores much sooner than the deadlines.

Dietary Components

What can consumers expect? First, they will see a new name for the nutrition panel. It used to go by "Nutrition Information Per Serving." Now, it will be called "Nutrition Facts." That title will

Old Label

NUTRITION INFORMATION		PER SERVING	PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)
SERVING SIZE.....	5 OZ.		PROTEIN.....10
SERVINGS PER CONTAINER.....	4		VITAMIN A.....*
CALORIES.....	250		VITAMIN C.....*
PROTEIN.....	9g		THIAMINE.....8
CARBOHYDRATE.....	19g		RIBOFLAVIN.....15
FAT.....	11g		NIACIN.....2
SODIUM.....	530mg		CALCIUM.....20
			IRON.....4

*CONTAINS LESS THAN 2% OF THE U.S. RDA OF THIS NUTRIENT

Starting this year, the 'old' nutrition label format above will be replaced by the one on the right. Both labels are for a frozen macaroni and cheese product.

Key Aspects of the New Nutrition Label

A number of consumer studies conducted by FDA, as well as outside groups, enabled FDA and the Food Safety and Inspection Service of the U.S. Department of Agriculture to agree on a new nutrition label. The new label is seen as offering the best opportunity to help consumers make informed food choices and to understand how a particular food fits into the total daily diet.

New heading signals a new label.

More consistent serving sizes, in both household and metric measures, replace those that used to be set by manufacturers.

Nutrients required on nutrition panel are those most important to the health of today's consumers, most of whom need to worry about getting too much of certain items (fat, for example), rather than too few vitamins or minerals, as in the past.

Conversion guide helps consumers learn caloric value of the energy-producing nutrients.

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260 **Calories from Fat** 120

% Daily Value*

Total Fat 13g **20%**

Saturated Fat 5g **25%**

Cholesterol 30mg **10%**

Sodium 660mg **28%**

Total Carbohydrate 31g **10%**

Dietary Fiber 0g **0%**

Sugars 5g

Protein 5g

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

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

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

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

New mandatory component helps consumers meet dietary guidelines recommending no more than 30 percent of calories from fat.

%Daily Value shows how a food fits into the overall daily diet.

Reference values help consumers learn good diet basics. They can be adjusted, depending on a person's calorie needs.

Types of Labels

A tabular format label (top) is allowed on packages, such as this can of tuna, that have less than 40 square inches for nutrition labeling. A simplified nutrition label (bottom), in which information about some nutrients otherwise required in nutrition labeling is omitted, will appear on labels of foods, such as this can of cola, that do not contain significant amounts of certain nutrients.



Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	Total Carb. 0g	0%
Sat. Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	Protein 17g	
Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%			



Nutrition Facts

Serving Size 1 can (360 mL)

Amount Per Serving

Calories 140

% Daily Value*

Total Fat 0g	0%
Sodium 20mg	1%
Total Carbohydrate 36g	12%
Sugars 36 g	
Protein 0g	0%

* Percent Daily Values are based on a 2,000 calorie diet.

signal to consumers that the product is newly labeled according to FDA and FSIS' new regulations.

The new panel will be built around a new set of dietary components. (See graphic, page 23.) The mandatory (underlined) and voluntary dietary components and order in which they must appear are:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- stearic acid (on meat and poultry products only)
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
- other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, if declared)
- protein
- vitamin A
- percent of vitamin A present as beta-carotene
- vitamin C
- calcium
- iron
- other essential vitamins and minerals.

If a food is fortified or enriched with any of the optional components, or if a claim is made about any of them, the pertinent nutrition information then becomes mandatory.

These mandatory and voluntary components are the only ones allowed on the nutrition panel. The listing of single amino

acids, maltodextrin, calories from polyunsaturated fat, and calories from carbohydrate, for example, may not appear on the label.

The reason, according to Wilkening, is to help consumers focus on nutrients of public health significance. "Too much additional information could clutter the label or mislead or confuse the consumer," she said.

Nutrients required on the label, she pointed out, reflect current public health concerns and coincide with current public health recommendations. She noted that the order in which the food components and nutrients are required to appear reflects their public health significance and the order in which they were specified in NLEA.

On the new food label, the listing of thiamin, riboflavin and niacin will not be mandatory. Under the old nutrition labeling program, these vitamins were required to be listed. But because deficiencies of these are no longer a public health problem in this country, listing them is now optional.

New Format

Consumers also will see a new format, one that calls for many of the macronutrients (such as fat, cholesterol, sodium, carbohydrate, and protein) to be declared as a percent of the Daily Value—a new label reference value. The amount, in grams or milligrams per serving, of these nutrients still must be listed to their immediate right. But, for the first time, a column headed "%Daily Value" will appear.

According to Wilkening, the percent declaration of the Daily Value offers an advantage over amount declaration: The percent Daily Values put the nutrients on an equal footing in the context of a total daily diet.

For example, she said, a food is low in sodium if it has less than 140 mg of so-

dium. "But people look at that number, 140, and think it's a tremendous amount, when it actually is less than 6 percent of the Daily Value."

On the other hand, she said, a food with 5 g of saturated fat could be construed as being low in that nutrient just because 5 is a small number. Actually, that food would provide one-fourth the total Daily Value of 20 g of saturated fat for a 2,000-calorie diet.

"People are affected by the size of numbers," she said. "That's why percentages are helpful. They put all of the nutrients on a level playing field."

The percent Daily Value listing will carry a footnote stating that the percentages are based on a 2,000-calorie diet and that a person's individual dietary goal is based on his or her calorie needs. Some nutrition labels—at least those on larger packages—will list daily values for selected nutrients for a 2,000- and a 2,500-calorie diet and the number of calories per gram of fat, carbohydrate and protein. The calorie conversion information is required as a general guide about the caloric contributions of fat, carbohydrate and protein.

The content of micronutrients—that is, vitamins and minerals—will continue to be expressed as a percent, although the term "Daily Value" will replace "U.S. Recommended Daily Allowance."

Modifications

Some foods will carry a variation of this format. For example, the label of foods for children under 2 (except infant formula, which is exempt from nutrition labeling under NLEA) will not carry information about calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol.

The reason, according to Wilkening, is to prevent parents from inadvertently assuming that infants and toddlers should restrict their fat intake, when in fact, they

should not. Fat is important during this life stage, she said, to ensure adequate growth and development.

The labels of food for children under 4 cannot include percentages of Daily Values for macronutrients, except protein, nor any footnote information, including the lists of Daily Values for selected nutrients. The reason: Other than protein, FDA has not established Daily Values for macronutrients for this age group. The percent Daily Values for vitamins and minerals is allowed, however. The content of the other nutrients must be expressed as an amount by weight in a separate column to the right of the macronutrients.

Other foods may qualify for a simplified label format. (See bottom label, page 24.) This format is allowed when the food contains insignificant amounts of seven or more of the mandatory dietary components, including total calories. "Insignificant" means that a declaration of "zero" could be made in nutrition labeling or, for total carbohydrate, dietary fiber, and protein, a declaration of "less than 1 g."

For foods for children under 2, the simplified format may be used if the product contains insignificant amounts of six or more of the following: calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron.

When the simplified format is used, information on total calories, total fat, total carbohydrate, protein, and sodium—even if they are present in insignificant amounts—must be listed. Calories from fat and other nutrients must be listed if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too.

Serving Sizes

Whatever the format, the serving size remains the basis for reporting each nutrient's amount. However, unlike in the past, serving sizes now will be more uniform and closer to the amounts that many

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formation Per Serving."**

***Now it will be called
"Nutrition Facts."***

people actually eat. They also must be expressed in both common household and metric measures. (See accompanying table.)

Before, the serving size was up to the discretion of the food manufacturer. As a result, said Youngmee Park, Ph.D., a nutritionist in FDA's Office of Special Nutritionals, serving sizes often varied widely, making it difficult for consumers to compare nutritional qualities of similar products or to determine the nutrient content of the amount of food they normally ate.

The uniformity also is important, she said, for giving consistency to health claims and words describing nutrient content, such as "high fiber" and "reduced fat."

FDA and FSIS define serving size as the amount of food customarily eaten at one time. It is based on FDA- and USDA-established lists of "Reference Amounts Customarily Consumed Per Eating Occasion."

These reference amounts, which are part of the new regulations, are broken down

into 139 FDA-regulated food product categories, including 11 groups of foods for children under 4, and 23 USDA meat and poultry product categories. They list the amounts of food customarily consumed per eating occasion for each food category, based primarily on national food consumption surveys. FDA's list also gives the suggested label statement for serving size declaration.

For example, the category "breads (excluding sweet quick type), rolls" has a reference amount of 50 g, and the appropriate label statement for sliced bread is "___ piece(s) ___ (g)" or, for unsliced bread, "2 oz (56 g/___ inch slice)."

The serving size of products that come in discrete units, such as cookies, candy bars, and sliced products, is the number of whole units that most closely approximates the reference amount. For example, cookies have a reference amount of 30 g. The household measure closest to that amount is the number of cookies that comes closest to weighing 30 g. Thus, the serving size on the label of a cookie package in which each cookie weighs 13 g would read "2 cookies (26 g)."

If one unit weighs more than 50 percent but less than 200 percent of the reference amount, the serving size is one unit. For example, the reference amount for bread is 50 g; therefore, the label of a loaf of bread in which each slice weighs more than 25 g would state that a serving size is one slice.

For food products packaged and sold individually, if an individual package is less than 200 percent of the applicable reference amount, the item qualifies as one serving. Thus, a 360-milliliter (mL) (12 fluid-ounce) can of soda is one serving because the reference amount for carbonated beverages is 240 mL (8 fluid ounces).

However, if the product has a reference amount of 100 g or 100 mL or more and the package contains more than 150 percent but less than 200 percent of the reference amount, manufacturers have the op-

Metric Conversion Chart

Units as they will appear for serving sizes on label

Household Measure	Metric Measure
1 tsp	5 mL
1 tbsp	15 mL
1 cup	240 mL
1 fl oz	30 mL
1 oz	28 g

tsp = teaspoon

tbsp = tablespoon

fl oz = fluid ounce

oz = ounce

mL = milliliter

g = gram

tion of deciding whether the product is one or two servings.

For example, the serving size reference amount for soup is 245 g. So a 15-ounce (420 g) can can be listed as either one or two servings.

Presentation

There also are rules governing how the nutrition information is displayed. Under existing FDA regulations, nutrition information must appear on the information panel to the immediate right of the principal panel. Thus, on boxed foods, for example, in which the principal panel is on the front of the box, the nutrition information appears on the right side of the box. Packages whose area to the immediate right is too small or not suited for such labeling may provide information on the next panel to the right.

FSIS allows nutrition information to be listed on the principal or information panels.

The new food labeling rules call for one additional variation: For packages that are 40 square inches or less, the nutrition information may be placed on any label panel.

