FOCUS ON FOOD LABELING

READ THE LABEL

Using the New Food Label To Choose Healthier Foods

Cómo leer la Nueva Etiqueta de los Alimentos

Nutrition Facts

Food and Drug Administration

Set A Healthy Table
Food Labeling Education Serves Many Groups

FDA and the Department of Agriculture have embarked on a program spanning several years to educate diverse groups about how to make the most out of the new food label.

To Reduce Birth Defects: FDA Proposes Folic Acid Fortification

After studies showed that women eating diets rich in folic acid are less likely to give birth to babies with brain and spinal cord defects, FDA proposed adding the vitamin to all bread and grain products. The trick is to add enough to help, but not enough to hurt.

A Consumer’s Guide to Fats

Is margarine better for your blood vessels than butter? Is dousing your salad with olive oil wise? Is it true what they say about omega fatty acids? The latest in fat science gives some of the answers.

Decoding the Cosmetic Label

Figuring out the contents listed on a cosmetic label with terms like methylisothiazolinone and phenoxyethanol can be a challenge, even for the well-educated. But there are ways to decipher this chemical lingo.

No Human Risks: New Animal Drug Increases Milk Production

Allowing a genetically engineered hormone to be given to dairy cows to increase milk production was a decision based on solid science. But that hasn’t prevented controversy.

Updates

Investigators’ Reports

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Summaries of Court Actions

FDA materials are among those being produced by a wide variety of organizations as part of a campaign to educate various groups of consumers about how the new food label can help them eat nutritiously.
**Company Recalls Asthma Inhaler**

Boehringer-Ingelheim Pharmaceuticals Inc. has voluntarily recalled four lots of Alupent Inhalation Aerosol, a metered-dose inhaler used by asthma patients to help ease breathing, because these lots may not provide effective medication doses.

The company began the recall last February with three lots and expanded it in March to include a fourth.

Using a subpotent inhaler is especially risky for patients with potentially life-threatening asthma attacks. Patients whose asthma worsens should seek prompt medical help.

Boehringer-Ingelheim notified doctors and pharmacists in letters that “in no case should patients abruptly discontinue use of their Alupent Inhalation Aerosol.” Instead, patients should promptly return inhalers with these lot numbers to their pharmacies for replacement: 930186A, 930729A, 930730A, and 930731A. No other Alupent dosage forms or asthma medications are involved.

Doctors and patients having questions about the recall may call the company at (1-800) 542-6257.

**Immune Globulin Intravenous Removed from World Market**

Baxter Healthcare Corporation, at the end of February, announced it was removing its immune globulin intravenous (IGIV) product Gammmagard from the market worldwide because of the possibility that it may have transmitted the hepatitis virus, including hepatitis C. Baxter’s IGIV is also distributed by the American Red Cross under the name Polygam.

The company reported to FDA five confirmed cases of patients contracting hepatitis C infection after receiving Gammmagard. Three patients were in Spain and two in Sweden. However, it has not been confirmed that the product transmitted the virus, and FDA is unsure whether these cases resulted from the administration of IGIV or some other cause. These are the first cases of hepatitis associated with licensed IGIV, although a few cases of hepatitis C had previously been linked to unlicensed IGIV products in clinical trials.

FDA is monitoring Baxter Healthcare’s efforts to identify implicated lots of the product and to analyze the laboratory and clinical evidence of infection in the five reported cases. Other patients who received IGIV and have shown evidence of having hepatitis are being studied.

Baxter’s IGIV products are derived from human blood plasma and are used to treat a number of congenital and acquired immunological abnormalities. All donors of plasma used to manufacture injectable products for treatment and prevention of disease are screened for five blood-borne disease agents, including hepatitis C, hepatitis B, and HIV (the virus that causes AIDS).

**U.S. Drugs Speed To Russian Markets**

An agreement between the Russian Ministry of Health and Medical Industry and the Food and Drug Administration, signed early this year, ensures that U.S. medications meeting FDA standards for safety and efficacy will have nearly automatic entry into the Russian Federation.

Commenting on the agreement, Health and Human Services Secretary Donna E. Shalala said, “This is the best kind of international cooperation. It can quickly bring some of the world’s safest and most effective drugs to millions to relieve their suffering and improve the quality of their lives.”

Previously, time-consuming and costly Russian registration requirements had been imposed on U.S. medications. The registration procedure required before products could be marketed in Russia had had no time limit.

The agreement gives U.S. pharmaceutical companies speedier and greater access to Russian markets. The Russian health ministry will allow importation of FDA-approved, U.S.-made drugs and biologies without additional clinical trials and will limit its review period to 90 days. U.S. firms will have to submit...
about the company, the FDA approval letter and approved labeling for the product, a statement verifying the company's compliance with good manufacturing practices, and a copy of the company's most recent FDA inspection report. Firms will not have to provide a Russian translation of the thousands of pages of scientific information about their products, which previously had been required.

The Russian health ministry also agreed to accept FDA inspections of U.S. firms as a guarantee that proper manufacturing practices are being followed.

**Last Defendant Sentenced In Orange Juice Scheme**

The final defendant in a $40 million orange juice fraud case was sentenced on Jan. 28, 1994.

Jeffrey K. Bennett, vice president for manufacturing of Peninsular Products Co., Lansing, Mich., received three years probation and a $1,000 fine after cooperating with government prosecutors.

Flavor Fresh Foods Corp., Chicago, and 11 of the two firms' corporate officers, including Bennett, pleaded guilty in the U.S. District Court for the Western District of Michigan last Sept. 1 to defrauding consumers by selling products containing low-cost, inferior ingredients but labeled as pure orange juice from concentrate. (See "Juice Maker Cheats Consumers of $40 Million" in the January-February 1994 FDA Consumer.)

For over 12 years, Flavor Fresh and Peninsular Products had sold more than 40 million gallons of adulterated orange juice in at least 25 states under at least 23 different labels.

**HIV Transmission to Babies Reduced in Early Study Results**

Preliminary results of a binational trial of Retrovir (zidovudine, also known as AZT), announced last February, indicate that treatment with the drug can reduce by two-thirds the risk of HIV-infected pregnant women transmitting the virus to their babies.

The double-blind, randomized, placebo-controlled study was sponsored by the United States' National Institute of Allergy and Infectious Diseases through the AIDS Clinical Trials Group. Also participating were sites affiliated with the National Institute of Child Health and Human Development and France's Institute National de la Santé et de la Recherche Medical and Agence Nationale de Recherches sur le SIDA. Both the allergy and child development institutes are part of the National Institutes of Health.

An interim review of the study showed a transmission rate of 8.3 percent when both mothers and babies received Retrovir, compared with a transmission rate of 25.5 percent when they received a placebo. As a result of this statistically significant finding, enrollment in the study was stopped, and all those then enrolled were offered Retrovir.

The study data were examined through Dec. 20, 1993. At that time, 477 women had enrolled in the trial and 421 babies had been born. Of these, 364 babies had been followed to determine whether they were infected with HIV.

The women were randomly assigned to one of two groups and treated beginning in the second or third trimester of pregnancy. One group received Retrovir and the other received a placebo during pregnancy and labor. The babies received the same treatment as the mothers in syrup form for six weeks after birth. Neither the researchers nor the patients knew who was getting the Retrovir.

Of the 364 babies for whom definite test results were available, 53 were infected with HIV; 13 were born to mothers receiving Retrovir and 40 to mothers on placebo.

Because the results reported are preliminary and long-term effects of treatment on the infants are unknown, no recommendations about treatment to prevent HIV transmission during pregnancy and delivery are being made at this time. Study investigators plan to follow the infants for a number of years and to follow the women in the trial for six months after delivery.

HIV is the fifth leading cause of death in U.S. children younger than 15 years, according to the National Center for Health Statistics. As of Sept. 30, 1993, the na-
tional Centers for Disease Control and Prevention received reports of 4,906 AIDS cases in children under 13 years. Of these, 4,328 had a mother with or at risk of having HIV, and 2,615 of the children died. Each year in the United States, about 7,000 HIV-infected women give birth and about 25 percent of their babies are HIV-infected.

**New Office for AIDS, Special Health Issues**

A new Office of AIDS and Special Health Issues was recently announced by FDA.

An expansion of the former Office of AIDS Coordination, the new office coordinates all of FDA’s outside activities related to serious and life-threatening diseases such as AIDS, cancer, and Alzheimer’s disease.

In addition, the office works closely with those parts of FDA responsible for helping to ensure the safety of the blood supply and the safety and effectiveness of drugs, biologics, vaccines, medical devices, and diagnostic test kits used for these illnesses. It will also assist in communications with other government and community-based groups with interests in these areas.

Randolph F. Wykoff, M.D., is associate commissioner of the new office. He has been director of the Office of AIDS Coordination since its inception, nearly five years ago.

The new office, may be reached at FDA (HF-12), 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-0104; facsimile (301) 443-4555.

**National AIDS Task Force**

Health and Human Services Secretary Donna E. Shalala, Ph.D., named members of a new National Task Force on AIDS Drug Development that is charged with expediting the search for new therapies for AIDS and HIV infection. Assistant Secretary for Health Philip R. Lee, M.D., will head the panel, which includes representatives from government, academia, the drug industry, medicine, and AIDS-affected communities.

Announcing the panel members last Feb. 4, Shalala said, “AIDS now kills an average of 92 Americans a day. It is urgent that we expedite the development and use of better drugs. I’ve asked this panel to identify new approaches in research and to remove any barriers or obstacles to developing effective treatments.”

Other government representatives include FDA Commissioner David A. Kessler, M.D., and National Institutes of Health director Harold Varmus, M.D.

Other members and their affiliations are: Moises Agosto, National Minority AIDS Council, Washington, D.C.; Arthur Ammann, M.D., Pediatric AIDS Foundation, Novato, Calif.; Stephen K. Carter, M.D., Bristol-Myers Squibb, Princeton, N.J.; Ben Cheng, Project Inform, San Francisco; Deborah J. Cotton, M.D., Harvard Medical School, Boston; Mindy Fullilove, M.D., New York State Psychiatric Institute, New York; David Ho, M.D., Aaron Diamond AIDS Research Center, New York; Daniel Hoth, M.D., Cell Genesys, Foster City, Calif.; Theresa McGovern, HIV Law Project, New York; Charles Nelson, Morehouse School of Medicine, Atlanta; G. Kirk Raab, Genentech, San Francisco; Robert Schooley, M.D., University of Colorado, Denver; Edward Scolnick, M.D., Merck Research Laboratories, Rahway, N.J.; Peter Staley, Treatment Action Group, New York; and Flossie Wong-Staal, Ph.D., University of California, San Diego.

**Hair Dye Study**

Most use of permanent hair dyes does not significantly increase a woman’s risk of cancer, according to a study conducted jointly by FDA and the American Cancer Society. The study of more than 575,000 women was published in the February 1994 issue of the *Journal of the National Cancer Institute*.

The results of the study did suggest that prolonged, constant use—for 20 years or more—of black hair dye may slightly increase the risk of some rare types of cancer. These findings are based on only a few cases, however, and constitute a small percentage of all deaths from cancer.

The study was undertaken to address concerns raised by a smaller, earlier National Cancer Institute study about a possible link between the use of hair dyes and the development of non-Hodgkin’s lymphoma in women.

FDA and the American Cancer Society will continue to evaluate the data from the 1994 study.

**Gallup Polls Women About Birth Control Pills**

Most American women don’t believe birth control pills are safe enough to buy without a doctor’s prescription, according to a Gallup Poll released last January. However, the proportion of women who believe substantial health risks are associated with the pills has declined significantly since 1985.
The American College of Obstetricians and Gynecologists commissioned the poll to compare women's views with a similar poll in 1985. Based on telephone interviews nationwide with 997 women 18 and over, the results show that:

- 86 percent of women overall, and 91 percent of women on birth control pills, don't believe the pills are safe enough to buy without first seeing a doctor.
- 54 percent of women believe there are substantial risks associated with use of the pills, down from 76 percent who held such views in 1985; of these women, 29 percent cite cancer as the chief risk, as did 31 percent in 1985.
- 41 percent believe the pills provide no health benefits other than preventing pregnancy, and only 6 percent are aware of the pills' protection against cancer, such as ovarian and endometrial cancer.
- 65 percent believe using birth control pills is more risky or as risky as childbirth, as did 64 percent in 1985; in fact, childbearing carries twice the risk of death as use of birth control pills.

**Correction**

The order number for the *FDA Consumer* special report *Focus on Food Labeling* was incorrectly stated in “New Food Label Close-Up” in the April 1994 *FDA Consumer*. The correct number is S/N 017-012-00360-5. Orders should be addressed to Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7594.

**Reports to MEDWATCH**

As of Feb. 18, 1994, MEDWATCH, FDA's medical product reporting program received reports of 6,442 adverse events or other problems. FDA launched the program last June. The chart on the left shows reports according to type of product; the chart on the right shows reports by profession of reporter.