The rules also address size and prominence of the typeface. For example, the heading "Nutrition Facts" must be set in the largest type on the nutrition panel and be highlighted in some manner, such as boldface, all capital letters, or another graphic to distinguish it from the other information. Such highlighting also is required for headings such as "Amount per serving" and "%Daily Value" and for the names of dietary components that are not subcomponents—that is, calories, total fat, cholesterol, sodium, total carbohydrate, and protein.

Exceptions and Exemptions

In some instances, special provisions exist for providing nutrition information. For example:

- Nutrition information about game meat, such as deer, bison, rabbit, quail, wild turkey, and ostrich, may be provided on

counter cards, signs, or other point-of-purchase materials. Because little nutrient data exists for these foods, FDA believes that allowing this option will enable game meat producers to give first priority to collecting appropriate data and make it easier for them to update the information as it becomes available.

- FDA-regulated food packages with less than 12 square inches available for nutrition labeling do not have to carry nutrition information. However, they must provide an address or telephone number for consumers to obtain the required nutrition information.

- Packages with less than 40 square inches for nutrition labeling may present nutrition information in a tabular format (see top label, page 24), abbreviate the names of dietary components, and omit the footnotes with the list of daily values and caloric conversion information but include a footnote stating that the percent

Daily Values are based on a 2,000-calorie diet or place nutrition information on other panels.

Some foods are exempt from nutrition labeling. These include:

- food produced by small businesses. (As mandated by NLEA, FDA defines a small business as one with food sales of less than \$50,000 a year or total sales of less than \$500,000. FSIS defines a small business as one employing 500 or fewer employees and producing no more than a certain amount of product per year.)
- food served for immediate consumption, such as that served in restaurants and hospital cafeterias, on airplanes, and by food service vendors (such as mall cookie counters, sidewalk vendors, and vending machines)
- ready-to-eat foods that are not for immediate consumption, as long as the food is primarily prepared on site—for example, many bakery, deli, and candy store items
- food shipped in bulk, as long as it is not for sale in that form to consumers
- medical foods
- plain coffee and tea, flavor extracts, food colors, some spices, and other foods that contain no significant amounts of any nutrients
- donated foods
- products intended for export
- individually wrapped FSIS-regulated products weighing less than half an ounce and making no nutrient content claims.

Although these foods are exempt, they are free to carry nutrition information, when appropriate—as long as it complies with the new regulations.

But, there will be plenty of other foods carrying the new nutrition information. Dietitian Susan Thom sees that as a plus.

"We'll all know exactly what we're putting in our mouths," she said. "So there'll be little room for excuses." ■

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

'DAILY VALUES'

Encourage Healthy Diet

by Paula Kurtzweil

If you haven't added "DV" to your vocabulary yet, you probably will before long.

It stands for Daily Value, a new dietary reference value to help consumers use food label information to plan a healthy overall diet.

DVs actually comprise two sets of reference values for nutrients: Daily Reference Values, or DRVs, and Reference Daily Intakes, or RDIs. But these two sets are "behind the scenes" in food labeling; only the Daily Value term will appear on the label to make label reading less confusing.

In fact, said Christine Lewis, Ph.D., a registered dietitian and director of the division of technical evaluation in FDA's Office of Food Labeling, the Daily Value term is the only one of the terms that will be used in the government's food labeling education campaign. "The DV term is the one we expect consumers and professionals to use," she said.

FDA-regulated products must begin using the Daily Value as the basis for declaring nutrient content by May 8, 1994. U.S. Department of Agriculture-regulated products—meat and poultry—have until July 6, 1994.

The move to Daily Values is due in large part to the Nutrition Labeling and Education Act of 1990. Among other things, the law requires nutrition label information to be conveyed in a way that en-

ables the public to observe and comprehend the information readily and to understand its relative significance in the context of a total daily diet.

According to Lewis, the DV does that in two ways: First, it serves as a basis for declaring on the label the percent of the Daily Value for each nutrient that a serving of the food provides.

For example, the Daily Value for fat, based on a 2,000-calorie diet, is 65 grams (g). A food that has 13 g of fat per serving would state on the label that the "percent Daily Value" for fat is 20 percent.

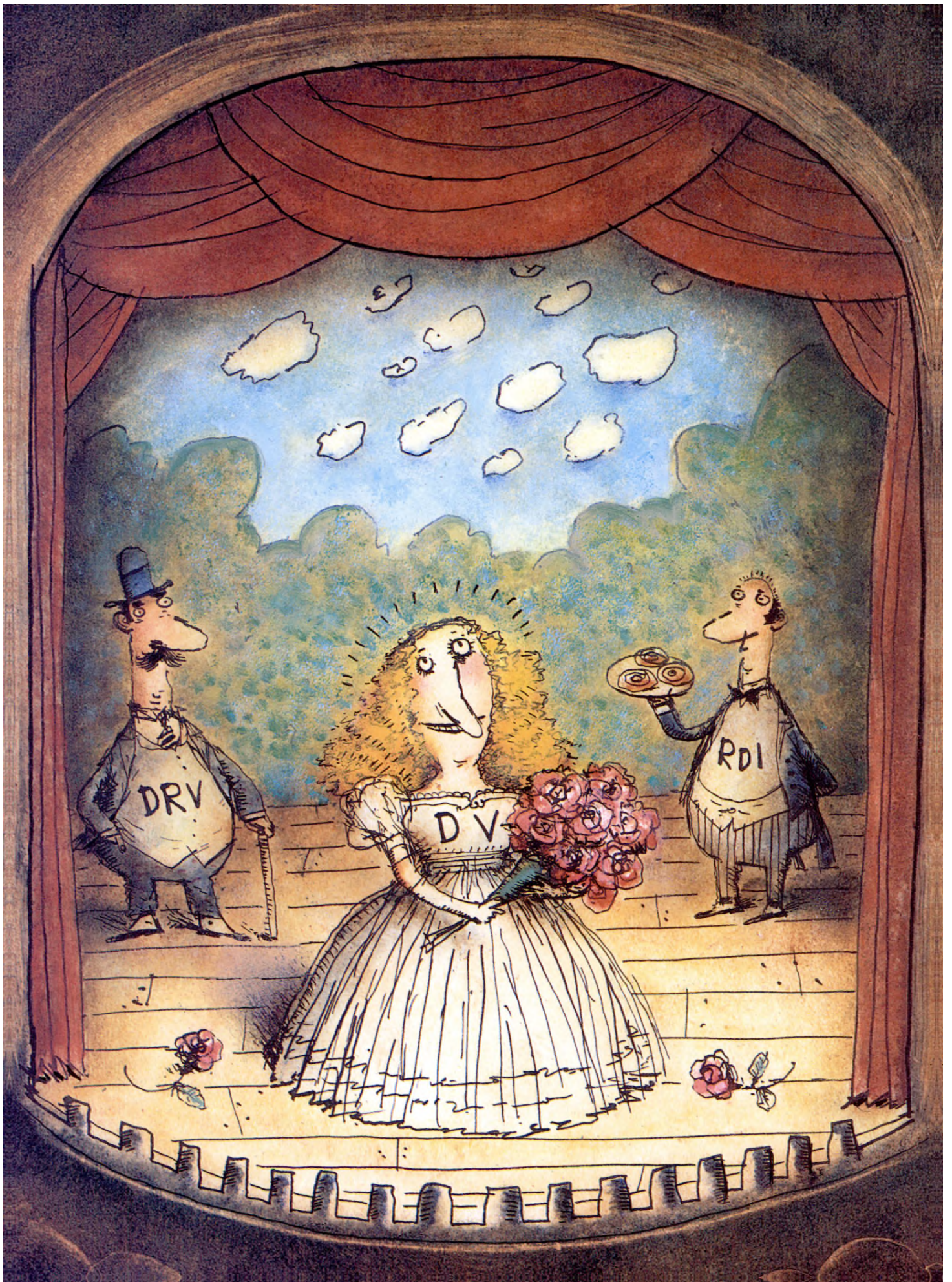
Second, it provides a basis for thresholds that define descriptive words for nutrient content, called descriptors, such as "high fiber" and "low fat." For example, the descriptor "high fiber" can be used if a serving of food provides 20 percent or more of the Daily Value for fiber—that is, 5 g or more.

What it is *not* intended to do is tell people what amounts of nutrients they should eat every day.

"They're not recommended intakes," Lewis said. "They're really just reference points to help people get some kind of perspective on what their overall daily dietary needs should be."

New References

Although they won't show up on the label, DRVs and RDIs have an important regulatory role. They serve as the basis for calculating percent Daily Values.



Daily Reference Values(DRVs) *

Food Component	DRV
fat	65 grams (g)
saturated fatty acids	20 g
cholesterol	300 milligrams (mg)
total carbohydrate	300 g
fiber	25 g
sodium	2,400 mg
potassium	3,500 mg
protein**	50 g

*Based on 2,000 calories a day for adults and children over 4 only

**DRV for protein does not apply to certain populations; Reference Daily Intake (RDI) for protein has been established for these groups: children 1 to 4 years: 16 g; infants under 1 year: 14 g; pregnant women: 60 g; nursing mothers: 65 g.



Reference Daily Intakes (RDIs)*

Nutrient	Amount
vitamin A	5,000 International Units (IU)
vitamin C	60 milligrams (mg)
thiamin	1.5 mg
riboflavin	1.7 mg
niacin	20 mg
calcium	1.0 gram (g)
iron	18 mg
vitamin D	400 IU
vitamin E	30 IU
vitamin B ₆	2.0 mg
folic acid	0.4 mg
vitamin B ₁₂	6 micrograms (mcg)
phosphorus	1.0 g
iodine	150 mcg
magnesium	400 mg
zinc	15 mg
copper	2 mg
biotin	0.3 mg
pantothenic acid	10 mg

*Based on National Academy of Sciences' 1968 Recommended Dietary Allowances.

DRVs are for nutrients for which no set of standards previously existed, such as fat and cholesterol. RDIs, on the other hand, replace the term "U.S. RDAs" (Recommended Daily Allowances), which were introduced in 1973 as a reference value for vitamins, minerals and protein in voluntary nutrition labeling. Despite the name change, the actual values (except the value for protein) will remain the same—at least for the time being. FDA will consider revising these values in the near future.

U.S. RDAs should not be confused with RDAs. The latter are short for Recommended *Dietary* Allowances, which are set by the National Academy of Sciences. FDA used the RDAs as the basis for setting U.S. RDAs (now called RDIs).

The confusion caused by the similarity of those terms was one of the reasons for the switch to RDI.

"The comments we received about the proposed name change generally agreed that there was a need to change the terminology," Lewis said. "People reported that it caused problems both in consumer education and with professional communication."

DRVs

DRVs for the energy-producing nutrients (fat, carbohydrate, protein, and fiber) are based on the number of calories consumed per day. For labeling purposes, 2,000 calories has been established as the reference for calculating percent Daily Values. This level was chosen, in part, because many health experts say it approximates the maintenance calorie requirements of the group most often targeted for weight reduction: postmenopausal women.