If you suspect you have had a serious adverse event due to a medical product, let your doctor or other health professional know so they can report it to the MEDWATCH program.
Food Labeling Education Serves Many Groups

by Paula Kurtzweil

Wayne Jacobs, president of the Baltimore-based Jacobs Jenner & Kent, is feeding his audience questions. He wants to find out how the members feel about the food label in general and a proposed food labeling brochure in particular.

His questions go something like this:

"Do you read food labels? Why? What do you look for? How would this brochure help you change your behavior?"

He gets a variety of answers.

"I have to watch for too much sodium," says one, explaining why he reads food labels. "I look for the cholesterol levels all the time," says another.

As for how the brochure might change behavior: "I'm going to start reading [labels]," a woman replies. "I'm going to pay more attention to ingredients," says another. And still a third: "Am I going to apply [the food label] daily? Probably not."

Jacobs isn't asking his questions out of idle curiosity. He's asking because the Food and Drug Administration has hired his company to develop and test a food labeling brochure for consumers with limited reading skills.

The brochure is one of many educational materials being developed as part of a food labeling education campaign headed by FDA and the U.S. Department of Agriculture. (USDA regulates meat and poultry; FDA is responsible for all other food.) The campaign focuses on helping people—especially those at greatest risk for poor nutrition—become aware of the new food label and use it to make healthy food choices.

Jacob's questioning took place in Greenbelt, Md., where he conducted a small-group survey of men and women enrolled in local literacy development classes. Their responses will be used to produce an FDA-USDA brochure targeted for an audience with no more than a fifth-grade reading ability.

The project demonstrates one way public and private organizations are trying to help diverse consumer groups learn about the new food label. Other groups targeted for education efforts are non-English-speaking people, older Americans, children, people with special dietary needs, and those in lower socioeconomic groups.

The campaign takes on added meaning and activity May 8, when most of FDA's food labeling regulations go into effect. On that day, by law, food manufacturers must start putting nutrition information on the labels of most of their products, presenting the information in a new, easy-to-use format. FDA is highlighting the event with new radio and TV public service announcements focusing on the labeling changes.

The new labeling regulations apply only to foods labeled on or after May 8. So consumers may continue to see the old nutrition label on some food packages after May 8. "This campaign is not simply about a better food label on food packages," noted FDA Commissioner David A. Kessler, M.D. "It is about Americans living longer, better quality lives, and about lower healthcare costs. That's why our real focus needs to be on education."

The intent, according to Kessler, is to "institutionalize" the message about the new food label by making sure it is in appropriate textbooks, such as home economics and health books, and in materials used by nutritionists, dietitians and health educators in years to come.

A Campaign Begins

FDA took on this food labeling education challenge in 1990, when the Nutrition Labeling and Education Act (NLEA) became law. NLEA is responsible for most of the...
Checking out the new food label on a package of corn tortillas at a Southwest Supermarket in Phoenix, Ariz., are (from left) Elizabeth Valdes, M.D., Linda Ferriere, and Pascual Avitia. They're preparing for a series of English/Spanish seminars on the new food label to be held for Phoenix-area residents this month. Valdes is the chief executive officer of Concilio Latino de Salud, an organization sponsoring the seminars with FDA.
food labeling changes taking place. But, as its name implies, the act also emphasizes education. In particular, it calls for activities to educate consumers about the availability of nutrition information in food labeling and the importance of using that information to make healthy dietary choices.

Charged with that mandate, FDA set out, with USDA, to establish a national consumer education campaign. The agencies enlisted the help of other federal agencies, the food industry, trade associations, consumer groups, health professionals, and educators. The groups pooled their ideas and, in some cases, their funds to develop educational activities targeting diverse populations.

The result was the establishment of the National Exchange for Food Labeling Education, or NEFLE.

A centerpiece of NEFLE is the Food Labeling Education Information Center of the National Agricultural Library in Beltsville, Md. Through a computerized database of education and research activities, the center can help organizations and individuals learn what food labeling activities are under way across the country.

**Educational Activities**

The educational activities involve a variety of media. Chief among them are publications—brochures, magazine articles, and backgrounders—some of which give a general overview of the food labeling changes. An example is *How to Read the New Food Label*, a brochure by FDA and the American Heart Association, 3 million copies of which were distributed within the first six months of the brochure's availability. Many of these were ordered from the federal Consumer Information Center in Pueblo, Colo., which is helping to distribute other government-produced food labeling materials.

Ready-to-print newspaper articles on the food label also were prepared by FDA and USDA and sent to newspapers across the country. Several hundred papers have published these articles.

Some food labeling publications give more detailed information. One of the first was *Label Facts for Healthful Eating*, a 92-page educator’s resource guide by the

Many organizations have produced written materials to help teach Americans about the new food label.

**Database of Campaign Activities**

From brochures to lesson plans to a giant milk carton, the Food Labeling Information Center provides information on many food labeling education projects now under way.

The information is available via the center’s 1 ½-year-old database. From it, consumers, educators and others can find out what projects are planned or under way, who their target audiences are, and how copies can be obtained. They even can find potential partners for an educational project. The database now gives information on nearly 150 projects.

The information is important, said Gina McNeal, an information specialist who oversees the database, to avoid duplication of materials and identify groups whose educational needs are not being met.

For example, she said, few projects specifically target minority groups with foods, activities, diseases, and language that they can relate to. And only a few are geared to elementary school kids. “Materials for these special groups are needed,” she said.

To find out more about the database or the information center, write to McNeal at the Food and Nutrition Information Center/National Agricultural Library, 10301 Baltimore Blvd., Room 304, Beltsville, MD 20705-2351; or call (301) 504-5719, facsimile (301) 504-6409.

—P.K.
FDA has available the following free brochures on the new food label. For one copy only, write to: FDA (HFE-88), 5600 Fishers Lane, Rockville, MD 20857.

To receive two to 25 copies, write to FDA (HFI-40) at the same address. Or, fax your order to (301) 443-9057.

Please include publication numbers with all orders.

An Introduction to the New Food Label (FDA 94-2271) by FDA and the U.S. Department of Agriculture. An overview of food labeling changes with a poster of the "Nutrition Facts" panel.

How to Read the New Food Label (FDA 93-2260) by FDA and the American Heart Association. An introduction to food labeling changes, particularly those that apply to heart disease prevention.

Cómo Leer la Nueva Etiqueta de los Alimentos (FDA 93-2260S) by FDA and the American Heart Association. A Spanish version of How to Read the New Food Label.

For example, in Georgia, Robert Purvis, an agricultural manager with the state’s Department of Agriculture, is working with community colleges in rural areas to offer night classes on the new food label. He plans to hold his first class this spring.

“We’ve had several requests for it from the community,” Purvis said. “People want to know about this new food label.”

In Detroit, people in lower socioeconomic groups will receive individual or group instruction on how information on the food label can be used to reduce fat intake. FDA’s Detroit district office and the Michigan State University Extension Service are developing a workbook to accompany the instruction. They plan to make the workbook available throughout the country.

And in Phoenix, Ariz., Gil Meza, a public affairs specialist in FDA’s resident post there, is working with the Concilio Latino de Salud (Latino Council on Health), a community health organization, to present four bilingual seminars on the new food label. The seminars will target Spanish-speaking residents and feature a shopping tour to one of the city’s largest grocery stores.

Other FDA public affairs specialists in the agency’s district offices around the country participate in similar educational projects. They can help consumers and local groups learn more about the new food label, too. They can be found in the blue pages of the telephone book under “Department of Health and Human Services.”
Mass Media and Research

The mass media also play an important part in the campaign, mainly by helping to spread the word about the new food label. FDA, along with other public and private organizations, maintains the media’s interest in food labeling by updating them on current activities and arranging for interviews with agency officials.

“The media still are the best megaphones for getting the word out on the food label,” said James A. O’Hara III, FDA’s associate commissioner for public affairs. “That’s why we plan to work with every reporter, producer, and talk show host possible during the next few months.”

Research, too, is an important part of the education campaign. It’s important, campaign officials say, because it helps ensure that the materials developed are properly targeted, carry clear and understandable messages, and reach the right people.

Some research is designed to examine consumers’ use of food labels. For instance, USDA and the Department of Health and Human Services’ Public Health Service, including FDA, are now involved in a multi-year study of consumers’ use of food labels. These results will enable the government to learn what effect the new food label is having on people’s eating habits.

Other studies look at consumers’ perception and understanding of various educational materials. For example, in focus groups, a small number of consumers with similar backgrounds meet as a group and give their opinions on proposed instructional material—from brochures to TV public service announcements. Although not scientific surveys, these studies have proven useful in predicting how well consumers will understand label information and print and video materials that explain the food label.

The FDA-sponsored survey of adults with limited reading skills is one example of a focus group study. It resulted in a 10-page brochure suitable for Americans with no more than a fifth-grade reading ability. (See “‘Daily Values’ Encourage Healthy Diet” in the May 1993 FDA Consumer.) It’s appropriately called How the New Food Label Can Help You Plan a Healthy Diet.

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

Health officials hope consumers will take home at least these points about the new food label:

• You can believe the claims on the package.

These include claims describing a food as “low fat” or “high fiber” or citing a relationship between a food or nutrient and a disease or health-related condition; for example, a diet with enough calcium may lower the risk of osteoporosis. These claims are believable because the government now defines how they can be used. (See “Starting This Month Look for ‘Legit’ Health Claims on Foods” in the May 1993 FDA Consumer and “A Little ‘Lite’ Reading” in the June 1993 FDA Consumer.)

• You can more easily compare products because serving sizes will be more comparable for similar products.

As before, the serving size is the amount of food that will give the calories and nutrient amounts listed below it. But now, serving sizes must be about the same for similar products. With like serving size amounts, it will be easier to compare the nutritional qualities of related foods. Also, serving sizes will now reflect the amount of food that most people eat at one time. (See “‘Nutrition Facts’ to Help Consumers Eat Smart” in the May 1993 FDA Consumer.)

• By using the (% percent) Daily Value, you can quickly determine whether a product is high or low in a nutrient.

The %Daily Value shows how much a serving of food will contribute to the total day’s recommended nutrient intake. Although these percentages are based on 2,000 calories a day, they still can be used by people who eat more or less because they give a general idea of how well the food fits into the total day’s diet. The goal is to choose foods that together give you close to 100 percent of each nutrient for a day or average about 100 percent a day over a few days.

• By consulting the daily values, you can determine how much, or how little, of the major nutrients you should eat on a daily basis.

The labels of some larger packages, as well as some others, will list daily values for a 2,000- and a 2,500-calorie diet. These values are based on current dietary guidance and can help consumers understand good diet basics and choose nutritious foods. (See “‘Daily Values’ Encourage Healthy Diet” in the May 1993 FDA Consumer.)

P.K.
The message to pregnant women is clear. A little investment in nutrition now pays off richly in your baby’s health later.

For that reason, the Food and Drug Administration proposed last October that all bread and grain products be fortified with folic acid, one of the B vitamins. Just 0.4 milligrams (mg) of the nutrient every day can greatly reduce the risk of neural tube defects, which affect the brain and spinal cord.

Folate is in many healthful foods. (Folate and folic acid are interchangeable terms. Folic acid is the synthetic form of folate, which is found naturally in some foods.) A bowl of lentil soup or fortified breakfast cereal, a large spinach salad, or a tall glass of orange juice will put a woman well on her way to 0.4 mg of folic acid.

The tricky part is that neural tube defects occur in an embryo before a woman may realize she’s pregnant. Since more than half of pregnancies are unplanned, FDA has taken steps to fortify food so that all women of childbearing age get a daily dose of folic acid.

Without it, most women 19 to 50 get only 0.2 mg of folic acid each day, according to U.S. Department of Agriculture estimates. If the regulation is finalized within the next six months, FDA estimates that the fortified food will reach the plates of more than 90 percent of American women by 1995. If the move is successful in boosting women up to 0.4 mg of folic acid daily, it could cut the incidence of neural tube defects in this country by as much as half.

A Difficult Decision

Despite this benefit, the decision to add folic acid to food is difficult because it’s so tricky to estimate what people eat. Most of the folic acid studies have been done with vitamin pills, not plates of food. It’s hard for scientists to translate the results of
those controlled studies into recommendations for the everchanging eating habits of Americans.

“As a scientific and policy matter, it is one of the more difficult [issues] I have confronted,” said FDA Commissioner David A. Kessler, M.D., addressing a meeting of the March of Dimes last January. “Before we fortify the food supply for 250 million Americans, we have to make sure we get it right.”

The amount of folic acid FDA has proposed adding is tiny—140 micrograms per 100 grams (3.5 ounces) of bread and other grain products like flour, rolls, buns, corn grits, commeal, farina, rice, and noodles. A microgram is one millionth of a gram. This alone will probably not meet a woman’s need for 0.4 mg (400 micrograms) each day, depending on what she eats. She will have to get the rest of her folic acid either from a vitamin supplement or from other foods in her diet. FDA is considering whether to allow food manufacturers to make health claims about which foods and vitamin supplements are rich in folic acid.