Also, unlike the 2,350-calorie reference that FDA used in its proposal, 2,000 calories is a rounded number, which makes it easier for consumers to calculate their in-

dividual nutrient needs.

The label will include—at least on larger packages—a footnote on the nutrition panel in which daily values for selected nutrients for both a 2,000- and a 2,500-calorie diet are listed. Manufacturers have the option of listing daily values for other calorie levels, if label space allows and as long as the Daily Values for the other two levels are listed, too.

Whatever the calorie level, DRVs for the energy-producing nutrients are always calculated as follows:

- fat based on 30 percent of calories
- saturated fat based on 10 percent of calories
- carbohydrate based on 60 percent of calories
- protein based on 10 percent of calories. (The DRV for protein applies only to adults and children over 4. RDIs for protein for special groups have been established. See table on facing page.)
- fiber based on 11.5 g of fiber per 1,000 calories.

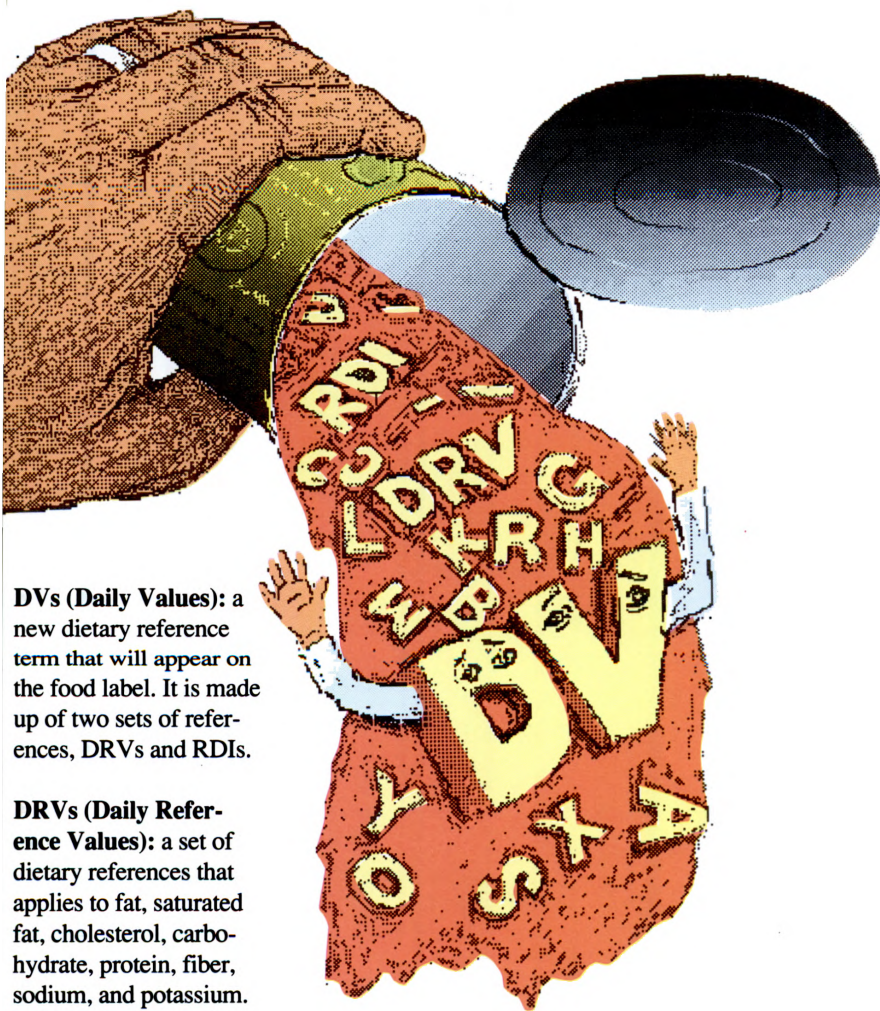
Thus, someone who consumes 3,000 calories a day—a teenage boy, for example—would have a recommended intake for fat of 100 g or less per day. $[0.30 \times 3,000 = 900; 900 \text{ (calories)} \div 9 \text{ (calories per g of fat)} = 100 \text{ g}]$

The DRVs for cholesterol, sodium and potassium, which do not contribute calories, remain the same whatever the calorie level. (See table on facing page.)

Because of the links between certain nutrients and certain diseases, DRVs for some nutrients represent the uppermost limit that is considered desirable. Eating too much fat or cholesterol, for example, has been linked to an increased risk of heart disease. Too much sodium can heighten the risk of high blood pressure in some people.

Therefore, the label will show DVs for fats and sodium as follows:

Alphabet Soup Made Appetizing



DVs (Daily Values): a new dietary reference term that will appear on the food label. It is made up of two sets of references, DRV's and RDIs.

DRVs (Daily Reference Values): a set of dietary references that applies to fat, saturated fat, cholesterol, carbohydrate, protein, fiber, sodium, and potassium.

RDIs (Reference Daily Intakes): a set of dietary references based on the Recommended Dietary Allowances for essential vitamins and minerals and, in selected groups, protein. The name "RDI" replaces the term "U.S. RDA."

RDAs (Recommended Dietary Allowances): a set of estimated nutrient allowances established by the National Academy of Sciences. It is updated periodically to reflect current scientific knowledge.

Although consumers will continue to see vitamins and minerals expressed as percentages on the label, these percentages now refer to the Daily Values.

- total fat: less than 65 g
- saturated fat: less than 20 g
- cholesterol: less than 300 mg (milligrams)
- sodium: less than 2,400 mg

RDIs Replace U.S. RDAs

Unlike DRVs, which are a new concept, many consumers may already have a good idea of what the RDIs are. That's because the RDIs (the former U.S. RDAs used by FDA) have been around for almost 20 years as the established estimated values for vitamins, minerals and protein.

The provisions of the Nutrition Labeling and Education Act and the Dietary Supplement Act of 1992 require FDA to retain these estimated values for at least another year.

Although consumers will continue to see vitamins and minerals expressed as percentages on the label, these percentages now refer to the Daily Values.

Getting to Know DVs

Like any new concept, DVs may take some getting used to but, through education and practice, FDA and USDA believe it soon will become second nature to many consumers.

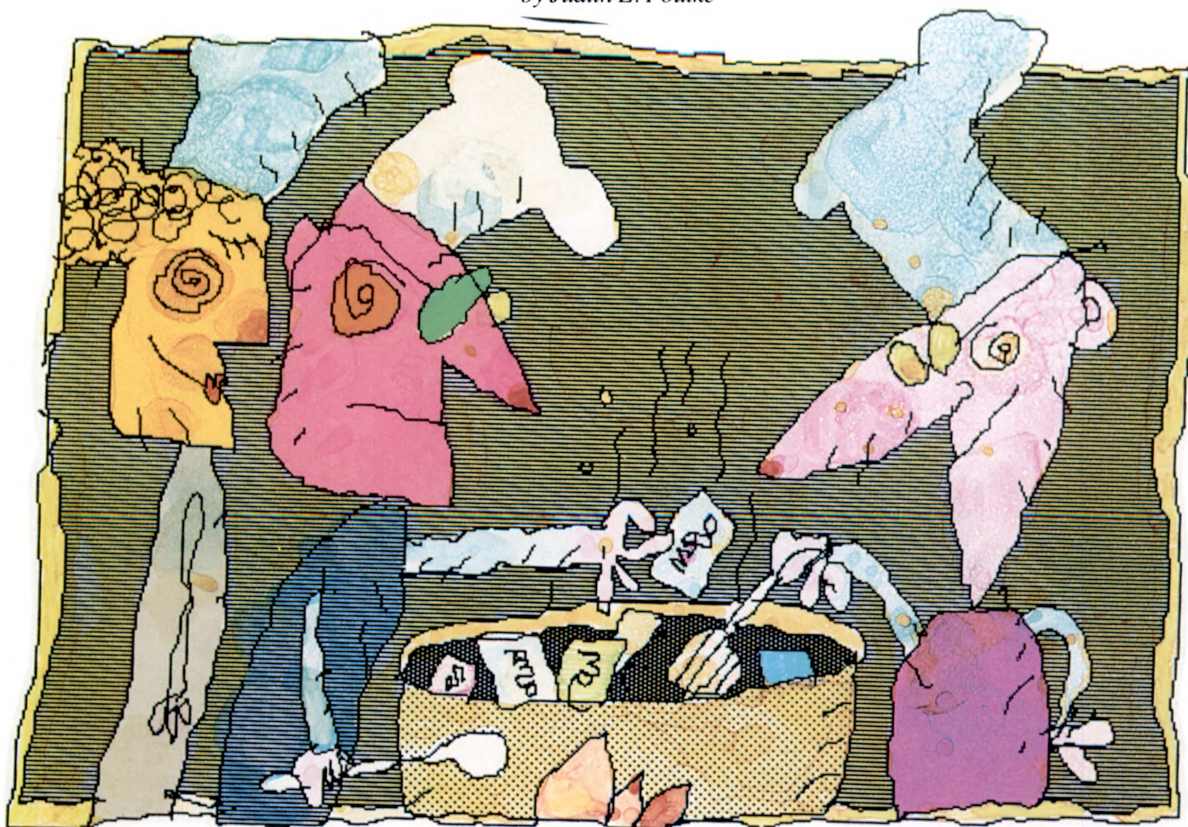
"As more and more new labels make their way into the marketplace," Lewis said, "people will gradually become familiar with the DV term and be able to use the information effectively."

"I think consumers are going to find it very helpful," she said. ■

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

Cooking Up the New Food Label

by Judith E. Foulke



READING THE NEW FOOD LABELS REQUIRED ON ALMOST ALL FOODS WILL MAKE PLANNING HEALTHY DIETS EASIER FOR CONSUMERS. WRITING THE REGULATIONS THAT SPELL OUT WHAT SHOULD BE ON THOSE LABELS HAS BEEN EVERYTHING BUT EASY FOR THE RULE-MAKERS.

ASK ANY NUMBER OF FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE (FSIS) STAFFERS

WHO WERE INVOLVED IN WRITING THE REGULATIONS.

THEY'LL SAY THAT IN ALMOST EVERY INSTANCE, BEFORE PEN MET PAPER THERE WAS A TUG-OF-WAR BETWEEN WHAT THE LAW REQUIRES AND THE MANY OPINIONS ABOUT THE MOST PRACTICAL WAY TO PRESENT

NUTRITION INFORMATION ON THE FOOD LABEL. BY THE

TIME REGULATIONS WERE WRITTEN, MANY COMPROMISES

HAD BEEN MADE. HOWEVER, BOTH AGENCIES BELIEVE

THAT NONE OF THE TRADEOFFS WAS AT THE EXPENSE OF



F. Edward Scarbrough
Director, Office of Food Labeling



Margaret O'K. Glavin
*Deputy Administrator,
Regulatory Programs, USDA*

*"What neither agency
wanted to do was to tell
consumers exactly what
they should be eating."*

*—F. Edward Scarbrough, Ph.D.,
FDA's Office of Food Labeling*

consumer interests or resulted in an excessive burden to the food industry.

First on FDA's and FSIS' agenda for food label reform was to solicit advice from consumers, health professionals in and out of government, and members of the food industry. (See "Good Reading for Good Eating," on page 7.)

"Having the clear legal authority paved the way for us to write the regulations," says F. Edward Scarbrough, Ph.D., director of FDA's Office of Food Labeling, who coordinated the Nutrition Labeling and Education Act (NLEA) rule-making process in the Center for Food Safety and Applied Nutrition. It also sped up the entire project because it established deadlines. For example, it required FDA to propose regulations by November 1991.

"That was a blessing and a curse," says Scarbrough. "The timetable forced us to get the proposals out without a lot of over-review, re-drafting, and going back and forth, but staffers put in long hours, often working on weekends, to meet the one-year deadline."

By November 1991, FDA had published 26 proposals. At the same time, FSIS published a parallel proposal for the nutrition labeling of meats and poultry.

Although meat and poultry products were not covered by NLEA, FSIS shared FDA's concern for consistent labeling re-

quirements so that all foods would carry the same type of information and labels would appear at about the same time. FSIS Deputy Administrator Margaret O'K. Glavin, leader of USDA's label reform effort for more than three years, says, "The combined effort was a success because of the excellent staff work of FSIS and FDA. That's what made it possible."

In January 1992, FDA and FSIS called a public hearing on the proposals. Ninety-two representatives from the food industry, the scientific community, and consumer groups presented their comments in person to a panel of FDA and FSIS officials.

In addition to the oral comments, FDA received more than 40,000 others in writing, the largest number ever received in response to an FDA proposed regulation. About 30,000 were form letters from organized campaigns.

FSIS received 1,109 comments. "Consumer groups, industry, and medical groups overwhelmingly asked for 'harmonization' of the FDA and FSIS labels," says Cheryl Wade, chief, FSIS Nutrition Branch and coordinator of the rule-making process for FSIS.

Dealing with Details

The details called for by NLEA were often a problem for FDA rule-makers,



Youngmee K. Park
Nutritionist, Office of
Special Nutritionals



Gerard L. McCowin
Special Assistant to the Director,
Office of Food Labeling

FDA and FSIS relied on a great number of outside resources. Both used the expertise of scientists within their own agencies and from the National Institutes of Health and the Centers for Disease Control and Prevention, and reviewed a number of scientific studies.

says Scarbrough. "For example," he says, "the law says 'the label shall have' and named nutrients. One of the nutrients named was complex carbohydrates." In order to enforce the law, Scarbrough says, FDA would have had to come up with a way to measure complex carbohydrates.

"The problem is," he says, "there's no good definition for complex carbohydrates. Had we been working on nutrient list requirements without NLEA, we would not have included complex carbohydrates—we might have made a more general term, such as 'carbohydrates other than sugar'."

FSIS had fewer constraints than FDA because FSIS was not bound by the labeling law. However, in order to provide consistent nutrition information on all foods, FSIS rule-makers stayed in tune with NLEA's restrictive details. "For many years we have used prior label approval—a very different system to regulate labeling," Glavin says. "Also, USDA regulates meat and poultry, so the focus for us was on nutrients such as protein and fat, for example, rather than on fiber," she says.

Troublesome Issues

Most NLEA requirements raised troublesome issues, Scarbrough says. Evaluating health claims as they relate to certain nutrients was one of them. The job

was large—FDA received more than 7,000 public comments concerning its proposal on health claims and each comment was considered.

"Some health claims were very specific, and the evidence was rather limited," he said. "Others were broad, and yet we were given a mandate to come up with a general set of principles and apply them to all 10 claims." Of the 10 diet-health relationships the law required FDA to evaluate, seven were approved. (See "Starting This Month, Look for 'Legit' Health Claims on Foods" on page 14.)

FSIS had not finalized a health claims proposal when the final regulations were published, but the agency intends to issue a proposal similar to FDA's final rule.

None of the regulations was easy to write, Scarbrough says. Even when there were general principles that everyone accepted, there were still compromises to be made. The regulation for serving sizes was one such case.

"No one seriously argued that the law shouldn't set serving sizes," Scarbrough says. "But there were arguments with industry about numbers—is it one ounce or an ounce and a half—that sort of thing," he says.

Youngmee Park, Ph.D., of FDA's Office of Special Nutritionals, principal writer of the serving size rule, explains



Charles R. Edwards
Director, Product Assessment
Division, USDA



Christine Lewis
Acting Director, Division of
Technical Evaluation

"The FDA and food industry cooperative consumer research project to test nutrition label formats is a good example of FDA's commitment to involve interested groups in the process of developing well-reasoned food labeling rules."

—E. Toni Guarino, Grocery Manufacturers of America

that foods were grouped into 139 categories. The amount of food customarily eaten per occasion, called the "reference amount," was established for each category, and the agency established rules for converting the reference amounts into label serving sizes.

But special consideration had to be given to certain foods, for example shrimp, that naturally vary in size (how many jumbo-sized shrimp are customarily consumed in one meal as opposed to small-sized shrimp?). There was also a difference in serving sizes when products were aerated, such as whipped peanut butter or aerated waffles.

Healthier Products Encouraged

In developing the regulations, FDA wrote rules that would not limit manufacturers' incentive to produce healthier products in the future, Scarbrough explains. For example, a manufacturer of cooking oils could not label products with claims of reduced risk of heart disease because oil is not a low-fat food. However, if the manufacturer produced a cooking oil lower in saturated fat than its other products, it could make a comparative claim for the nutrient content, calling attention to what the saturated fat level really was.

Soy sauce is another product that would not qualify for a health claim because it

has a high sodium content. But under the regulations, a manufacturer could make a "light" soy sauce, making it clear on the label that "light" referred to a reduced sodium content, if that were the case, and if its sodium content were sufficiently reduced from its regular product.

When NLEA was written, says Scarbrough, Congress decided that such information would be useful to consumers—it would balance the picture so that consumers could make choices. Although it may create a cluttered label, the principle is to give complete disclosure about the food and to encourage nutrition information, versus not allowing some products to make any claims at all.

FSIS rule-makers wanted nutrition labeling to facilitate the development of lower-fat meat and poultry products. "Meat and poultry products are good foods," Glavin says. "The descriptors helped us capture the characteristics unique to meat and poultry on the nutrition label," she says.

In its advanced notice of proposed rule-making, FSIS asked for comments on descriptors for meats. The American Heart Association comment suggested definitions for the descriptors so that consumers could rely on the descriptive terms to help them select meat and poultry products with different levels of fat, saturated fat,



Virginia L. Wilkening
*Nutritionist, Division of
 Technical Evaluation*



Elizabeth Campbell
*Director, Division of Programs
 Enforcement Policy*

The effort to get NLEA ready for implementation touched almost everyone in FDA's Center for Food Safety and Applied Nutrition, from scientists to secretaries.

and cholesterol. FSIS proposed the AHA-suggested definitions for "lean" and "extra lean." FDA adopted those definitions for the products it regulates, including fish and game meat.

"What neither agency wanted to do was to tell consumers exactly what they should be eating," says Scarbrough. "Industry is very creative describing and promoting their products, and I'm sure manufacturers will come up with ways of doing that without cluttering the label and still stay within the law."

Many Resources Tapped

The effort to get NLEA ready for implementation touched almost everyone in FDA's Center for Food Safety and Applied Nutrition, from scientists to secretaries. Field offices throughout the country were involved also. Charity Singletary, public affairs specialist for FDA's Baltimore district office, says that at a recent national convention of dietitians held in Washington, D.C., "almost every other person who visited our exhibit asked about NLEA." She says from early spring of 1992, all of her public affairs activities, such as exhibits at national meetings and talks to consumer groups and schools, were about NLEA.

In FSIS, staffers devoted thousands of hours, over more than two years, to the la-

bel reform effort. "It was hard work, but because we were working together with equally committed FDA staff, it was also satisfying work," Wade says.

In addition, FDA and FSIS relied on a great number of outside resources. Both used the expertise of scientists within their own agencies and from the National Institutes of Health and the national Centers for Disease Control and Prevention, and reviewed a number of scientific studies, including some from the National Academy of Sciences.

"We listen very carefully to the NAS because it's made up of scientists that come together from all parts of the country," Scarbrough says. "They have prestige and carry a certain amount of 'scientific authority' in the public view. If an NAS committee agrees on something, that's about as close as you can get to the 'general scientific agreement' that NLEA requires. NAS has also worked on Recommended Dietary Allowances for many years and has a lot of experience in that area. And NAS has put together a committee on food labeling with a number of scientific disciplines."

Industry and Consumer Groups React

Scarbrough says FDA worked closely with industry. "In general, the food industry was quite supportive because it knows



Elizabeth Yetley
Acting Director,
Office of Special Nutritionals

Shown on the inside front cover photo are: (front) Youngmee Park and Virginia Wilkening and (back) Gerard McCowin, Elizabeth Yetley, Edward Scarbrough, and Christine Lewis.



"Food labeling is a subject we'll continue to revisit for many years to come."

—F. Edward Scarbrough, Ph.D.,

FDA's Office of Food Labeling

that nutrition information is important to consumers, and it sells products," Scarbrough says. "The advantage for industry is that everyone now plays by the same rules."

E. Toni Guarino, vice president and general counsel of the Grocery Manufacturers of America, called the number of regulations required by NLEA and the time frame for issuing them "extraordinary." She said the FDA staff responded with "a high level of dedication and professionalism."

"The FDA and food industry cooperative consumer research project to test nutrition label formats is a particularly good example of FDA's commitment to involve all interested groups in the process of developing well-reasoned food labeling rules that achieve FDA's goals," she says.

FSIS sought to be responsive to industry without conflicting with the public interest. In doing so, FSIS extended the time frame for implementation of its rules, giving industry time for compliance and minimizing costs to consumers. FSIS also made exemptions for firms that met its "small business" definition.

"Consumer groups are generally happy with the law," Scarbrough says. "They'd like us to go even further and be more restrictive with what we're allowing," he says.

Public Voice spokeswoman Patti Morris says her group is pleased that ingredient listings will now be required on standardized foods and that nutrient content claims will be defined.

"FDA, as usual, is trying to strike that balance between consumer interests and what's fair to industry," Scarbrough says. "In general," he adds, "I think both consumer and industry groups support our labeling effort, but each has its own viewpoint about how the effort could have been better or have been done a little differently."

How Final Are the Final Regulations?

Final regulations can be modified. "Industry, or anyone, can petition us to change a regulation," explains Scarbrough. "And NLEA gives us a time frame to react to those petitions."