This is no problem for those who eat foods rich in folate. Leafy green vegetables, citrus fruits, beans, and fortified breakfast cereals are great folate sources. In fact, anyone who follows the USDA Food Pyramid Guide, which suggests 3 to 5 servings of vegetables, 2 to 4 of fruits, and 6 to 11 servings of grains daily, can easily get 400 to 500 micrograms of folate each day.

The amount FDA is proposing be added to food is set below the level likely to cause harm from too much folate. A number of scientists believe that up to 1 mg (one-thousandth of a gram) of folic acid per day is safe. So even if someone followed USDA’s guide, including eating fortified bread, and took a multivitamin with another 400 micrograms of folic acid, he or she would still be within safe limits.

The main problem is for older Americans. One in five people 65 to 95 lack sufficient vitamin B12, a deficiency that can cause pernicious anemia. Extra folic acid can mask the symptoms of the condition, which may lead to permanent nerve damage if left untreated.

FDA’s proposal has drawn both support and criticism from a wide range of health officials and scientists. Experts in health and nutrition have taken opposite positions on the issue.

For instance, a working committee of scientists from the national Centers for Disease Control and Prevention in Atlanta wants FDA to require the addition of even more folic acid than proposed. The committee believes the amount FDA has proposed is insufficient to prevent large numbers of neural tube defects.

“I’ve seen the trauma [of neural tube defects]. It’s a very stressful situation for a family,” says Joseph Mulinare, M.D., a pediatrician and medical epidemiologist at CDC. As a member of CDC’s working group on folic acid, Mulinare and his colleagues would like to see FDA require two and a half times more folic acid in breads than it is considering.

On the other hand, other scientists have urged caution before fortifying the food supply. “I’m a little nervous about using large doses of folic acid,” says James Mills, M.D., chief of pediatric epidemiology at the National Institute of Child Health and Human Development. “We don’t really know what will happen if we add folic acid to the diets of 250 million people, and it may be difficult to identify any adverse effects.”

Some nutritionists oppose fortification on principle, arguing that women can get all the folic acid they need from a well-balanced diet. And some consumer groups urged FDA to act sooner to prevent birth defects.

Since the Public Health Service recommended in 1992 that FDA require folic acid fortification, the agency has worked toward a policy that will reduce birth defects without harming anyone.

“FDA is criticized for being conservative, but in the area of uncertainty, it’s best to be cautious,” says Jeanne Rader, Ph.D., a biochemist with FDA’s Office of Food...
A number of tests are available to diagnose neural tube defects before a baby is born.

One such test, the maternal serum alpha-fetoprotein (AFP) test, is a blood test for the mother at 16 to 18 weeks into the pregnancy. It was approved by FDA in the early 1980s as a prenatal test for neural tube defects (a second approved use is as an aid for a certain kind of testicular cancer).

The test measures alpha-fetoprotein, a substance produced by the fetus and secreted into the amniotic fluid, eventually entering the mother’s blood. As it grows, the baby produces increased amounts of AFP. The level of AFP in a mother’s blood peaks at about 30 to 32 weeks.

Abnormally high amounts of AFP may indicate a baby has a neural tube defect. But the test is not perfect.

Up to 20 percent of spina bifida cases do not produce high levels of AFP, so the test does not detect them. And when the test does indicate a high level of AFP, a neural tube defect is present only 10 percent of the time. Most commonly, the AFP level is high because the pregnancy is just further along than was thought.

Other possible causes of high AFP values are that the mother is carrying twins or that there is a placental problem. Women with diabetes or liver disease also have elevated AFP levels. Birth defects in the fetus such as kidney and heart problems may produce high AFP levels as well.

If a woman has an elevated AFP test, her doctor will usually give her a second AFP test, followed by ultrasound. If still no explanation for a high AFP value can be found, the physician may perform amniocentesis. In this test, the doctor takes a sample of the amniotic fluid and measures it for AFP levels. The results of these tests together will identify a high percentage of spina bifida cases.

—R.D.W.
With proper medical care, a person with spina bifida can live a long and productive life.

Compelling Research

Scientists first hypothesized in the 1950s that diet had something to do with neural tube defects. The incidence of these conditions has always been higher in low socioeconomic populations in which women, presumably, have poorer diets. Also, babies conceived in the winter and early spring are more likely to be born with spina bifida, perhaps caused by a lack of fresh foods in early pregnancy.

In addition, researchers discovered in the 1960s that folic acid deficiency causes birth defects in animals. The nutrient plays an important role in cell division and growth.

But there appear to be factors other than nutrition in the development of spina bifida. Genetics also seems to play a role. People of Northern European and Hungarian ancestry have the highest rates of the disease, and the condition tends to run in families, although not consistently.

In fact, 90 to 95 percent of children with spina bifida are born to women who have no other children or anyone in their family with the defect.

In 1991, a study by British researchers found that women who already had one child with a neural tube defect could reduce by 72 percent the chance of another child being affected if they took high doses of folic acid.

Later studies showed that women with no history of giving birth to children with neural tube defects could reduce their risk by up to 60 to 75 percent if they took dietary supplements of between 0.4 mg and 0.8 mg of folic acid daily. The more folic acid the women took, the less was their chance of having a baby with a neural tube defect. One study also suggested that folate from food alone reduced the risk.

Scientists are in general agreement that folic acid reduces the risk of neural tube defects. What remains to be seen is the effect it will have on the general population if it is added to breads and grains.

Historically, fortification with nutrients has produced good results. The United States has had success in fortifying bread with other B vitamins: riboflavin, niacin and thiamin, for example. Those nutrients were added to bread years ago and have virtually eliminated once common and serious diseases such as pellagra. Those vitamins were added in very small quantities, however. Whether bread fortified with higher doses of folic acid will work the same wonders without ill effects is not easy to determine.

Says FDA’s Rader, “As a consumer, what you want is something that’s going to be safe and effective, and that’s not going to be dangerous, either.

“Fortifying the nation’s food supply is not something where someone waves a magic wand and makes it happen. It’s a very serious matter,” she adds. “People think this is an easy decision, but it’s not.”

Rebecca D. Williams is a writer in Oak Ridge, Tenn.
Once upon a time, we didn't know anything about fat except that it made foods tastier. We cooked our food in lard or shortening. We spread butter on our breakfast toast and plopped sour cream on our baked potatoes. Farmers bred their animals to produce milk with high butterfat content and meat “marbled” with fat because that was what most people wanted to eat.

But ever since word got out that diets...
Experts tell us there are several different kinds of fat, some of them worse for us than others.

High in fat are related to heart disease, things have become more complicated. Experts tell us there are several different kinds of fat, some of them worse for us than others. In addition to saturated, monounsaturated and polyunsaturated fats, there are triglycerides, trans fatty acids, and omega 3 and omega 6 fatty acids.

Most people have learned something about cholesterol, and many of us have been to the doctor for a blood test to learn our cholesterol “number.” Now, however, it turns out that there’s more than one kind of cholesterol, too.

Almost every day there are newspaper reports of new studies or recommendations about what to eat or what not to eat: Lard is bad, olive oil is good, margarine is better for you than butter—then again, maybe it’s not.

Amid the welter of confusing terms and conflicting details, consumers are often baffled about how to improve their diets.

FDA recently issued new regulations that will enable consumers to see clearly on a food product’s label how much and what kind of fat the product contains. (See “A Little ‘Lite’ Reading” in the June 1993 FDA Consumer.) Understanding the terms used to discuss fat is crucial if you want to make sure your diet is within recommended guidelines (see accompanying article).

Fats and Fatty Acids

Fats are a group of chemical compounds that contain fatty acids. Energy is stored in the body mostly in the form of fat. Fat is needed in the diet to supply essential fatty acids, substances essential for growth but not produced by the body itself.

There are three main types of fatty acids: saturated, monounsaturated and polyunsaturated. All fatty acids are molecules composed mostly of carbon and hydrogen atoms. A saturated fatty acid has the maximum possible number of hydrogen atoms attached to every carbon atom.

It is therefore said to be “saturated” with hydrogen atoms.

Some fatty acids are missing one pair of hydrogen atoms in the middle of the molecule. This gap is called an “unsaturation” and the fatty acid is said to be “monounsaturated” because it has one gap. Fatty acids that are missing more than one pair of hydrogen atoms are called “polyunsaturated.”

Saturated fats (which contain saturated fatty acids) are mostly found in foods of animal origin. Monounsaturated and polyunsaturated fats (which contain monounsaturated and polyunsaturated fatty acids) are mostly found in foods of plant origin and some seafoods. Polyunsaturated fatty acids are of two kinds, omega-3 or omega-6. Scientists tell them apart by where in the molecule the “unsaturations,” or missing hydrogen atoms, occur.

Recently a new term has been added to the fat lexicon: trans fatty acids. These are byproducts of partial hydrogenation, a process in which some of the missing hydrogen atoms are put back into polyunsaturated fats. “Partially hydrogenated vegetable oils,” such as vegetable shortening and margarine, are solid at room temperature.

Cholesterol

Cholesterol is sort of a “cousin” of fat. Both fat and cholesterol belong to a larger family of chemical compounds called lipids. All the cholesterol the body needs is made by the liver. It is used to build cell membranes and brain and nerve tissues. Cholesterol also helps the body produce steroid hormones needed for body regulation, including processing food, and bile acids needed for digestion.

People don’t need to consume dietary cholesterol because the body can make enough cholesterol for its needs. But the typical U.S. diet contains substantial amounts of cholesterol, found in foods such as egg yolks, liver, meat, some shell-
Saturated fats are mostly found in foods of animal origin.

Fat Words

Here are brief definitions of the key terms important to an understanding of the role of fat in the diet.

**Cholesterol:** A chemical compound manufactured in the body. It is used to build cell membranes and brain and nerve tissues. Cholesterol also helps the body make steroid hormones and bile acids.

**Dietary cholesterol:** Cholesterol found in animal products that are part of the human diet. Egg yolks, liver, meat, some shellfish, and whole-milk dairy products are all sources of dietary cholesterol.

**Fatty acid:** A molecule composed mostly of carbon and hydrogen atoms. Fatty acids are the building blocks of fats.

**Fat:** A chemical compound containing one or more fatty acids. Fat is one of the three main constituents of food (the others are protein and carbohydrate). It is also the principal form in which energy is stored in the body.

**Hydrogenated fat:** A fat that has been chemically altered by the addition of hydrogen atoms (see trans fatty acid). Vegetable oil and margarine are hydrogenated fats.

**Lipid:** A chemical compound characterized by the fact that it is insoluble in water. Both fat and cholesterol are members of the lipid family.

**Lipoprotein:** A chemical compound made of fat and protein. Lipoproteins that have more fat than protein are called low-density lipoproteins (LDLs). Lipoproteins that have more protein than fat are called high-density lipoproteins (HDLs). Lipoproteins are found in the blood, where their main function is to carry cholesterol.

**Monounsaturated fatty acid:** A fatty acid that is missing one pair of hydrogen atoms in the middle of the molecule. The gap is called an “unsaturation.” Monounsaturated fatty acids are found mostly in plant and sea foods.

**Monounsaturated fat:** A fat made of monounsaturated fatty acids. Olive oil and canola oil are monounsaturated fats. Monounsaturated fats tend to lower levels of LDL-cholesterol in the blood.

**Polyunsaturated fatty acid:** A fatty acid that is missing more than one pair of hydrogen atoms. Polyunsaturated fatty acids are mostly found in plant and sea foods.

**Polyunsaturated fat:** A fat made of polyunsaturated fatty acids. Safflower oil and corn oil are polyunsaturated fats. Polyunsaturated fats tend to lower levels of both HDL-cholesterol and LDL-cholesterol in the blood.

**Saturated fatty acid:** A fatty acid that has the maximum possible number of hydrogen atoms attached to every carbon atom. It is said to be “saturated” with hydrogen atoms. Saturated fatty acids are mostly found in animal products such as meat and whole milk.

**Saturated fat:** A fat made of saturated fatty acids. Butter and lard are saturated fats. Saturated fats tend to raise levels of LDL-cholesterol (“bad” cholesterol) in the blood. Elevated levels of LDL-cholesterol are associated with heart disease.

**Trans fatty acid:** A polyunsaturated fatty acid in which some of the missing hydrogen atoms have been put back in a chemical process called hydrogenation. Trans fatty acids are the building blocks of hydrogenated fats.

—E.M.

A person’s cholesterol “number” refers to the total amount of cholesterol in the blood. Cholesterol is measured in milligrams per deciliter (mg/dl) of blood. (A deciliter is a tenth of a liter.) Doctors recommend that total blood cholesterol be kept below 200 mg/dl. The average level in adults in this country is 205 to 215 mg/dl. Studies in the United States and other countries have consistently shown that total cholesterol levels above 200 to 220 mg/dl are linked with an increased risk of coronary heart disease. (See “Lowering Cholesterol” in the March 1994 **FDA Consumer**.)

LDL-cholesterol and HDL-cholesterol act differently in the body. A high level of LDL-cholesterol in the blood increases the risk of fatty deposits forming in the arteries, which in turn increases the risk of a heart attack. Thus, LDL-cholesterol has been dubbed “bad” cholesterol.
A person's cholesterol "number" refers to the total amount of cholesterol in the blood.

On the other hand, an elevated level of HDL-cholesterol seems to have a protective effect against heart disease. For this reason, HDL-cholesterol is often called "good" cholesterol.

In 1992, a panel of medical experts convened by the National Institutes of Health (NIH) recommended that individuals should have their level of HDL-cholesterol checked along with their total cholesterol.

According to the National Heart, Lung, and Blood Institute (NHLBI), a component of NIH, a healthy person who is not at high risk for heart disease and whose total cholesterol level is in the normal range (around 200 mg/dl) should have an HDL-cholesterol level of more than 35 mg/dl. NHLBI also says that an LDL-cholesterol level of less than 130 mg/dl is "desirable" to minimize the risk of heart disease.

Some very recent studies have suggested that LDL-cholesterol is more likely to cause fatty deposits in the arteries if it has been through a chemical change known as oxidation. However, these findings are not accepted by all scientists.

The NIH panel also advised that individuals with high total cholesterol or other risk factors for coronary heart disease should have their triglyceride levels checked along with their HDL-cholesterol levels.

As seen in these cross-section drawings, a high level of LDL-cholesterol in the body increases the risk of fatty deposits and plaque clogging the arteries, which can produce atherosclerosis—and possibly a heart attack.

Avoiding a diet high in saturated fats can help keep LDL levels down.

Dietary Fat and Cholesterol Levels
Many people are confused about the effect of dietary fats on cholesterol levels. At first glance, it seems reasonable to think that eating less cholesterol would reduce a person's cholesterol level. In fact, eating less cholesterol has less effect on blood cholesterol levels than eating less saturated fat. However, some studies have found that eating cholesterol increases the risk of heart disease even if it doesn't increase blood cholesterol levels.

Another misconception is that people can improve their cholesterol numbers by eating "good" cholesterol. In food, all cholesterol is the same. In the blood, whether cholesterol is "good" or "bad" depends on the type of lipoprotein that's carrying it.

Polyunsaturated and monounsaturated fats do not promote the formation of artery-clogging fatty deposits the way saturated fats do. Some studies show that eating foods that contain these fats can reduce levels of LDL-cholesterol in the blood. Polyunsaturated fats, such as safflower and corn oil, tend to lower both HDL- and LDL-cholesterol. Edible oils rich in monounsaturated fats, such as olive and canola oil, however, tend to lower LDL-cholesterol without affecting HDL levels.

How Do We Know Fat's a Problem?
In 1908, scientists first observed that rabbits fed a diet of meat, whole milk, and eggs developed fatty deposits on the walls of their arteries that constricted the flow of blood. Narrowing of the arteries by these fatty deposits is called atherosclerosis. It is
Edible oils rich in monounsaturated fats, such as olive and canola oil, tend to lower LDL-cholesterol without affecting HDL levels.

a slowly progressing disease that can begin early in life but not show symptoms for many years. In 1913, scientists identified the substance responsible for the fatty deposits in the rabbits' arteries as cholesterol.

In 1916, Cornelius de Langen, a Dutch physician working in Java, Indonesia, noticed that native Indonesians had much lower rates of heart disease than Dutch colonists living on the island. He reported this finding to a medical journal, speculating that the Indonesians' healthy hearts were linked with their low levels of blood cholesterol.

De Langen also noticed that both blood cholesterol levels and rates of heart disease soared among Indonesians who abandoned their native diet of mostly plant foods and ate a typical Dutch diet containing a lot of meat and dairy products. This was the first recorded suggestion that diet, cholesterol levels, and heart disease were related in humans. But de Langen's observations lay unnoticed in an obscure medical journal for more than 40 years.

After World War II, medical researchers in Scandinavia noticed that deaths from heart disease had declined dramatically during the war, when food was rationed and meat, dairy products, and eggs were scarce. At about the same time, other researchers found that people who suffered heart attacks had higher levels of blood cholesterol than people who did not have heart attacks.

Since then, a large body of scientific evidence has been gathered linking high blood cholesterol and a diet high in animal fats with an elevated risk of heart attack. In countries where the average person's blood cholesterol level is less than 180 mg/dl, very few people develop atherosclerosis or have heart attacks. In many countries where a lot of people have blood cholesterol levels above 220 mg/dl, such as the United States, heart disease is the leading cause of death.

High rates of heart disease are commonly found in countries where the diet is heavy with meat and dairy products containing a lot of saturated fats. However, high-fat diets and high rates of heart disease don't inevitably go hand-in-hand.

Learning from Other Cultures

People living on the Greek island of Crete have very low rates of heart disease even though their diet is high in fat. Most of their dietary fat comes from olive oil, a monounsaturated fat that tends to lower levels of “bad” LDL-cholesterol and maintain levels of “good” HDL-cholesterol.

The Inuit, or Eskimo, people of Alaska and Greenland also are relatively free of heart disease despite a high-fat, high-cholesterol diet. The staple food in their diet is fish rich in omega-3 polyunsaturated fatty acids.

Some research has shown that omega-3 fatty acids, found in fish such as salmon and mackerel as well as in soybean and canola oil, lower both LDL-cholesterol and triglyceride levels in the blood. Some nutrition experts recommend eating fish once or twice a week to reduce heart disease risk. However, dietary supplements containing concentrated fish oil are not recommended because there is insufficient evidence that they are beneficial and little is known about their long-term effects.

Omega-6 polyunsaturated fatty acids have also been found in some studies to reduce both LDL- and HDL-cholesterol levels in the blood. Linoleic acid, an essential nutrient (one that the body cannot make for itself) and a component of corn, soybean and safflower oil, is an omega-6 fatty acid.

At one time, many nutrition experts recommended increasing consumption of monounsaturated and polyunsaturated fats because of their cholesterol-lowering effects. Now, however, the advice is simply to reduce dietary intake of all types of fat. (Infants and young children, however, should not restrict dietary fat.)

The available information on fats may be voluminous and is sometimes confusing. But sorting through the information becomes easier once you know the terms and some of the history.

The “bottom line” is actually quite simple, according to John E. Vanderveen, Ph.D., director of the Office of Plant and Dairy Foods and Beverages in FDA’s Center for Food Safety and Applied Nutrition. “What we should be doing is removing as much of the saturated fat from our diet as we can. We need to select foods that are lower in total fat and especially in saturated fat.” In a nutshell, that means eating fewer foods of animal origin, such as meat and whole-milk dairy products, and more plant foods such as vegetables and grains.

Eleanor Mayfield is a writer in Silver Spring, Md.
Decoding The Cosmetic Label

by Judith E. Foulke

How can you be sure your shampoo that claims to have all natural ingredients does not also contain some synthetic chemicals? Or that your hand lotion actually does contain the vitamin E it claims? The logical response should be, “Read the ingredient label on the back of the product.” Logical, if you happen to be a chemist or a cosmetic scientist. Perplexing, if you are the average cosmetic consumer.

A quick glance at the back of the cosmetic label is all it takes to see that the ingredients are written in the language of chemistry. (See accompanying article.) Unless you know that one of the shampoo ingredients—methyl paraben—is a synthetic preservative derived from a petroleum base, or that tocopherol is vitamin E, you may never be able to check the claims against the contents.

John Bailey, Ph.D., director of the Food and Drug Administration’s Office of Cosmetics and Colors, understands such consumer dilemmas. He and the scientists on his staff admit that most of us don’t recognize the names of the ingredients listed. But there’s no way to change that and still accurately identify the ingredients.

Chemical names are the only way ingredients can be listed because that’s what they are. Most are cosmetic formulations, but in some products, such as an underarm deodorant that also claims to stop perspiration, the first chemical listed may be a drug ingredient and FDA would classify the product as a drug as well as a cosmetic.

Many ingredients are marketed with trade names, but these often provide little clue to the identity and intended use of the material. Trade names in the ingredient list could be confusing to consumers purchasing a cosmetic because they would have no way to compare similar ingredients in similar products. Also, some trade names include mixtures of raw materials—for example, an ingredient could be combined with a preservative.

Despite the highly technical language of the ingredient list, Bailey says it’s entirely possible for consumers to get valuable information about a product by checking the label—front and back. To decode the cosmetic label, here’s what you need to know.

**Image vs. Reality**

Don’t be fooled by claims made for certain cosmetic ingredients. Their presence in the products could be pure puffery because the law does not require cosmetic manufacturers to substantiate performance claims.

“Image is what the cosmetic industry sells through its products,” Bailey says, “and it’s up to the consumer to believe it or not.” (See “Cosmetic Ingredients: Understanding the Puffery” in the May 1992 FDA Consumer.)

FDA considers the labeling of vitamins in cosmetics a separate issue, however, and does not recognize health claims for them in cosmetics. A product that features a vitamin—for example, vitamin E—must list it by its chemical name—tocopherol—on the ingredient list. Listing it as a vitamin in the ingredient statement would give the misleading impression that vitamin E in the product offers a nutrient or health benefit. (Vitamin E is usually added as an antioxidant to prevent chemical deterioration of the product.)

Consumers can get important health and value information by checking the ingredient list. For example, if you need fragrance-free hair spray because you have a sensitivity, a product containing a fragrance—even one that just masks the chemical odors of the raw materials—could be a waste of money if you can’t use it.

Ingredient statements on cosmetics were first required in 1973 under the Fair Packaging and Labeling Act, enforced by FDA. Before then, consumers could only guess what was in a cosmetic product or if the product contained what it claimed. That requirement is especially valuable today with the industry competition for new ingredients.

The law allows a manufacturer to ask FDA to grant “trade secret” status for a
They must, however, state the name and as those distributed free at hotels, are not by beauticians in beauty salons or cos for home use. Products used exclusively tions apply only to retail products intended for reference at many public libraries, or atognizes to name ingredients, are available the dictionary, and all other compendia FDA rec tions and all other cosmetic ingredients. The dic widely known cosmetic ingredients and provides a complete list of the most tional Cosmetic Ingredient Dictionary,cosmetic can find answers in the Interna suggest that not much of that ingredient is tured ingredient listed close to the end for example, would have more of that ingred ient than any other ingredient. A fea tured ingredient listed close to the end suggests that not much of that ingredient is present.

Anyone curious about an ingredient in a cosmetic can find answers in the Interna tional Cosmetic Ingredient Dictionary, published by the Cosmetic, Toiletries, and Fragrance Association. The dictionary provides a complete list of the most widely known cosmetic ingredients and their definitions and trade names. The d ictionary, and all other compendia FDA recognizes to name ingredients, are available for reference at many public libraries, or at the Office of the Federal Register, 1100 L St., N.W., Washington, DC 20408.

Cosmetic ingredient declaration regulations apply only to retail products intended for home use. Products used exclusively by beauticians in beauty salons or cosmetic studios, and cosmetic samples such as those distributed free at hotels, are not subject to the ingredient labeling rules. They must, however, state the name and address of the manufacturer, packer or dis tributor, and give an accurate statement of quantity and all necessary warning state ments, as do all other cosmetics that weigh over one-fourth ounce or one-eighth fluid ounce.

Cosmetics That Are Also Drugs

Cosmetics making therapeutic claims— that they may affect the structure or func tion of the body—are regulated as drugs and cosmetics and must meet the labeling requirements for both. One way you can tell if you’re dealing with such a product is if the first entry in the ingredient list says “Active Ingredient.” (The active ingredient is the chemical that makes the product effective, and it must be safe for its intended use.) However, active ingredients are not legally required to be identified by this term. The law does require the active ingredient(s) to be listed first, followed by a list of all inactive cosmetic ingredients.

Examples of products that are both cosmeti cs and drugs are shampoos that treat dandruff, fluoride toothpastes to prevent dental decay, and sunscreens and sun-blocking cosmetics, including foundations that contain sunscreens. (See “Dodging the Rays” in the July-August 1993 FDA Consumer.)

A product with a drug and cosmetic classification must be scientifically proven safe and effective for its therapeutic claims before it is marketed. If the product is not, FDA considers it to be a misbranded drug and can take regulatory action.

Preventing Problems

Under FDA’s good manufacturing prac tice guidelines, even cosmetic products that are not regulated as drugs should be thoroughly tested for safety and subject to quality control during manufacture. But the law does not require the agency to review these tests before the cosmetics are marketed. Nevertheless, FDA does require safety warnings when problems become apparent.

Misuse of some cosmetic products can cause problems that range in severity from a mild rash to skin burns, or from burning eyes to blindness.

Look for warnings about the conse quences of misuse required on products that could be hazardous, in addition to the detailed directions for use that appear on almost all cosmetics.

For example, products containing halo carbon or hydrocarbon propellants, such as aerosol hairsprays or deodorants, must bear the exact wording: “Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.”