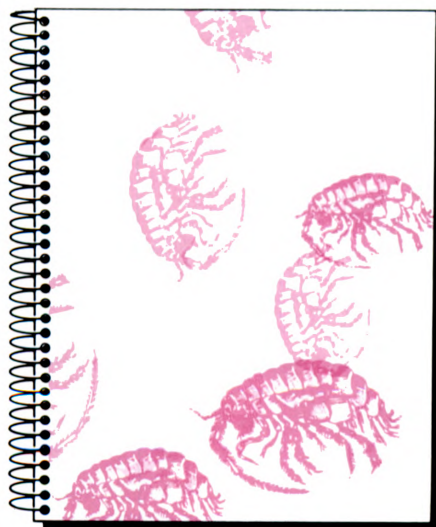
"With new processed foods coming on the market all the time and changes in eating habits," he says, "I think we'll be re-addressing serving sizes for a long time. The same applies with new health claims or terms a manufacturer would want to use on the label. Food labeling is a subject we'll continue to revisit for many years to come." ■

Judith E. Foulke is a staff writer for FDA Consumer.



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

■ **Shellfish contamination guidance documents** are available from FDA. The four documents offer guidance for state officials on arsenic, cadmium, chromium, and nickel contaminants. The information can be used to decide when to issue consumption advisories or close fishing waters because of contaminated seafood. To order free copies, request docket number 93D-0057 from: FDA, Policy Guidance Branch (HFS-416), 200 C St., S.W., Washington, DC 20204. (FR Feb. 26)



■ **New analgesic drug evaluation guidelines** have been published by FDA. "Guideline for the Clinical Evaluation of Analgesic Drugs" updates guidelines issued in November 1979 and presents recommended approaches for the clinical study of analgesic drugs intended to treat pain. To order free copies, send two self-addressed labels to CDER Executive Secretariat Staff (HFD-8), Center for Drug Evaluation and Research, 7500 Standish Place, Rockville, MD 20855. (FR Feb. 10)

■ **Many ozone-depleting products** will soon have new warning labels. They will be required on all products manufactured with or containing class I or class II ozone-depleting substances, according to an Environmental Protection Agency final rule, which takes effect May 15. Class I and class II substances include halons, chlorofluorocarbons (CFCs), carbon tetrachloride, methyl chloroform, and hydrochlorofluorocarbons (HCFCs). These substances destroy the stratospheric ozone layer that protects Earth from ultraviolet radiation. (FR Feb. 11)

■ **National Library of Medicine database access fees** were reduced Jan. 1, by 40 percent—from about \$30 per hour of connect time to \$18 per hour. Some 6,000 users in the United States and Canada conduct about 6 million searches on the library's computers each year. Free copies of the schedule are available from the Office of Public Information, National Library of Medicine, Bethesda, MD 20894; telephone (301) 496-6308, facsimile transmission (301) 496-4450. (Public Health Reports, January-February 1993)

■ **HIV transmission in health-care settings** concerns more people now than in 1988, but more would allow HIV-infected physicians, surgeons and dentists to continue working, according to a survey by Barbara Gerbert, Ph.D., and colleagues. The survey showed that 73 percent of the public endorsed mandatory testing for the three groups and 93 percent believed HIV-infected health-care professionals should be required to disclose their HIV status. (Archives of Internal Medicine, Feb. 8)

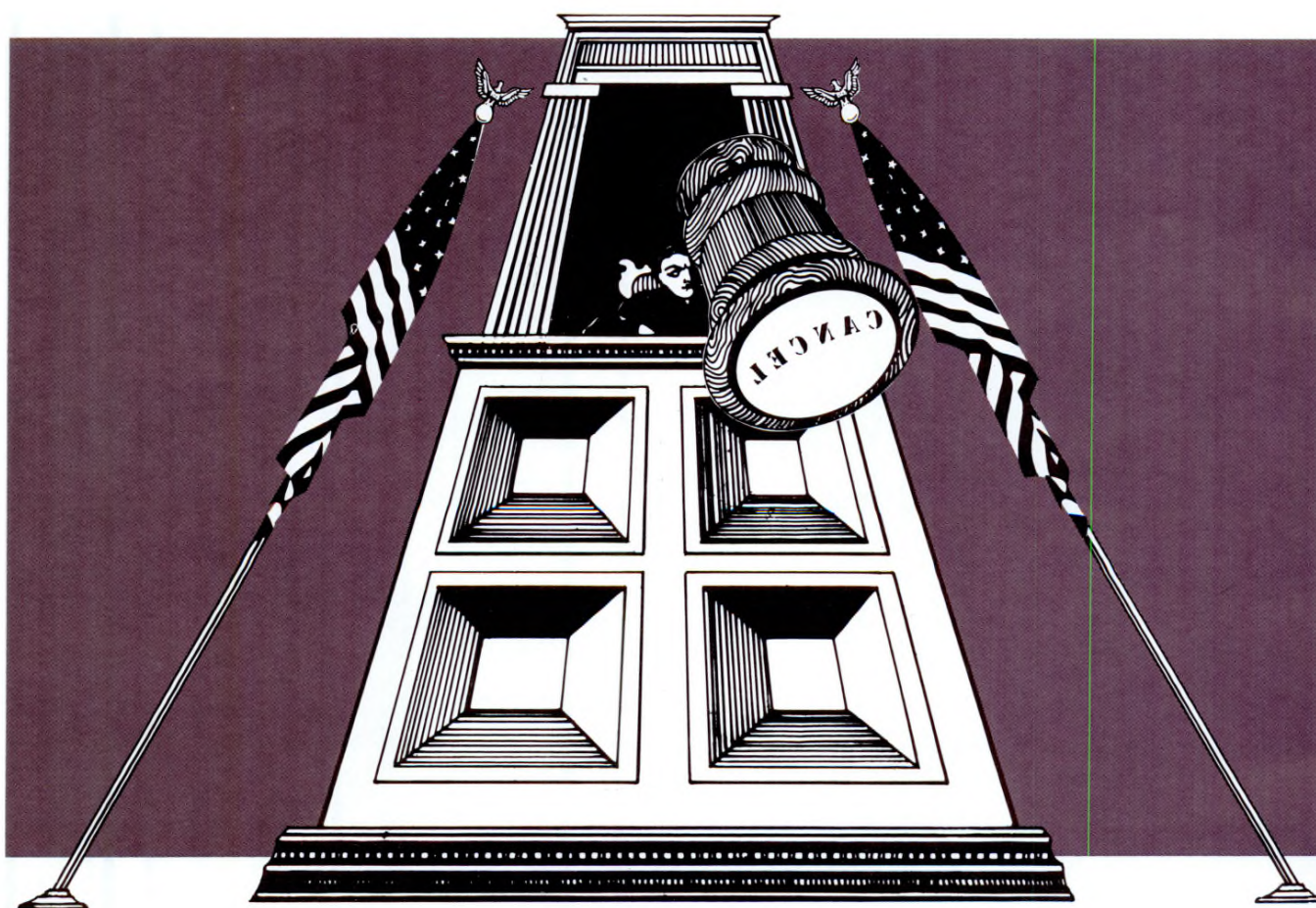
■ **Life expectancy** for all Americans in 1991 matched the 1989 record high of 75.7 years, according to the National Center for Health Statistics. However, life expectancy for one subgroup, black men, dropped 0.4 years, continuing the downward trend of the mid-1980s. (Public Health Reports, January-February 1993)

■ **Male-pattern baldness** in men under 55 may indicate an increased risk for heart attack, according to a study by Samuel M. Lesko, M.D., Boston School of Medicine, Brookline, Mass., and colleagues. Frontal baldness was not associated with increased risk. But severe baldness of the top of the head (vertex) indicated a 3.4 times greater risk of heart attack, while minor vertex baldness was associated with a 1.4 times greater risk. (Journal of the American Medical Association, Feb. 23)



Court Says to Cancel the CanCell

by Marian Segal



After a 12-year FDA investigation that entailed numerous unheeded warnings, an injunction, and a civil contempt finding, the judge found the defendant in compliance with the law at last, determining he had indeed stopped distributing an unapproved drug.

Judge Bernard A. Friedman, U.S. District Court for the Eastern District of Michigan, Southern Division, had ordered Edward J. Sopcak to appear before him

last Jan. 26 to show that he had ceased the illegal activities he and his colleague, James Sheridan, had regarded as a humanitarian service.

"The formulation [for CanCell] came to James Sheridan in a dream 50 years ago," wrote FDA compliance officer Kenneth Shelin. "For the last 50 years Mr. Sheridan has been telling people about the 80+ percent cure rate the product has in all types of cancer plus diabetes, arthritis, lupus,

and that latest scourge, AIDS," Shelin continued in a memo he wrote in June 1987 recommending injunction proceedings against Sheridan and Sopcak.

The two were manufacturing and distributing an unapproved new drug. CanCell was never proved effective against the serious illnesses for which it was promoted, and FDA never approved it for any use. CanCell presented a particular danger because Sopcak told patients to

stop chemotherapy and other conventional therapies. During a December 1987 inspection, Sopcak told investigators he tells cancer patients chemotherapy is an “unapproved therapy” that “kills 100 percent of the people who use it.”

When FDA first learned about CanCell (then called Entelev) in 1980, Detroit district investigators inspected Sheridan’s house where, operating alone at the time, he manufactured the product. Sheridan, a chemist, admitted he was making and distributing the product with health claims and that about 600 people used it to treat cancer. He said he had stopped making the product, however, and did not intend to resume production.

But that turned out not to be the case, and the 1980 inspection proved to be only the first step in an investigation that would continue for 10 years.

Subsequent inspections of Sheridan’s residence from June 1981 until October 1986 showed he continued to manufacture the product. During an inspection in December 1987, Sheridan said he stopped making and distributing CanCell but was referring patients to Sopcak. Sheridan still maintained that CanCell cured AIDS and told FDA officials he intended to continue promoting it as a cure for cancer, AIDS, and other serious diseases.

Sopcak had begun making CanCell in July 1984, although FDA did not learn this until investigators inspected his residence in October 1986. Follow-up inspections through March 1988 showed he continued to make the drug, despite warnings from FDA that these activities were illegal.

Over the years, Sheridan and Sopcak received numerous letters from FDA warn-

ing that their distribution of CanCell—an unapproved drug—is illegal. They were also informed of good manufacturing practice violations, which included failure to test raw materials or finished products and failure to maintain complaint files. They had no detailed written manufacturing procedures and controls or written procedures for maintaining and cleaning manufacturing equipment.

During one inspection, investigators observed Sheridan carrying out pH testing in the kitchen at the same time his wife was cooking chicken for dinner. Sopcak manufactured the product in his kitchen, too, without regard to good manufacturing practice.

Initially, the proposed defendants made halfhearted, ineffective attempts at compliance. Subsequently, however, they acknowledged their conduct was illegal but pledged nonetheless to continue it.

From 1977 to 1984, Sheridan had sponsored several studies to evaluate the safety and effectiveness of the drug, but none showed any therapeutic benefit. In April 1982, he filed an investigational new drug application with FDA, but never submitted adequate information to support it. The application has never been approved.