All cosmetics in self-pressurized contain ers, such as shaving creams, must have specifically worded warnings against spraying near the eyes, puncturing, inciner ating, storing, and intentionally misusing. “Keep out of the reach of children” is also required for all products in pressurized containers. In the case of products intended for use by children, such as foaming soap, the phrase “except under adult supervi sion” may be added.

Other products requiring specific wording include:

- Detergent bubble bath products—may irritate skin and the urinary tract through excessive use or prolonged exposure. The labeling instructs users to discontinue the product if rash, redness or itching occur, to consult a physician if irritation persists, and to keep out of reach of children. These adverse reactions reportedly occur mostly with prolonged soaks. According to some studies, the adverse reactions either subside or disappear with discontinued use. In 1987, FDA started requiring all foaming detergent bath products not labeled as intended for exclusive adult use to display the caution statement in addition to direc tions for use.

- Feminine deodorant sprays intended for use in the genital area—are for external use only and should not be applied to bro ken, irritated or itching skin. A physician should be consulted if persistent, unusual odor or discharge occurs. The statement instructs users to discontinue immediately if rash, irritation or discomfort develops. Labeling on self-pressurized containers must state that the product should be sprayed at least 8 inches from the skin.

- Coal-tar color-containing hair-dye products—contain ingredients that may cause skin irritation on certain individuals, and a preliminary test according to the product’s accompanying directions should first be made. Users are cautioned not to dye eyelashes or eyebrows because doing so may cause blindness. In addition, the ammonia, soaps, detergents, conditioning agents, and dyes in hair-dye products are all strong eye irritants and could also cause allergic reactions in other areas. (See “Hair Dye Dilemmas” in the April 1993 FDA Consumer.)

The following products require explicit warnings, though not with specific word ing:

- Depilatories and hair straighteners—are highly alkaline; if they are used incor rectly, they may cause serious skin irrita tion.

- Shampoos, rinses and conditioners— can cause eye problems that range from ir ritation to permanent damage. If the eye’s cornea is scratched or otherwise damaged, a contaminated product could cause infec-
Where's the Label Information?

Products Sold by Mail

Small Packages and Decorative Containers

Perfume Bottles

Freestanding Displays

The placement of required information on the cosmetic label may vary with the packaging and container.
Chemical Translations

At present, the cosmetic industry selects from more than 5,000 different ingredients. It’s no wonder consumers can be perplexed when they see the list. Here are some common cosmetic ingredients and their usual functions (active drug ingredients are not included):

Moisturizers function as a moisture barrier or to attract moisture from the environment:
- cetyl alcohol (fatty alcohol)—keeps oil and water from separating, also a foam booster
- dimethicone—silicone skin conditioner and anti-foam ingredient
- isopropyl lanolate, myristate, and palmitate
- lanolin and lanolin alcohols and oil (used in skin and hair conditioners)
- octyl dodecanol—skin conditioner
- steanic acid and stearyl alcohol

Preservatives and antioxidants (including vitamins) prevent product deterioration:
- trisodium and tetrasodium edetate (EDTA)
- tocopherol (vitamin E)
- EDTA

Antimicrobials fight bacteria:
- butyl, propyl, ethyl, and methyl parabens
- DMDM hydantoin
- methylisothiazolinone
- phenoxyethanol (also rose ether fragrance component)
- quaternium-15

Thickeners and waxes used in stick products such as lipsticks and blushers:
- candelilla, carnauba, and microcrystalline waxes
- carommer and polyethylene—thickeners

Solvents used to dilute:
- butylene glycol and propylene glycol
- cyclomethicone (volatile silicone)
- ethanol (alcohol)
- glycerin

Emulsifiers break up and refine:
- glyceryl monostearate (also pearlescent agent)
- lauramide DEA (also foam booster)
- polysorbates

Color additives—synthetic organic colors derived from coal and petroleum sources (not permitted for use around the eye):
- D&C Red No. 7 Calcium Lake (lakes are dyes that do not dissolve in water)

Inorganic pigments—approved for general use in cosmetics, including for the area of the eye:
- iron oxides
- mica (iridescent)

Hair dyes—phenol derivatives used in combination with other chemicals in permanent (two-step) hair dyes:
- aminophenols

pH adjusters stabilize or adjust acids and bases:
- ammonium hydroxide—in skin peels and hair waving and straightening
- citric acid—adjusts pH
- triethanolamine—pH adjuster used mostly in transparent soap

Others:
- magnesium aluminum silicate—absorbent, anti-caking agent
- silica (silicon dioxide)—absorbent, anti-caking, abrasive
- sodium lauryl sulfate—detergent
- stearic acid—cleansing, emulsifier
- talc (powdered magnesium silicate)—absorbent, anti-caking
- zinc stearate—used in powder to improve texture, lubricates.

...continued. These cosmetics, as well as others that contain water, usually have antimicrobials that discourage growth of bacteria.
- Nail builders (elongators, extenders, hardeners, and enamels)—can cause irritation, inflammation and infection of the nail bed and nail fold (where the nail meets the finger) due to residual traces of the methacrylate monomers. Also, nail hardeners and enamels often contain formaldehyde and formaldehyde-releasing preservatives, which may cause allergic reactions in people who are sensitive to them. In addition, the solvents or plasticizers may be irritating. Nail enamels that are also nail hardeners cause the most problems. Their high resin content or low concentration of plasticizer seals the nail surface to air and makes the nail too brittle. Another frequent problem is flammability during and shortly after application. These products require a flammability caution.

Flammable products such as aerosol hair sprays containing alcohol and an isobutane propellant—include caution statements on the label. Also, the label usually cautions about avoiding heat, fire and smoking during use until the product is fully dry. Last year, FDA received reports of a fatality that occurred from burns suffered when a woman’s hair ignited. Apparently, she tried to light a cigarette before her hair spray had completely dried.

Manufacturers often use warning statements on labels when there is even a small chance of a problem. Baby products often contain such warnings. Baby powder, for example, if used carelessly and accidentally inhaled by the baby in large amounts, can block the infant’s bronchial and lung passages and cause suffocation. (For more about cosmetic safety, see “Cosmetic Safety: More Complex Than At First Blush” in the November 1991 FDA Consumer.)

Cosmetic labels are more than product advertising. They connect cosmetic science with consumer protection by providing a means for consumers to know what’s in a product and how to safely use it. A wise consumer will take the time to read the label to get the best value and results without incurring any of the possible harmful effects.

Judith E. Foulke is a staff writer for FDA Consumer.
No Human Risks

New Animal Drug Increases Milk Production

by Kevin L. Ropp

It's been a staple for ages among children, adolescents and adults. We're told milk helps build strong teeth and bones and healthy bodies.

Over the last several years, scientists have been developing genetically engineered products to help dairy cows produce more milk.

Last Nov. 5, the Food and Drug Administration approved one such product, sometribove (Posilac), Monsanto Co.'s genetically engineered bovine somatotropin (bST).

Genetically engineered, or recombinant, bST is virtually identical to a cow's natural somatotropin, a hormone produced in its pituitary gland that stimulates milk production. The primary difference between the two is that rbST may include additional amino acids. Injecting rbST can increase a cow's milk production by 10 to 15 percent.

"This has been one of the most extensively studied animal dmg products to be reviewed by the agency," said FDA Commissioner David A. Kessler, M.D. "We examined more than 120 studies. There were several advisory committees. The public can be confident that milk and meat from bST-treated cows are safe to consume."

At press time, FDA was still reviewing rbST products from American Cyanamid, Eli Lilly & Company, and Upjohn Company. "Each of the remaining products will be reviewed as stringently as the first," said Suzanne Sechen, Ph.D., an animal scientist in FDA's Center for Veterinary Medicine's division of biometrics and production drugs.

Recombinant bST is made in much the same way as synthetic human insulin for treating diabetes. The gene for bST is inserted into special bacteria, which then reproduce, replicating the gene. During
manufacture, the bST is collected from these bacteria and further processed. The finished, sterile product is then formulated for use in dairy cows.

**FDA Review**

Recombinant bST first came under FDA review in the early 1980s, when the four companies submitted investigational new animal drug applications. Since that time, the agency has authorized bST testing on more than 20,000 cows in the United States.

During FDA’s review of rbST, there has been much public debate on safety and economic issues related to the drug. Some organizations opposed to the use of rbST have contended that it causes health problems for cows injected with the drug, for their calves, and for humans who consume milk or meat from these animals.

“We went to unprecedented lengths to resolve every issue raised,” said Richard Teske, D.V.M., acting director of FDA’s Center for Veterinary Medicine, “not only through our own rigorous review process, but also by subjecting our findings to peer review through a published journal article and by an outside committee of experts.”

The agency’s conclusion—that rbST poses no risk to human health—has been affirmed by scientific reviews in the last several years by the National Institutes of Health; the Congressional Office of Technology Assessment; drug regulatory agencies of Canada, the United Kingdom, and the European Union; and by the Department of Health and Human Services’ Office of the Inspector General.

**FDA’s Findings**

Under the Federal Food, Drug, and Cosmetic Act, FDA is responsible for ensuring the safety to humans of the milk, meat, and other food products from food animals treated with a new drug, as well as the safety and effectiveness of the drug for the animals. The agency also must ensure that the manufacture and use of the product does not pose environmental hazards.

FDA’s Center for Veterinary Medicine determined in the mid-1980s that food products from rbST-treated cows are safe for human consumption. In the Aug. 24, 1990, issue of Science, FDA scientists summarized more than 120 studies that examined the safety of milk and meat from dairy cows treated with rbST, concluding that use of rbST presents “no increased health risk to consumers.”

The agency’s determination was based on a number of scientific findings. Because it is a protein-based hormone, rbST is broken down during digestion, which renders it biologically inactive and incapable of having any effect in humans or animals. Even if injected in humans, bST has no effect, according to studies done in the 1950s that looked at natural bST as a possible treatment for human dwarfism. (It didn’t work.)

In addition, studies show that pasteurization destroys approximately 90 percent of bST, natural or otherwise, present in milk.

Also, studies have shown that rbST does not affect the nutritional qualities of milk. Scientists are unable to detect a difference between milk from rbST-treated cows and from untreated cows.

Summing up the public health issues surrounding rbST, Kessler said, “there is virtually no difference in milk from treated and untreated cows. In fact, it’s not possible using current scientific techniques to tell them apart.”

**NIH Review**

In 1990, a special panel of the National Institutes of Health also looked at recombinant bST. Its members unanimously concluded that rbST is effective in increasing milk production and that the composition and nutritional value of the milk from the treated cows are essentially the same as from untreated cows.

In addition, the panel found that well-managed, rbST-treated cows experience no greater health problems than untreated cows of equal production and that calves from cows administered rbST have normal birth weights, growth, and development.

FDA also reviewed scientific data to see how rbST affects cows. It concluded that rbST causes no serious or long-term health effects in treated cows or their offspring.

**Mastitis and Antibiotics**

However, FDA found evidence in the clinical trial data submitted by Monsanto that cows treated with sometribove have a slightly increased incidence of mastitis, a common infection of the udder. A September 1992 report by the General Accounting Office raised concerns that, because mastitis is often treated with antibiotics, sometribove use could lead to increased antibiotic residues in milk or meat. This could pose a potential health problem, for example, to people allergic to the antibiotics who consume the meat or milk.

In March 1993, FDA brought these concerns to an advisory committee. The committee concluded that the effect of sometribove use on the incidence of mastitis was much less than other factors, such as the season, age of the cows, and herd-to-herd variation. They also concluded that adequate safeguards are in place to prevent unsafe levels of antibiotic residues from entering the milk supply.

Drugs such as antibiotics may be used in food-producing animals only under government-approved conditions and with appropriate withdrawal periods, as established by FDA, to ensure that the food is safe for people to eat.

**Ensuring Milk Safety**

Milk safety is ensured through a joint effort of FDA and the National Conference on Interstate Milk Shipments, an organization of state health officials and members of the dairy industry. The conference oversees a Voluntary Cooperative State-Public Health Service Program for
Processing of Milk Treated with rbST

Milk from rbST-treated and untreated cows is collected in the same manner. Milk from each farm is tested for antibiotic drug residues. If there are unsafe drug residues, the entire tanker of milk is dumped. If no residues are found the tanker delivers the milk to the processor who readies it for market. Antibiotics are used to treat mastitis, an inflammation of the cow’s udder, which is more common in rbST-treated cows.

Certification of Interstate Milk Shippers (IMS) to administer milk safety rules. Responsibilities under this program are divided between state agencies with FDA oversight.

The states are the primary operators of the IMS program, with FDA providing scientific, technical and inspection assistance, as well as auditing state programs. All 50 states, the District of Columbia, and Puerto Rico participate in IMS, and nearly 150,000 dairy farms and 800 milk plants, representing almost 90 percent of the total milk production in the United States, are covered.

Milk tanker-trucks may stop at five to 10 different farms to collect a load of raw milk. A sample of each farm’s milk is collected, labeled and stored in a special section on the truck. The rest of the milk is loaded into the truck’s usually common milk tank.

When the tanker is full, the load is delivered to a milk processor. The dairy industry currently tests all tankers for penicillin-like beta-lactam drugs before processing the milk. Beta-lactams are the most commonly used drugs for treating mastitis.

If a load is found to have unsafe residues, all the milk must be discarded. The individual samples collected from each farm are then tested to determine the source of the residue. Producers responsible for unsafe residues are subject to regulatory sanctions that may include suspension or revocation of permits or monetary fines.

In addition, once every three months state inspectors randomly sample 10 percent of the tanker-trucks coming into milk processing plants. The states also randomly collect samples from every farmers’ milk storage tank at least four times every six months.

Because of these safeguards, FDA’s Veterinary Medicine Advisory Committee concluded that the increased risk to human health posed by mastitis and the use of antibiotics is insignificant and manageable.

Additional Monitoring

Nevertheless, at FDA’s request, Monsanto has agreed to take additional steps to ensure that sometribove use does not lead to an increase in antibiotic residue levels.

“In addition to all of the studies, and the current nationwide milk monitoring system, we have put in place an extensive post-approval marketing program that will assure that food products from bST-treated cows meet the high standard of safety required by our statute and demanded by the public,” Kessler said.

Monsanto will conduct a post-approval monitoring program that includes:

- a two-year tracking system of milk production and drug residues in top dairy states, representing over half of the nation’s milk supply, that will periodically compare the amount of milk discarded after sometribove is marketed to the amount discarded before approval
- a 12-month comparison of the proportion of milk discarded due to positive drug tests between sometribove-treated and untreated herds
- a reporting system to monitor all sometribove use and follow up on all complaints
- a sampling of 24 commercial dairy herds using sometribove with specific monitoring for mastitis, animal drug use, and the resulting loss of milk.

Labeling

Labeling milk and other foods from rbST-treated cows was another issue FDA considered during its review. Last May, the agency’s food and veterinary medicine advisory committees met for two days to discuss labeling. Based on the committee members’ conclusions and on its own review, FDA concluded that it lacks a basis under the statute to require special labeling of foods from rbST-treated cows. Food companies may voluntarily label their products as long as the labeling is truthful and not misleading.

Recently, several states, industry, and consumer representatives have asked FDA for guidance on voluntary labeling of milk—both from cows that have been treated with rbST and those that have not. The agency issued interim guidance Feb. 8, which should help ensure that consumers receive truthful and non-misleading information about milk and milk products.

The guidance states: “Because of the
“We went to unprecedented lengths to resolve every issue raised.”

—Richard Teske, D.V.M., acting director, Center for Veterinary Medicine

Social and Economic Concerns

During the years recombinant bST has been under review, some organizations also have publicly expressed their concern about potential social and economic effects of rbST on small dairy farmers, the federal dairy price-support program, and milk demand.

Those groups have contended that since rbST increases milk production there would be more milk on the market. The groups say that more milk would drive small, family dairy farmers out of business because they couldn’t compete with big farms when milk prices are lower. More milk, they’ve said, would also drive up the cost of the Agriculture Department’s dairy support program, which buys surplus milk.

In addition, some independent research of consumer attitudes has indicated that individual milk consumption would decrease after introduction of rbST in the marketplace.

Social and economic issues, by law, are not part of FDA’s drug approval decision-making process and, therefore, were not considered by the agency. However, following FDA approval, Congress included a 90-day moratorium on the sale of rbST in its budget reconciliation bill, which President Clinton signed on Aug. 10, 1993. During the 90-day period, the Office of Management and Budget evaluated those concerns.


Among other findings, the report states:

• Income for individual farmers who adopt rbST is likely to increase. Productivity and profit per cow should rise for both small and large farms. Recombinant bST favors good herd management rather than small or large farms.
• Recombinant bST use will increase U.S. milk production by about 1 percent through fiscal year (FY) 1999. This production will likely lead to slightly lower prices for milk, averaging about 2 percent lower over the next six years.
• Lower milk prices from rbST use are also expected to contribute to higher federal government dairy price-support costs, but decreased federal costs for nutrition programs like Food Stamps and the Special Supplemental Food Program for Women, Infants and Children (WIC).
• Federal dairy price-support program costs would increase by approximately $150 million in the peak year, FY 1996, and decline in later years. This would represent a 1.8 percent increase in total projected federal farm commodity subsidies for that peak year.
• Savings in the costs of federal feeding programs would begin in FY 1997, and could completely offset the increased cumulative costs of the federal dairy price-support program over 10 years.
• No significant reduction of demand for milk and dairy products is expected to result from rbST use. While some surveys reveal strong consumer resistance to rbST, others indicate confidence in the milk supply, and no substantial intent to forego use of rbST milk.

The moratorium on the sale of rbST was lifted Feb. 3, 1994, as planned.

Kevin L. Ropp is a staff writer for FDA Consumer.

presence of natural bST in milk, no milk is ‘bST-free,’ and a ‘bST-free’ labeling statement would be false.

“Also, FDA is concerned that the term ‘rbST free’ may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as ‘from cows not treated with rbST’ or in other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.”

In response to consumers’ safety concerns, FDA’s Teske sums it up: “FDA’s review of a new animal drug is a very rigorous process. When a product has completed that process and our conclusion is that it’s safe and effective, we have a great deal of confidence in our decision. We feel the public can have that same degree of confidence as well.”

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

- The public advisory committee meeting list for 1994 was published by FDA Feb. 4. The list includes tentative meeting dates of advisory committees to FDA. The agency will continue to publish Federal Register notices with more definite dates 15 days before each meeting. (FR Feb. 4)

- FD&C Red No. 40 and Blue No. 1 were recently approved by FDA for coloring drugs and cosmetics to be used in the eye area. (FR Feb. 16)

- Eggland's Best can no longer advertise that eating its eggs won't raise blood cholesterol, or that its eggs are low in saturated fat. The Federal Trade Commission charged that Eggland's advertising was unfair or deceptive. Eggland agreed to cease making the claims, and to include a statement on its cartons and in advertising that its eggs are no different from other eggs in their effect on blood cholesterol. (FR Feb. 23)

- Smokeless tobacco ingredient lists must now be provided annually to the Secretary of Health and Human Services. Each person or firm who manufactures, packages or imports smokeless tobacco must provide the list by Dec. 31 yearly. (FR Feb. 1)

- Child Nutrition Programs' annual income guidelines for child nutrition programs take effect July 1, according to the Food and Nutrition Service of the Agriculture Department. The guidelines establish eligibility for reduced-price or free meals and milk, and are used by institutions participating in the National School Breakfast and Lunch Programs, Special Milk Program for Children, Child and Adult Care Food Program, and Commodity School Program. (FR Feb. 25)

- Stronger alcohol misuse rules went into effect March 17 for the transportation industry. Under testing programs implemented by the Federal Aviation, Highway, Railroad, Transit, and Research and Special Programs Administrations, employees may not perform safety-sensitive functions if tests indicate an alcohol concentration of 0.04 or greater, if they have used alcohol within the previous four hours or are using it on the job, if they refuse to submit to required tests, and if they have an accident—at least until they are tested. (FR Feb. 15)

- Alcohol consumption and liver cirrhosis deaths have declined in the United States since 1990, according to the Eighth Special Report to the Congress on Alcohol and Health. The report also states that between 1982 and 1989, thanks to a raised minimum drinking age, there were fewer fatal crashes among people under 21. For free copies of the report, call (1-800) 729-6686. (Public Health Reports, January-February 1994)

- Drug-related emergency room visits increased 10 percent from 1991 to 1992, according to a report by the Substance Abuse and Mental Health Services Administration (SAMHSA). Cocaine-related visits increased 18 percent, heroin-related visits increased 34 percent, and marijuana-related visits increased 48 percent. For free copies of the report, call the SAMHSA Press Office, (301) 443-8956. (Public Health Reports, January-February 1994)

- Handgun buyers must wait five days before taking delivery of the gun, according to a Bureau of Alcohol, Tobacco, and Firearms rule that became effective Feb. 28. The rule implements the Brady Handgun Violence Prevention Act, which requires licensed importers, manufacturers or dealers to wait five days before transferring a handgun to a nonlicensed individual, and sets reporting requirements for labeling, theft and license fees. (FR Feb. 14)
Washington State FirmProsecuted for
Distributing Non-Sterile Drugs

by John Henkel

A Kent, Washington, pharmacy received a $6,000 fine and three years’ probation after its president pleaded guilty to manufacturing and distributing a non-sterile injectable drug, Magnesium-ATP.

Raymond Suen, 45, who headed For Your Health Inc., also received a $5,000 fine and three years’ probation when sentenced last Feb. 4. A separate civil suit brought against Suen by the Drug Enforcement Agency for illegally manufacturing the drug testosterone resulted in an additional $5,000 fine. Earlier, following a search that yielded incriminating evidence, Washington state revoked the pharmacy license held by Suen’s company. He may no longer sell prescription drugs in his store but may continue the business as a health-food establishment.

Suen ran afoul of the law when he started manufacturing his own drugs to sell. An FDA inspection uncovered serious mold and bacterial contamination in samples of the firm’s injectable Magnesium-ATP, a drug promoted for treating cardiac conditions.

Injecting non-sterile drugs can cause fever, shock, blood infection, and even death. According to Tom Piekarski, compliance officer for FDA’s Seattle district, there were no confirmed adverse reactions due to consumer use of the drug.

Suen’s wrongdoing might have gone undiscovered had it not been for an incident Piekarski calls “serendipity.” A 1991 consumer complaint tipped off FDA’s Seattle office that For Your Health was selling L-tryptophan, a substance FDA banned from U.S. sale in November 1989. FDA inspected the pharmacy in July 1991 and found L-tryptophan in the store. Suen then volunteered to recall distributed L-tryptophan.

Investigators from FDA and the Board of Pharmacy returned in August 1991 to ensure that Suen had undertaken the recall. While inspecting the pharmacy, investigators saw intact vials of injectable drugs that a customer had returned. Noticing mold in the vials, they questioned Suen, who told them the product had been made at his analytical laboratory, Meridian Valley Clinical Laboratory.

(FDA later determined that chemists from Meridian Valley manufactured more than 1,100 vials of Magnesium-ATP between January and December 1991. In 1992, Suen established manufacturing capabilities at the pharmacy and produced an additional 300 vials.)

In September 1991, FDA investigators attempted to inspect Meridian Valley but initially were refused entry. The firm’s attorney then agreed to allow a 20-minute walk-through, during which investigators saw paraphernalia—stoppers, crimps, and empty glass vials—used for injectable products. Soon after, an informant told FDA that Suen was gearing up for illegal large-scale drug production. Later, investigators also found, in a laboratory trash bin, boxes of intact returned vials containing mold-contaminated Magnesium-ATP.

In May 1992, FDA served a warrant and searched the facility. FDA investigators seized approximately 50 vials of Magnesium-ATP, along with documents, promotional material, and catalogs.

Suen conducted a voluntary recall of Magnesium-ATP immediately after the search, but was able to recover only 106 vials from among hundreds distributed.

FDA evidence indicated that Suen’s chemists tried to use sterile techniques in manufacturing the drug. But with no training in proper procedures, their efforts failed. Also, the environment at Suen’s laboratory was inadequate to produce a sterile product. For example, chemists made Magnesium-ATP in the same area where they performed tests on urine, blood and feces.

FDA investigators determined that Suen and his chemists were unaware of
The good manufacturing practice procedures required by food and drug law to ensure product sterility. The U.S. Pharmacopoeia prescribes a 14-day sterility test period to ferret out bacteria- or mold-contaminated batch portions. Instead, Suen’s firm observed a three-day test period described in a general laboratory chemistry book. As a result of Suen’s method, as many as a third of all prepared batches emerged contaminated, yet the firm falsely labeled some of them sterile. FDA later concluded that none of the 1,400 vials Suen’s company made between January 1991 and May 1992 were reliably sterile.

In the related Drug Enforcement Agency civil proceeding, Suen pleaded guilty to sending a controlled substance, testosterone, to an Oregon laboratory to be encapsulated for sale.

John Henkel is a staff writer for FDA Consumer.

N.J. Firm Ordered to Stop Selling Contaminated Drugs

What began as a routine inspection of an East Rutherford, N.J., drug manufacturer ended in a product recall, a mass seizure, and a court order to stop the firm from making and selling drugs under unsanitary and other violative conditions.

Ambix Laboratories, Division of Organics Corporation of America, signed a consent decree of permanent injunction Jan. 4, 1994. The decree resulted when an FDA investigation found that two of the firm’s products were contaminated with bacteria and the firm’s manufacturing and laboratory operations were not in compliance with government regulations.

FDA has received no reports of illness or injury resulting from use of the drugs.

In signing the consent decree, Ambix agreed to stop selling drug products not manufactured under good manufacturing practice (GMP) requirements.

Ambix manufactures a variety of prescription and over-the-counter drug products, including creams, ointments, nasal sprays, ear drops, and syrups.