Sheridan and Sopcak acknowledged to FDA that they changed CanCell’s formulation over the years, as a result of frequent consultations about how to improve it. A complaint for permanent injunction filed Feb. 21, 1989, in the U.S. District Court for the Eastern District of Michigan, Southern Division, to enjoin Sheridan and Sopcak from distributing CanCell listed the active ingredients at that time as inositol, nitric acid, sodium sulfate, potassium hydroxide, sulfuric acid, and catechol.

The complaint also notes that the product had been known over the years variously as Jim’s Juice, Croconic Acid, Sheridan’s Formula, JS-114, 126-F,

Entelev, and CanCell. (In a letter to FDA dated Oct. 24, 1981, Sheridan explained that the name Entelev was derived from “ENTEL—from ‘entelechy’—that part of a living process known only to God” and “EV—from electrovalent—added just so the name would have something for everyone.”)

On June 21, 1989, Sheridan signed a consent decree of permanent injunction, agreeing to stop distributing the product.

On Jan. 17, 1990, the court granted a decree of permanent injunction against Sopcak, which he appealed to the Circuit Court of Appeals in Cincinnati. The appeal was dismissed Nov. 1, 1990.

Nevertheless, defying the injunction, Sopcak continued to distribute CanCell. At a show-cause hearing Nov. 13, 1992, Judge Friedman found him to be in civil contempt and ordered him to comply with the injunction immediately. Sopcak was allowed two weeks to:

- notify all people he was supplying with CanCell that he would no longer be distributing the drug and that drugs distributed since Jan. 17, 1990, violated a court injunction; he was also to provide FDA’s Detroit district office a copy of the notice
- place a recorded message on his answering machine stating that he has been enjoined from distributing CanCell
- report to FDA by Nov. 27, 1992, the actions he has taken to comply with the order.

Sopcak’s final appearance before Judge Friedman in January satisfied the judge he was in compliance.

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

O₂ Canister Claims Are Full of Hot Air

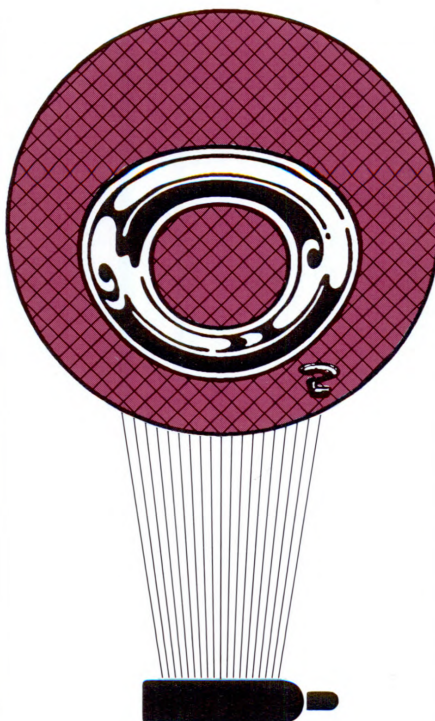
"A blast of pure power." "Boosts your game to its maximum potential." These were some of the promises a New Jersey firm made in advertisements for the firm's oxygen-filled canisters. The canisters contained oxygen but the promises were empty, a federal court judge decided.

On Oct. 27, 1992, Judge Dickinson Debevoise, U.S. District Court for the District of New Jersey, granted the government's motion for summary judgment and ordered the destruction of 18 portable oxygen canisters manufactured by Leland Limited, of Bedminster, N.J. Federal marshals had seized the canisters on Oct 12, 1989.

The condemned canisters, sold under the brand name Sports Oxygen, consisted of a hand-sized cylinder of oxygen with an attached mask and an adjustable valve to control oxygen flow.

In October 1987, FDA's division of drug labeling compliance received a complaint about Sports Oxygen from a respiratory therapist concerned about its misuse by people not under a physician's care.

A month later, the agency received a complaint from a physician concerned that people with health problems requiring oxygen might use Sports Oxygen instead, with potentially lethal results.



In response to these complaints, on Nov. 12, Karen Thomas, an investigator with FDA's Newark district office, inspected Leland's plant in Bedminster. In reviewing Leland's records, Thomas found the firm was distributing Sports Oxygen without an approved new drug application.

Based on Thomas' inspection, on Jan. 11, 1988, the Newark district office warned Leland in a letter that Sports Oxygen is a drug, and distributing the canisters without FDA approval violated the Food, Drug, and Cosmetic Act. In addition, Leland was not registered as a drug manufacturer and the product did not have adequate directions for use. The letter also warned Leland that further distribution of Sports Oxygen would subject the firm to possible regulatory action, including seizure of the canisters.

At a Feb. 18 meeting with FDA officials, George Stanford, Leland's vice

president, argued that Sports Oxygen was not a prescription drug. He said the product was an over-the-counter drug, because inhaling such a small amount of oxygen caused no ill effects. In addition, he said, the company considered Sports Oxygen effective for "refreshment" and "enhancing a sense of well being" by temporarily increasing the rate of oxygen intake from 21 percent to 28 percent per minute.

That increase, however, doesn't do anything for well being or athletic performance, according to FDA's expert witness, Edward Miller, M.D., chairman of the department of anesthesiology at Columbia University. Inhaling oxygen does not increase oxygen to fatigued muscles, because the molecules that carry oxygen to muscle cells remain almost fully saturated at all times.

Pure oxygen administered by a health professional *may* help athletes recover after an unusual amount of exercise; however, extra oxygen can't be effectively stored in advance, says David Scally, M.D., an anesthesiologist with FDA's Center for Drug Evaluation and Research.

FDA agreed to review Leland's arguments, and the firm agreed to stop marketing the product during the review period.

But Leland's arguments did not sway the agency in its determination that the oxygen canisters were unapproved drugs. In addition, on April 28, 1988, an individual complained to FDA about nausea and a burning sensation in his throat after inhaling Sports Oxygen.

Leland ignored FDA's decision and continued to market Sports Oxygen without the agency's approval.

On Sept. 1, 1988, George Stanford refused to allow FDA investigator Francis O'Sullivan Jr. to inspect Leland's manufacturing facility in South Plainfield, N.J. The agency insisted, and finally, on Nov. 7, Stanford relented. During this inspection, Stanford gave investigators O'Sullivan and Diana Amador revised, but still inaccurate, labels for Sports Oxygen. Stanford admitted that there were no batch records, control numbers, or other quality control procedures in place, as FDA requires for drug manufacturers.

Since 1986, Leland had promoted Sports Oxygen as a product that enhances athletic performance by enabling the user to "perform to the limit" and "get that second effort" and to provide the user with a "blast of pure power," "extra energy," and an "enhanced sense of well being."

Leland revised the advertising to claim only that the product provides "A Breath of Fresh Oxygen." However, in his ruling for summary judgment, Debevoise said the current advertising, depicting the product in the grip of a hand with an athletic sweatband around the wrist, and the name of the product itself ("Sports Oxygen") imply that the intended use is in fact to enhance athletic performance.

On May 11, 1989, FDA requested seizure of the Sports Oxygen canisters at the firm's South Plainfield plant. The U.S. marshal seized the canisters on Oct. 12, 1989, and destroyed them Oct. 30, 1992.

—Dori Stehlin

Caterer Cleans Up, Flies Right

FDA declared a St. Croix airline catering establishment a "no-fly zone," so to speak, until the operation cleaned its kitchen and complied with FDA sanitation regulations. It did so in five days time and reopened with the agency's approval.

San Juan district office's interstate travel sanitation specialist Jaime Pares found a myriad of sanitation violations when he inspected the St. Croix, U.S. Virgin Islands, facility of Caterair International, a firm headquartered in Potomac, Md., just outside Washington, D.C.

Pares rated the facility at Alexander Hamilton Airport a poor 57 percent, and the district office classified it "Not Approved" that same day. (A minimal acceptable rating is 85 percent with no critical defects, such as rodent filth in food; a rating of 60 to 84 percent is "Provisional" and requires reinspection within three weeks.) Caterair was told to stop serving any interstate carriers out of St. Croix until it regained an "Approved" rating. Airlines served by the firm—Delta, American and Continental—were notified of the action.

Pares based his rating on a long list of unappetizing findings, including:

- rodent pellets on a tray of salad plates ready to be served, on a plastic wrapper of two bread biscuits stored in a carton, and on the shelf of a storage cart of vegetables and fruits
- live flies throughout the kitchen, washing room, and tray assembling room
- cockroaches on the kitchen floor and tray assembling room
- food cans with dented seams and rust
- improperly stored raw and cooked foods
- a hose attached to a sink faucet, with the potential for back-siphonage, and a drain from a cooler directly connected to the sewer system with no backflow preventer
- old food and grease encrusted on the stove and food storage shelves
- rust on metal shelves and walls of the stove.

In a letter to Caterair dated Dec. 21, FDA's San Juan district director Stephanie Gray briefly summarized the "appalling sanitary conditions at the facility" that led to the shutdown Dec. 10. The same letter went on to note, however, that Caterair's "Approved" classification had been rein-



stated Dec. 15, when Pares conducted a follow-up inspection and awarded the facility a score of 96 percent.

"Caterair had immediately sent five people from its regional office in Miami to supervise the cleanup," Pares said. "They were closed on Friday and reopened the next Wednesday after putting in 15-hour days to get the place in shape. During that time, flights coming in from the States brought on board enough food to serve on their departures as well," he said.

Under the supervision of a Virgin Islands Department of Health inspector, Caterair voluntarily destroyed 5,487 pounds of food valued at \$5,062.27. The food had been stored in a cooler where Pares observed rodent pellets during his Dec. 10 inspection. Openings in various areas were sealed to prevent entry of vermin, new screens were installed, and a pest control firm was signed on.

Backflow prevention devices were installed where needed, and the walls, ceilings and floor of the plant were cleaned thoroughly. The ovens, stove, and other food equipment were cleaned and sanitized.

"The kitchens appeared like new," Pares said, adding that Caterair's accountant in St. Croix said the firm spent \$150,000 in the effort and fired the general manager. Maintenance will be the big factor now, Pares says, in part because the facility's proximity to the sea presents a constant problem of rust and corrosion. In its Dec. 21 letter to Caterair, FDA acknowledged the effort expended in such a quick and thorough cleanup, but reminded the firm that the agency could reinspect at any reasonable time.

—*Marian Segal*

Defective Syringes Seized in St. Paul

Federal marshals, accompanied by an investigator from FDA's Minneapolis district office, seized approximately 273,900 defective insulin and general use syringes from a St. Paul, Minn., distributor.

The 3-cubic centimeter syringes, worth an estimated \$21,000, were seized from Mediverse, Inc., last Dec. 12 and ordered destroyed. The previous June, the firm had voluntarily recalled and destroyed more than 1.5 million 1-cc and 2-cc syringes, valued at \$100,000, because of similar defects.

Mediverse imports most of its syringes from Shina, a Seoul, Korea, firm in which it owns a one-third interest. Mediverse distributes them throughout the United States, primarily in the Midwest.