On March 12, 1993, FDA Newark district investigators Michael G. Higgins and Toniette K. Bynum initiated a routine inspection of Ambix. They and two microbiologists, Anita Stubbs and Dennis E. Guilfoyle, continued the investigation at the firm from March 16 to April 1.

According to FDA compliance officer Ray Abrahams, “Sometimes investigators have to dig deep to find [GMP] deviations—here, they were obvious.”

According to the investigators’ inspection report, the facility “demonstrates a severe lack of manufacturing, laboratory and processing control. Firm officials seemed unconcerned about the seriousness of a lack of process and method validation. The microbiological observations alone posed a threat to the consumer due to pathogenic bacterial contamination.”

The investigators found one lot of hydrocortisone cream had been distributed after being found contaminated with Staphylococcus aureus; the firm did not validate its deionized water systems, cleaning procedures, and microbiological test methods; and the manufacturing environment was unsanitary. The firm’s records showed a history of insect and rodent contamination.

When presented with the agency’s findings, Ambix promised to correct the problems. However, during a follow-up inspection June 3, 4, 7, and 9, Guilfoyle, investigator Nancy Draghi, and chemist Jean Hill found the same problems, in addition to:

• uncovered drums of product ingredients
• dried ointment-like material splattered on ceiling light fixtures
• water-stained, soiled and loose ceiling tiles
• water puddles
• instruments used in quality control covered with dirt, an oily residue, and particulate matter.

“There were some minor, superficial corrections,” Abrahams said, “but nothing that really changed the status of the firm.”

While FDA was preparing a recommendation to seize Ambix’ products, a Great Neck, N.Y., pharmacist called the agency June 11 to complain that plastic bottles of Kaolin Pectin Oral Suspension, an anti-diarrheal drug, were bulging. According to court documents, the pharmacist said he reported the problem to Alvin Goren, Ambix’ president and co-owner, the same day, but nothing was done until FDA contacted the firm about the problem on June 23.

Abrahams said, “We collected a sample from Hyde Park Nursing Home, Staatsburg, N.Y., and then followed up [with another inspection of the firm June 29 and 30]. FDA testing showed the product was contaminated with yeast and a gram-negative bacteria, Enterobacter gergoviae.” (E. gergoviae has been associated with urinary tract infections.)

According to Abrahams, Ambix had tested the Kaolin Pectin for microbiological contamination before release and did not detect any problems.

On June 25, Ambix ordered a recall of the product.

On July 29, at FDA’s request, U.S. marshals seized all of Ambix’ bulk and packaged finished drug products, valued at approximately $750,000.

Because Ambix’ GMP violations were serious, pervasive and persistent, and continued despite FDA’s warnings, the agency sought, and obtained, a consent decree of permanent injunction.

Before it can resume manufacturing prescription and over-the-counter drug products, Ambix’ entire production process must be validated by independent experts to ensure compliance with good manufacturing practices.

Ambix continues to manufacture and
market some food and cosmetic products. In addition, the firm distributes pharmaceutical products manufactured by other firms for their own label. The agency is planning follow-up inspections to make sure Ambix complies with the consent decree.

—Kevin L. Ropp

Researchers Admit Cover-Up of Wrongdoing

Under a deferred prosecution agreement in New York, a U.S. district court last Dec. 22 dismissed a complaint against cancer researchers Peter Wiernik, M.D., and Elisabeth Paietta, Ph.D., who six months earlier had admitted supplying an investigational biologic to two neurosurgeons for clinical brain tumor studies not approved by FDA.

The defendants, the neurosurgeons, and two technicians all participated in a cover-up of Wiernik and Paietta’s action, but later admitted lying after one technician revealed the truth.

The U.S. District Court for the Southern District of New York had agreed the previous June, when the complaint was filed, to dismiss it if the defendants complied in the next six months with “terms for lawful living” and admitted in sworn statements to the complaint’s charges. After they did, the charges were dismissed. This followed a six-year investigation by FDA, the National Institutes of Health, Montefiore Medical Center in the Bronx, N.Y., and the center’s affiliated Albert Einstein College of Medicine of Yeshiva University.

Wiernik and Paietta, in their collective statements, admitted to their roles in these events:

In early 1987, two doctors new to Montefiore’s Department of Neurosurgery asked Wiernik, director of the Department of Oncology, to assist in their experimental treatment of terminally ill cancer patients by providing small amounts of recombinant Interleukin-2 left over from authorized studies by Wiernik’s department. The neurosurgeons claimed their department would soon be getting its own supply.

Although Wiernik admitted he knew regulations restricted use of leftover investigational products, he agreed to the request. According to Wiernik, the unused Interleukin-2 would otherwise have been discarded.

Paietta, director of Montefiore’s Cellular Immunology Laboratory agreed to a request that her lab help prepare the Interleukin-2. Paietta said that, at the time, she didn’t know of any leftover Interleukin-2 or of any regulatory restrictions on such leftover products.

Wiernik and Paietta supplied the Interleukin-2 over the next several months. While the original request was for one or two patients, 16 were actually treated.

That same day, the two neurosurgeons told Wiernik that FDA had asked their department to identify the source of their Interleukin-2. After much discussion, they agreed to fabricate a story rather than reveal that Wiernik had consented to the illegal use of the product. Wiernik later told Paietta of these plans.

Wiernik told Paietta he was afraid that if he admitted the truth, he and his department would be severely penalized and their research jeopardized. He said he was concerned about unintended consequences to the physicians he had attracted to Montefiore. He told her he had agreed to say, if asked, that a laboratory technician had supplied the leftover Interleukin-2 without his or Paietta’s knowledge. He asked Paietta to do likewise, and she agreed.

At Wiernik’s request, Paietta suggested the name of a technician to give to FDA as the person they would claim had supplied the product. Paietta met with the woman, explained the situation, and asked if she would go along with the story. The technician agreed, and Paietta instructed her on what to say in an interview.

As the several concurrent investigations progressed, another technician’s name came up. Paietta asked her as well to join the cover-up, and the technician agreed.

For the next five years, when Wiernik or Paietta were asked to explain what happened, they continued to make false statements.

Wiernik repeated the story in October 1987 to NIH’s National Cancer Institute in a letter signed also by one of the neurosurgeons, and in 1988 to investigators from FDA and Montefiore.

Paietta told it to a Montefiore committee in February 1988, to FDA in August 1988, to a second Montefiore committee in July 1989, to an Albert Einstein hospital review board in March 1992, and to the FBI in May 1992.

But by April 16, 1992, the first techni-
cian had told the FBI about the cover-up.

In the June 22, 1993, complaint against Wiernik and Paietta, FBI Special Agent Paul Higgins set forth the charges based on FBI interviews and review of the defendants' statements, FDA and hospital records and other documents, witness statements, and reports of interviews by FDA and other investigating institutions.

Higgins said in the complaint, "The defendants, the neurosurgeons, and the technicians involved in the brain tumor trials agree that no patients were harmed by the treatment and that some may have benefited, and there is no evidence indicating otherwise."

Shortly after the complaint was filed, Wiernik and Paietta each said in sworn statements: "There is no question that what I did was wrong. I am fully responsible for my actions and extremely sorry for my conduct."

—Dixie Farley

**Methadone Center Pays Fine With a Dose of Reality**

A narcotics treatment center in New York City with a long history of violating government regulations signed a consent decree agreeing to comply with all FDA and Drug Enforcement Agency requirements in the future and to pay $45,000 in penalties for violations of DEA regulations.

The document, filed in district court Dec. 2, 1993, also orders the treatment center, Reality House, Inc., to implement a quality assurance program to ensure compliance with FDA regulations, and provides for monetary penalties for future violations.

"This consent decree allows FDA for the first time to collect monetary penalties for these kinds of offenses," says New York compliance officer Melaine Small. "Unlike DEA, FDA doesn't have statutory authority to impose civil penalties for violations by a methadone treatment program. With the success of this action, we have a valuable enforcement tool to help us achieve better compliance in the future."

The clinic must pay $5,000 for each violation found during future inspections by either FDA or DEA. The penalty increases by $1,000 per violation at each subsequent inspection.

The consent decree followed an 18-year history of record-keeping and inventory violations by Reality House. (DEA's Comprehensive Drug Abuse Prevention and Control Act of 1970 contains record-keeping and inventory provisions designed to prevent diversion of controlled substances, including methadone.) Repeated warnings to the clinic over the years produced only failed promises to comply with the law.

On March 12, 1993, DEA investigator Neal Ebrus called FDA's New York district office to request that FDA inspect Reality House. He told investigator Maria Caride about the poor results of DEA's most recent inspection at Reality House and said his agency had started paperwork to take legal action against the clinic.

"The DEA wanted to have findings from a current FDA inspection as well as to assist their proposed action," says Caride. "I inspected the facility from March 18 to April 6." Caride found numerous violations of FDA regulations at Reality House, including:

- The program did not notify FDA it had replaced the program sponsor.
- The program did not notify FDA of the change in the laboratory performing the urine drug-screening tests.
- The patient consent form was not properly completed for 12 patients before they were admitted to the program.
- Eight patients did not have the required medical evaluations before being admitted to the program and receiving medication.
- A review of treatment plans for 10 patients showed no documentation of any annual review by the medical director for any of the patients.
- Psychosocial assessments were not done on 35 patients upon admission to the program.
- Records for nine patients showed that treatment plans were not done within the proper time period or were not done at all, or did not contain the required signature and date by the supervisory counselor.
- Treatment plans for three patients lacked adequate evaluation and follow-up.
- One patient did not receive the required quarterly drug-screening analysis.

At the end of the inspection, Caride presented the list of observations to Reality House's program sponsor and executive director, Sydney S. Moshette, and discussed the findings with him. On June 14, FDA sent a warning letter to Moshette, again enumerating the violations and requesting written notification of steps to be taken to correct the problems.

In July, DEA started injunction proceedings against Reality House. The assistant U.S. attorney handling the case informed FDA's New York compliance branch of the action and discussed the possibility of adding provisions to the consent decree that would provide for FDA violations as well. The resulting document, signed in November 1993, covered both FDA and DEA concerns.

—Marian Segal
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/Contamination, Spoilage, Insanitary Handling

PRODUCT: Anhydrous butter oil in bulk drums, at Chicago, N. Dist. Ill.; Civil No. 92C1311.
CHARGED 2-20-92: While held for sale, the article (which had been prepared from fire-damaged butter) was unfit for food due to the presence of an odor of smoke and had been prepared under insanitary conditions—402(a)(3), 402(a)(4).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66352; S. No. 91-610-437 et al.; S.J. No. 1)

PRODUCT: Peach halves in light syrup, canned, canned “fruit cocktail,” and two lots of canned pear halves, at Miami, S. Dist. Fl.; Civil No. 92-2840.
CHARGED 12-15-92: When re-shipped from Canada and diverted to Miami, Fla., the peach halves labeled “Heritage Peach Halves . . . Product of Greece . . . For Export Only” contained the filthy substance Geotrichum mold—402(a)(3); the “fruit cocktail” labeled “Renior . . . Fruit Cocktail Two Fruits . . . Packed for Morris National Inc., Montreal Toronto-Canada . . . Peaches, Pears, Water, Sugar . . . Product of Argentina” failed to conform to the definition and standard of identity for fruit cocktail, since it failed to contain all of the five specified types of fruit, and since the label lacked the name of the packing medium as specified by the standard—403(g)(1); the labels of the lot of canned pear halves labeled “Goldreelf. . . Pear Halves Bartlett . . . Packed by Langeberg Co-Up. Ltd . . . South Africa” lacked the name of the packing medium as specified by the standard—403(g)(2); and the other lot of pear halves labeled “Bartlett pear halves Pantry Shelf Brand . . . Product of Yugoslavia . . . For Export Only,” as well as the peach halves, fell below the prescribed standards of quality, since the pear halves failed to conform to the uniformity of size requirement and the peach halves contained excess pieces of pit—403(h)(1). In addition, all of the articles failed to have required information appearing on the label in the required manner, because the quantity of contents declarations were not expressed in the required avoirdupois pound and ounce—403(f).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66621; S. No. 92-271-336 et al.; S.J. No. 2)

PRODUCT: Plum “candy” and other Oriental preserved fruit products, at Rosemead, C. Dist. Calif.; Civil No. 92-6243-R.
CHARGED 10-16-92: When imported, the articles (e.g., preserved fruits labeled “Juicy Plum Candy [or “Kumquat Candy” or “Preserved Plum Mut Seedless”] . . . SFC International . . . South El Monte, CA . . . Made In Taiwan,” “Butter Candy . . . SFC International Rosemead, CA . . . Product of Taiwan; Taiwan Enterprise Co.,” and “Rose Prune . . . SFC International . . . Rosemead, CA . . . Product of Taiwan Nu Advance Trade Co., Ltd., Taichung Taiwan”) contained insect, animal and/or bird filth—402(a)(3).
DISPOSITION: The articles were claimed by SFC Trading Co., Inc., Rosemead, Calif. The claimant stated that the articles had been found to be adulterated by FDA laboratory procedures, that such adulterations had been unknown to the claimant at the time of importation, and that the claimant wished to return the articles to the original foreign producers. The government moved for summary judgment. Subsequently, pursuant to a stipulation of the parties (including the claimant’s assignee, Richard D. Donald), all claims and answers were withdrawn; and it was agreed that a default judgment condoning and forfeiting the articles might be entered. A default decree ordered the articles destroyed. (F.D.C. No. 66612; S. No. 92-683-341 et al.; S.J. No. 3)

PRODUCT: Tuna steaks, frozen, at Miami, S. Dist. Fla.; Civil No. 93-0322.
CHARGED 2-22-93: While held for sale, the article contained a decomposed substance or was otherwise unfit for food because it was rancid—402(a)(3).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66654; S. No. 92-556-582; S.J. No. 4).