FDA first learned of a problem with the syringes June 20, 1991, from a consumer complaint to the agency's Des Moines, Iowa, resident post about defective syringes distributed by Major Pharmaceuticals, Chicago. An investigation by FDA's Chicago district office Oct. 10, 1991, traced the syringes back to Mediverse.

In the meantime, the Minneapolis district had received two more complaints about the syringes.

Minneapolis district investigators inspected Mediverse Jan. 24, 27 and 28, 1992. They collected samples of the three different sizes of syringes and, in reviewing the firm's files, found several more complaints.

FDA sent the syringes to the agency's Winchester Engineering and Analytical Center, Winchester, Mass., for evaluation of the packaging, graduated scale markings, volume accuracy, and needle, barrel and lock quality.

The tests found the following defects:

- holes in some of the packages, which compromised the integrity of sterile packaging
- graduated scale markings that were unclear and thus not easily readable
- scale markings placed at an angle, rather than perpendicular to the syringe barrel, impairing the ability to determine exact drug measurements
- foreign material—usually lint—in the syringe needle or barrel.

As a result of the analysis, the firm recalled the 1-cc and 2-cc syringes and destroyed them on June 25, 1992. The firm requested FDA's permission to sell the 3-cc syringes for veterinary use, but, because these syringes also were defective, FDA denied the request to make sure they would not, at some time, be diverted back for human use.

On May 18, 1992, investigators returned to the firm and collected four more 3-cc syringe samples and further documentation. All four samples were defective, and the lots of 3-cc syringes at Mediverse were seized in December.

Since then, FDA has sampled additional syringes imported from Shina. All those sampled were detained and have either been destroyed or reexported because they were also defective.

As a result, all syringes imported from Shina are now subject to automatic detention, which means the importer must prove they are not defective before the syringes can enter the United States.

There were no reports of injuries attributed to use of the defective syringes.

—*Kevin L. Ropp*

SUMMARIES OF COURT ACTIONS



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

Food/Poisonous and Deleterious Substances

PRODUCT: **Shark Steaks, frozen**, at Hopkins, Dist. Minn.; Civil No. 4-92-228.

CHARGED 3-6-92: When shipped from outside of Minnesota, the articles labeled "Pacific . . . Mako . . . Steak Bl. 8 oz. Vac Pac . . . Peter Pan Seafoods Seattle Wash." and "Shark Steaks . . . Product of Singapore . . . Packed By Seattle Seafood . . . Seattle, Wa . . . Vacuum Packed . . . Ocean Beauty" contained the added poisonous and deleterious substance methyl mercury—402(a)(1).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66391; S. No. 92-573-167 et al.; S.J. No. 1)

Food/Contamination, Decomposition, Insanitary Handling

PRODUCTS: **Mung beans, rice, chickpeas, and other food stocks**, three seizure actions, at Baltimore, Langley Park, and Baltimore, Dist. Md.; Civil Nos. JFM-87-3426, B-87-3460, and 88-1160.

CHARGED 12-22-87, 12-28-87, and 4-20-88: While held by Transit Storage Corp, Baltimore, Md., S.T.N., Inc., Langley Park, Md., and S.L.F. Industries, Inc., Baltimore, Md., various lots of articles in the initial action (*e.g.*, black matpe, mung beans, rice, chanadall, millet, lentils) contained rodent and insect filth, and all of the articles in such action had been held under insanitary conditions—402(a)(3), 402(a)(4); various lots of articles in the second action (*e.g.*, rice and chanadall) contained insect filth; all of the articles in the second action had been held under insanitary conditions—402(a)(3),

402(a)(4); and various lots of articles in the third action (*e.g.*, mung beans and chickpeas) contained rodent filth, and all of the articles in the third action had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: In each action, articles were claimed by S.T.N., Inc., Langley Park, Md. In the second action (Civil No. B87-3460 at Langley Park, Md.), the claimant asserted that it had taken a number of corrective actions, had entered into a plan with court officials to throw out foods subject to reconditioning and to clean what was considered insanitary in the Langley Park warehouse, and had substantially complied with such plan before the seizure of foods by the U.S. marshal at the Langley Park warehouse. The claimant further asserted in a motion for a preliminary injunction that FDA advised, contrary to previous FDA advice, that goods brought into the warehouse after the date of seizure were subject to seizure. Such goods were seized; and the claimant thought the court should issue a preliminary injunction ordering the government to release all goods that came into the warehouse after the date of initial seizure and to order an immediate reinspection of the warehouse. After a hearing, the court denied the claimant's motion.

Subsequently, the claimant entered into consent decrees of condemnation in the first and second actions authorizing release of the articles to the claimant for the purpose of bringing the articles into compliance. The decree in the initial action was amended to permit additional time to post bond and to bring the seized articles into compliance. After the expiration of the extended period for bringing into compliance the articles seized in the first action, the government moved that such articles be destroyed and that the claimant pay court costs and fees. The government also filed a motion for contempt. The claimant opposed such motions, asserting that there was an agreement that the bond posted in the first action was subsequently to be posted for the second action and that FDA had not adhered to the terms of the decree. The claimant also moved for consolidation of the actions.

Meanwhile, a similar consent decree of condemnation was entered in the remaining action and the actions were consolidated. In the consolidated action, a subsequent consent decree amended the prior decrees and ordered the payment of outstanding court costs of \$1,068.50. In addition, the claimant was ordered to submit a detailed statement of the method or methods by which it proposed to bring into compliance the articles that had not been previously released or destroyed. Ultimately, the claimant devised a reconditioning plan that was approved by FDA, and the articles in the three actions were brought into compliance by reconditioning or destruction. (F.D.C. Nos. 65358, 65360, and 65451; S. Nos. 88-550-061 et al., 88-549-304 et al., and 88-549-309 et al.; S.J. No. 2)

PRODUCT: Sugar, and other bakery stocks, at Cicero, N. Dist. Ill.; Civil No. 92 C 0511.

CHARGED 1-22-92: While held by Walsh's Doughnuts, Inc., t/a Holiday Bakers of America, Cicero, Ill., the articles were prepared, packed and held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66355; S. No. 92-661-249 et al.; S.J. No. 3)

Animal Feed

PRODUCT: Tuna chunks in water, canned, at Teterboro, Dist. N.J.; Civil No. 92-1213(NAMW).

CHARGED 3-20-92: While held for sale, the article (which was labeled "Ocean King Chunk Light Tuna in water . . . Distributed By Ocean King Food Inc., New York, NY" and which had been imported from Canada) contained decomposed tuna fish—402(a)(3); the article was pet food which had been relabeled as human food—402(b)(3); and the article was offered for sale under the name of another food—403(b).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66399; S. No. 92-647-583 et al.; S.J. No. 4)

Food Additives

PRODUCT: Evening primrose oil capsules, in bulk and in retail bottles, at Glendale, C. Dist. Calif.; Civil No. 88-7177-MRP(Bx).

CHARGED 12-6-88: While held by Bronson Pharmaceuticals, Glendale, Calif., who had interstate bulk capsules repackaged, in part, into retail bottles labeled "Bronson Evening Primrose Oil with Vitamin E . . . capsules . . . Bronson Pharmaceuticals La Canada, California," the article contained the nonconforming food additive Oil of Evening Primrose (gamma linolenic acid)—402(a)(2)(C).

DISPOSITION: A default decree ordered destruction. Meanwhile, the subject matter was contested in another action. Subsequently, the article was destroyed. (F.D.C. No. 65413; S. No. 88-424-850 et al.; S.J. No. 5)

Drugs/Human Use

PRODUCT: DDS Acidophilus capsules, tablets and powder, and Q-10 Co-Enzyme capsules, at Minneapolis, Dist. Minn.; Civil No. 3-91-225.

CHARGED 4-16-91: When shipped by Shara Laboratories, Inc., Wautoma, Wis., the articles were new drugs without effective approved New Drug Applications—505(a); and while held by United Agri-Services, Inc., Minneapolis, Minn. (who was promoting, in accompanying labeling reading "DDS Acidophilus—Survives Stomach Acid," "DDS Shows Better Retention," and "Coenzyme Q-10: The Super Energy Link," the use of the articles for candidiasis, acne, heart disease, chronic gum disease, and boosting the immune system), the articles' labeling lacked adequate direc-

tions for use for the article's intended purposes—502(f)(1); the articles were prescription drugs (since the articles were offered for conditions not amenable to self-diagnosis and treatment by the laity) lacking the prescription legend—503(b)(4); and the DDS acidophilus capsules, tablets and powder were falsely and misleadingly represented for special dietary use, although the articles had no recognized special dietary nutritional value that was essential to consumers—403(a)(1).

DISPOSITION: The articles were claimed by the dealer, who denied the charges. Subsequently, upon stipulation of the parties, the dealer's claim was withdrawn, the dealer was ordered to pay costs, and the articles were condemned and ordered destroyed. (F.D.C. No. 65888; S. No. 90-572-592 et al.; S.J. No. 6)

PRODUCT: Oxygen for medical use in various-size cylinders, at Shirley, E. Dist. N.Y.; Civil No. 91-4886.

CHARGED 12-11-91: While held by Med-Line Ambulance and Rescue Supply Co., Corp., Shirley, N.Y., the circumstances used for the manufacture, processing, packing, and holding of the article failed to conform with current good manufacturing practice—501(a)(2)(B).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66291; S. No. 91-647-882; S.J. No. 7)

Medical Devices

PRODUCT: Gloves for medical examinations, latex, two lots, at Hato Rey, Dist. Puerto Rico; Civil No. 89-1482-JP.

CHARGED 11-14-89: The quality of the article, which was labeled "Summit . . . latex examination gloves . . . Disposable Non-Sterile . . . Made in Taiwan," fell below the article's purported quality since the article contained excessive holes and/or leaked—501(c); and the labels of the above article and an article labeled "Disposable . . . Latex Exam Gloves . . . Non-Sterile . . . Made In China" lacked the name and place of business of the manufacturer, packer or distributor—502(b)(1).

DISPOSITION: The articles were claimed by Enrique S. Melendez-Lugo, t/a ABCO Distributors, Hato Rey, Puerto Rico. The claimant moved that this and a similar seizure action be consolidated and that a stipulation having the effect of settling the matter be acceptable in lieu of an answer to the complaint. Subsequently, a consent decree of condemnation authorized release of the article to the claimant for salvaging. After the claimant posted the required bond, the parties litigated the reconditioning of the articles. Ultimately, the articles were relabeled and disposed of for nonmedical uses. (F.D.C. No. 65779; S. No. 89-511-010 et al.; S.J. No. 8)

PRODUCTS: Temporomandibular joint and anaform femoral prosthetic devices, two seizure actions, at Houston, S. Dist. Texas; Civil Nos. H-90-3000 and H-90-3001.

CHARGED 9-20-90 and 9-20-90: *Telge Street seizure; H-90-3000.* The temporomandibular joint (TMJ) devices (which consisted of

separately packaged glenoid fossas and condyles, along with fastening accessories such as bone screws, bolts and nuts and which, prior to June 7, 1990, had been manufactured by Vitek, Inc., Houston, Texas, and which were subsequently manufactured by Oral Surgery Marketing, Houston, Texas) were dangerous to health when used as directed in the articles' labeling—502(j); the labeling of the TMJ devices lacked adequate directions for use—502(f)(1); notice or other information respecting the TMJ devices had not been provided as required—502(o); and the anaform femoral endoprosthesis devices (two-part hip implant devices with a plastic laminate coating) were class III devices without the approval of an application for pre-market approval—501(f)(1)(B).

Intercontinental Airport seizure; H-90-3001. Twelve anaform femoral endoprosthesis devices (hip implants) labeled "NovaMed Incorporated Anaform Femoral Endoprosthesis . . . Shipped Non Sterile—Steam Sterilize Only . . . NovaMed, Inc. . . Telge Street, Houston, Texas" were class III devices without the approval of an application for pre-market approval—501(f)(1)(B). **DISPOSITION:** The 12 hip implant devices seized at the airport (H-90-3001) were claimed by NovaMed Corp., Houston, Texas, who denied that the articles were adulterated. The other articles (seized at Telge Street—H-90-3000) were claimed by Oral Surgery Marketing, Inc., Houston, Texas, who denied that the articles were adulterated or misbranded. The actions were consolidated for trial. The government moved for summary judgment. The court granted summary judgment to the government, condemning the hip joint devices as being adulterated and the TMJ devices as being misbranded and ordering the articles destroyed. (F.D.C. Nos. 65918/65919; S. No. 90-451-985 et al.; S.J. No. 9)

CRIMINAL ACTIONS

DEFENDANTS: Sercovich & Sons Seafood, Inc., Donald D. Sercovich, president, and **Marion Franicevich**, employee, E. Dist. La.; Criminal No. 90-153-SEC "J."

CHARGED 5-4-90 in a superseding indictment: *Count 1*—when shipped to Bayou LaBatre, Ala., by the firm and its employee, with intent to defraud and mislead, oysters labeled 'Area Dredged: "Q.B." ' were misbranded—403(a); *Count 2*—when shipped by the president of the firm to Bayou LaBatre, Ala., oysters labeled as above were misbranded—403(a); *Counts 3 & 4*—the firm and its employee knowingly attempted to transport and sell oysters in interstate commerce from Louisiana to St. Petersburg, Fla., when, in the exercise of due care, the defendants should have known that such oysters were unlawfully possessed—16 U.S.C. 3373(d)(2); *Count 5*—when shipped to Biloxi, Miss., by the firm and its employee, with intent to defraud and mislead, oysters labeled "Area Dredged: 'Quarantine Bay' Vessel: 'Old Bill' " were misbranded—403(a); and *Count 6*—when shipped by the president of the firm to Biloxi, Miss., oysters labeled as in count 5 were misbranded—403(a).

DISPOSITION: The employee pleaded guilty to counts 1, 3, 4 and 5, and was placed on probation for three years with special condi-

tions, including a \$250 fine. The firm and its president pleaded not guilty. The case came on for trial by court and jury. At the conclusion of the government's case, the court granted the defendants' motion for a directed verdict as to counts 1, 2, 5 and 6, thereby **acquitting** the firm's president. The jury returned a verdict of guilty as to the firm on counts 3 and 4 and a verdict of **not guilty** on counts 1 and 5. Imposition of sentence was suspended, but the firm was placed on probation for five years, and the probation included special conditions, including the payment of a \$10,000 fine. (F.D.C. No. 65720; S.J. No. 10)

INJUNCTION ACTIONS

DEFENDANT: Jeong C. Choi, t/a Han Yang Oriental Food Manufacturing, Tacoma, Wash.; Civil No. 91-5473.

CHARGED 11-15-91 in a complaint for injunction: That the defendant prepared, packed, held and distributed a variety of foods (e.g., soybeans, tofu, and rice cakes) at his Tacoma facility; that the defendant's foods were prepared, packed and held under insanitary conditions whereby they might have become contaminated with filth or rendered injurious to health due to harmful bacteria—402(a)(4); that FDA inspections revealed insanitary conditions in and around the food processing facility, including insanitary employee practices, flies, mold, rust, rodent excreta pellets, and static water on the floor and product spillages; that FDA analyses disclosed the presence of pathogenic *Yersinia enterocolitica* bacterium in a tofu sample, and yeast and mold in a rice cake sample; that FDA had discussed sanitation problems with the defendant on several occasions, and, notwithstanding the defendant's assurances of correction, the problems persisted.

DISPOSITION: A consent decree of permanent injunction enjoined the complained-of violations and enjoined the defendant's operations involving any interstate food unless and until a number of specified conditions were met, including the elimination of insect infestation, maintenance of the food facility so as to preclude contamination of food with filth or bacteria, the establishment of an employee training program that included instruction in sanitation, and the certification by an expert that an adequate sanitation control program had been established. (Inj. No. 1269; S. No. 91-534-052 et al.; S.J. No. 11)

MISCELLANEOUS ACTIONS

SUBJECT: Import detention of peeled shrimp and FDA action levels, Port of Miami, S. Dist. Fla.; Civil No. 91-0006.

PETITIONED 1-2-91 by Deep Sea Products Inc., Miami, Fla., against the United States of America and the HHS Secretary, for return of property pursuant to Rule 41(e) of the *Federal Rules of Criminal Procedure*: That FDA had detained petitioner's fresh shrimp, which had been produced in El Salvador; that the shipment in question consisted of 391 cases of shrimp (broken down into 31 lots based on the size of the product and several lots being composed

of mixed sizes); that one of the lots was sampled by FDA and allegedly found to exceed acceptable filth standards, and the goods were found to be inadmissible because it appears that the shipment contained insect filth and flies; that the petitioners had requested an opportunity to sample the shipment and have the samples independently tested; that the independent laboratory either found no filth in the samples or—in five samples—one element of filth (i.e., remnants of a single rodent hair in four lots and a whole fly in one lot); that, based upon such analysis and FDA operating guidelines, the shipment fell within FDA acceptable standards; that FDA questioned such results and denied the importer's application to segregate the shipment based on favorable lab results, because not all lots other than the lot sampled by FDA were sampled by the importer and because for the lots sampled and the results submitted, three subsample results were submitted instead of six; that, subsequently, an FDA notice released all of the lots sampled by the importer except the lot previously tested by FDA and found to be filthy; however, the lots not sampled continued to be detained. The importer argued that FDA had acted arbitrarily and capriciously; that there was no reason to believe that the remaining detained lots were adulterated; that the only filth detected by the importer's lab was so minute that it could only be measured in microns; that the sampling requirements and action levels established for imported shrimp were an abuse of discretion, were arbitrary and capricious, and—to the extent that it was not subject to the Administrative Procedure Act—were invalid. **DISPOSITION:** The government moved to dismiss the petitioner's suit, and the court granted such motion. The court dismissed the case on two grounds.

First, the court found that, because there was no seizure or deprivation of property, Rule 41(e) was inapplicable. The importer was free to take custody of its merchandise and export it elsewhere. Detention and refusal of admission into the United States is not a "taking" under the Fifth Amendment and the importer was not denied his property by such refusal.

Second, the importer had not exhausted its available administrative remedies, and FDA was explicit on the use of administrative remedies before bringing a case to district court. 21 *CFR* Section 10.45(b). The importer had failed to utilize any of the cited administrative remedies, arguing that further administrative action on its part would be futile. However, there was no reason to believe that, upon testing and investigation of the remaining lots, FDA would not reverse its decision to deny entry. It appeared to the court that the importer was deliberately trying to circumvent administrative proceedings in this case because of what it perceived as bias against the importer by FDA, and that the importer's reference to a previous shipment of shrimp by the importer which was denied entry was irrelevant to this action. The court concluded as follows: "The FDA has more expertise in this area, and this Court would be derelict in its duties if it were to trump the autonomy of the FDA without giving the Agency an opportunity to correct its errors, if any. Furthermore,

additional review by the FDA would promote efficiency and the development of facts that would aid this Court if it became necessary to review the FDA's action. Plaintiff must therefore exhaust his administrative remedies in accordance with 21 *CFR* Section 10.45 (1990), prior to bringing its cause of action before this court." (Misc. No. 938; S.J. No. 12)

SUBJECT: Standardized absorbency terminology for menstrual tampons and the issuance of FDA regulations, Washington, Dist. Columbia; Civil No. 88-1492.

PETITIONED 6-1-88 by Public Citizen Health Research Group (HRG), and Public Citizen, nonprofit public interest organizations in Washington, D.C., against FDA Commissioner Frank E. Young, HHS Secretary Otis R. Bowen, and Office of Management and Budget director James C. Miller, III, in a complaint for declaratory and injunctive relief: That FDA had tentatively concluded in 1981 that data supported the conclusion that users of high-absorbency tampons had a greater risk of contracting toxic shock syndrome (TSS) than users of low-absorbency tampons and had issued a regulation in 1982 requiring information about such syndrome on or with tampon packages. However, one manufacturer's "super" might be less absorbent than another manufacturer's "regular," and women could not intelligently select the tampons that would minimize their risk of contracting TSS. In 1983, in a final response to an HRG petition for a uniform nomenclature for tampon absorbency, FDA had stated its agreement with HRG's objectives, but indicated its preference that a task force of manufacturers, consumers, and FDA representatives establish voluntary standards.

Although the task force agreed upon a test for tampon absorbency, neither the task force nor the manufacturers on their own could agree on a standardized nomenclature. In 1985, after HRG had renewed its petition for a tampon absorbency standard and FDA had also concluded that a labeling regulation was necessary, an FDA advisory panel concurred that tampon packages should be labeled with an absorbency rating. In 1988, after a confirming epidemiological study and after HRG had filed another petition, FDA was scheduled to issue a notice of proposed rule-making, but failed to issue such notice. Since a regulation was necessary to protect the public health of tampon users and since failure to propose such a regulation under the circumstances constituted an unreasonable delay, the plaintiffs prayed that the defendant's failure to act be declared to violate the Administrative Procedure Act and that the defendants should be directed to issue a proposed regulation.

DISPOSITION: Upon consideration of the pleadings, supporting memoranda and exhibits, the arguments of counsel, and the entire record, the court found for the plaintiffs and enjoined the defendants to issue a final regulation. The defendants moved to modify the opinion of the court, but the court denied such motion. A final regulation was issued and was subsequently amended as to an item of testing procedure. (Misc. No. 866; S.J. No. 13)

In spring and summer, your appetite may turn to shellfish.

But before you dig in, be sure to know how to protect yourself from food-borne illness from raw molluscan shellfish such as oysters and clams.

(For people with certain chronic conditions, such as diabetes mellitus, immune disorders, liver disease, or gastrointestinal disorders, the best bet is *not* to eat raw or undercooked shellfish.)

For more information on how to prevent food poisoning from shellfish, write to :

Shellfish Kit
FDA (HFE-88)
5600 Fishers Lane
Rockville, MD 20895