Drugs/Human Use

CHARGED 3-2-92: While held by Lessors, Inc., Burton, Mich., the circumstances used for the packaging and holding of the article failed to conform with current good manufacturing practice—501(a)(2)(B).
DISPOSITION: The article was claimed by the dealer, who denied the charge. Ultimately, a consent decree of condemnation authorized release to the claimant for salvaging. In addition, the decree provided that the claimant should not engage in the filling or packing of gases for medical use unless and until current good manufacturing practices were established, reviewed and approved. Other provisions of the decree included one for the immediate discontinuance
... of operations upon written FDA notice within five years of any subsequent good manufacturing practice violation. (F.D.C. No. 66369; S. No. 92-577-082; S.J. No. 5)

**Drugs/Veterinary**


CHARGED 11-16-92: While held by the distributor, PRN Pharmacal, Inc., Pensacola, Fla., the articles were new animal drugs not generally recognized as safe and effective for their intended uses, and they had not been approved for marketing by FDA—501(a)(5).

DISPOSITION: The articles were claimed by the distributor, who denied the charge. Ultimately, a consent decree ordered the articles destroyed. (F.D.C. No. 66490; S. No. 92-556-686 et al.; S.J. No. 6)

**Medical Devices**

PRODUCTS: Colon-A-Sun colonic irrigator device, various Magna “magnetized” cushion devices, and various components of such devices, at Hutchinson, Dist. Kan.; Civil No. 92-1630-PFK.

CHARGED 12-21-92: The articles (which were manufactured and promoted by Sun Products Distributors, Inc., Hutchinson, Kan., and were identified by labeling such as (irrigator) “Colon-A-Sun 100—19g Sun Products Distributing Inc. . . . Hutchinson, Kansas” and (cushions) “Magn-Mat,” “Magn-Pillow,” and “Magna-Wrist Bands” and which were accompanied by labeling such as (information sheet) “Time-saving, comfortable, easy to use . . . colonic therapy. Colon-a-Sun 100,” (brochure) “Be Alive Magnetize . . . Hutchinson, Kansas,” and (booklet) “The Anatomy of Biomagnetism By Albert Roy Davis”) were class III devices and did not have approved pre-market approval applications in effect—501(f)(1)(B); and the circumstances used for the manufacture, packing and storage of the articles failed to conform with current good manufacturing practice regulations—501(h).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66494; S. Nos. 92-597-710/1; S.J. No. 7)

PRODUCT: HBCI microwave hyperthermia devices for cancer therapy, two seizure actions at Los Angeles and Culver City, C. Dist. Calif.; Civil Nos. 92-5435 HLH and 92-5436 HLH.

CHARGED 9-8-92: The articles (which were being used by or being stored for HBCI, Inc., v/ A Valley Cancer Institute, Los Angeles, Calif., and were accompanied by a videotape entitled “Valley Cancer Institute Hyperthermia” and various brochures, such as one reading “Valley Cancer Institute . . . state-of-the-art hyperthermia . . . heat to cancer tumors . . . maximum damage”) were class III devices, and no approved application for pre-market approval and no exemption was in effect—501(f)(1)(B); the articles’ labeling contained false and misleading statements concerning the regulatory status of the devices—502(a); the articles’ labeling lacked adequate directions for use—502(f)(1); and required information respecting the articles had not been filed—502(o).

DISPOSITION: The articles were claimed by HBCI, Inc., Los Angeles, Calif., who denied the charges and asserted that the articles were lawfully used. Pursuant to stipulation, the actions were consolidated for the purpose of joint proceedings and trial. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. Nos. 66485 & 66497; S. Nos. 92-684-342 et al.; S.J. No. 8)

PRODUCT: Medium anatomic hooks and other components, parts and accessories of a spinal fixation system for surgical implantation, at Elkridge, Dist. Md.; Civil No. MJG-91-1185.

CHARGED 4-29-91 and amended 6-3-91: The articles (which were being distributed by Scientific Spinal, Ltd., Elkridge, Md.) were class III devices and did not have an approved application for pre-market approval in effect—501(f)(1)(B); the labeling of the articles falsely and misleadingly claimed that the articles were the subject of “an FDA monitored study”—502(a); and the articles were neither included in a required list nor subject to notices or other information filed with FDA—502(o).

DISPOSITION: The articles were claimed by the distributor. Pursuant to stipulation by the parties, the time for the claimant to answer, plead or otherwise move was extended. Thereafter, the claimant filed its answer. The claimant also moved to dismiss, moved for summary judgment, and moved to quash the warrant of seizure. The government cross-moved for summary judgment.

After a hearing, the court denied the claimant’s motion to dismiss because, in the context of this case, the verified amended complaint cured any defect in the original complaint’s absence of verification. As to the labeling issue, the claimant asserted that it had affixed the label stating that the devices were for use in an “FDA monitored study” only at the express direction of an FDA employee. Since neither the claimant nor FDA wanted such label, the court understood that the claimant would remove all such labels (assuming the devices—categorized by the court as: (1) alleged surgical instruments; (2) anatomic hooks, rods, washers, and screws used for spinal fixation operations; and (3) an item referred to as a connector/adjustable hook—were returned); and FDA agreed that the issue was moot. Although the court did not grant summary judgment on any device, the court stated that a pertinent regulation, 21 CFR 888.4540(b), classified as a class I device and exempted from pre-market notification any “orthopedic manual surgical instrument.”

The court noted that FDA had been given access to all of the putative surgical instruments and directed that FDA advise the court of any of the items that FDA contended remained in issue for failing to fall within the exemption. For reasons stated on the record, it appeared to the court quite likely that FDA failed to provide timely notification of rejection of the claimant’s Investigational Device Exemption (IDE) for certain items for pedicle fixation. The court also found that various factual disputes remained with respect to the IDE, as well as the need for the filing of a 510(k) notification of intent to market a sacral screw device substantially equivalent to devices marketed...


DISPOSITION: An answer denying the charges was filed by the defendant. Thereafter, the trustee moved the court to allow him to disclaim the articles. The court granted such motion, and ultimately a default decree of condemnation was filed that ordered the destruction of the articles. (F.D.C. No. 66633; S. No. 92-603-792 et al.; S.J. No. 10)

CRIMINAL ACTIONS

CHARGED 4-19-89 by grand jury: Count 1—conspiracy, with others, to commit offenses against the government; Counts 2 & 3—when shipped, a drug labeled “Penicillin V Potassium for Oral Solution, USP Penar VK” was a new drug without an effective approved New Drug Application due to the presence of aspartame—505; Counts 4 & 5—when shipped, the above drug’s labeling lacked adequate directions for use since the labeling failed to warn of the presence of phenylalanine, a component of aspartame and also failed to reveal the presence and amount of phenylalanine, facts pertinent to the treatment of children affected with PKU—502(f), 502(a); and Counts 6-9—while held for sale, batches of injectable penicillin drug products were caused to become adulterated due to failure to comply with current good manufacturing practice since batch production and control records (including all laboratory control results) for each batch of drug product produced were not prepared and maintained (i.e., results of laboratory tests for sterility of specified injectable drug products showing contamination with bacteria of tested product samples)—501(a)(2)(B). Counts 10-17 concerned the making of materially false records—18 U.S.C. 1001; Count 18 concerned the making of a materially false statement; and Counts 19 & 20 concerned endeavors to impede the due administration of justice—18 U.S.C. 1505.

DISPOSITION: The defendants pleaded not guilty. However, after eight days of trial, the corporations and their president changed their pleas to guilty to counts 4 and 6. Each corporation was fined $185,000. The corporation president was sentenced to one year and one day in prison, was fined $185,000, and was placed on probation for four years. The employee pleaded guilty to a misdemeanor and was fined $15,000 and placed on probation for 18 months with required community service. Subsequently, the corporation presi-
dent moved that his sentence be reduced. However, the motion was denied. (F.D.C. No. 64567; S. No. 87-422-291; S.J. No. 11)

INJUNCTION ACTIONS

CHARGED 10-15-91 in a complaint for injunction: That the defendant Syntex Corp. was the parent corporation of the defendant Syntex Laboratories, Inc., and exercised ownership and control over Syntex Laboratories, Inc. Such defendants manufactured, processed, labeled, stored, promoted, and distributed the drug Naprosyn (the defendants’ brand of naproxen). Naprosyn was a new drug subject to an effective approved New Drug Application for use only as an anti-inflammatory analgesic and antipyretic agent in the treatment of the symptoms of rheumatoid arthritis, osteoarthrosis, juvenile arthritis, ankylosing spondylitis, tendinitis, bursitis, acute gout, primary dysmenorrhea, and other mild to moderate pain. Nevertheless, the defendants distributed to licensed practitioners promotional labeling and advertisements for Naprosyn that claimed the drug was “arthroprotective,” thereby suggesting that it protected against or prevented joint degeneration associated with arthritis. FDA notified Syntex Laboratories that the “arthroprotective” claim constituted a disease-modifying effect for which the drug was not approved and which was false and misleading—505(a), 502(a). Syntex Laboratories initially disagreed with FDA, but subsequently wrote FDA that a disease-modifying effect was not supported by the data available and agreed to stop claiming that their naproxen was “arthroprotective.”

Notwithstanding such letter, the defendants continued to promote their naproxen for the disease-modifying effect on arthritis through a coordinated campaign (the “bone and cartilage” campaign). Such campaign was carried out through Syntex Laboratories’ sales representatives, placement of medical-journal and cable-TV advertisements, and promotions presented to the public as educational activities (e.g., educational symposia, physician dinner meetings, medical writers’ articles, and lecture slide kits). Some of such promotions were carried out by Medical Publishing Enterprises, a paid agent of Syntex Laboratories. Other promotions involved researchers and scientific advisors who were paid consultants for Syntex Laboratories, but appeared at symposia and in cable-TV programs without disclosure of their financial relationship to Syntex Laboratories or their roles as consultants for the company. Other campaign components included brochures, placards, flip charts, hospital exhibits, and other written, printed and graphic matter that accompanied Naprosyn. The accompanying labeling contained false and misleading claims that Naprosyn had a disease-modifying effect, was superior in its effects on joint degeneration, and had animal and in vitro studies demonstrating clinically significant disease-modifying effects—502(a). Certain advertisements of the bone and cartilage campaign (although not accompanying the drug) also misbranded the drug because they failed to contain the required true statement of side effects, contraindications and effectiveness—502(n). In addition, the defendants’ naproxen labeling lacked adequate directions for use and was not exempt due to its new drug status since the labeling suggested indications and effects not authorized by the approved New Drug Application—502(f)(1).

DISPOSITION: The defendants, without admitting or denying any of the charges, and disclaiming liability, entered into a consent decree of permanent injunction. The decree enjoined the sale or distribution of Naprosyn or any related drug that was the subject of any promotional activity unless the defendants had provided FDA with specified information (e.g., a copy of all proposed promotional material, a description of all proposed promotional activities, and a description of all proposed media material, with certain specified exceptions). Other provisions of the decree enjoined the shipment of Naprosyn or any related drug following receipt of FDA notification to cease distribution of any promotional materials representing or suggesting that any such drug was clinically effective in modifying the arthritis disease process unless such claim had been approved by FDA. Additional provisions included a recall of “bone and cartilage” campaign promotional materials, a remedial advertising campaign, the payment of $131,000 in costs to FDA, and the establishment of a $2 million dedicated amount to finance remedial activities. (Inj. 1270; S. No. 91-625-086 et al.; S.J. No. 12)

MISCELLANEOUS ACTIONS

SUBJECT: Selenium food additive regulation amendment and FDA final rule, Dist. of Columbia, Court of Appeals Case No. 92-1466,
PETITIONED 9-24-92 by Micro Tracers, Inc., against FDA Commissioner David A. Kessler, in a suit for judicial review: That an FDA order had denied Micro Tracer’s objections, request for hearing, and stay of a final rule that amended the selenium food additive regulations, 21 C.F.R. 573.920. The petitioner, Micro Tracers, Inc., was in the business of sophisticated trace chemical analysis and the manufacture of specialty animal feed premixes. The FDA order had denied Micro Tracer’s objections, request for hearing, and stay of a final rule that amended the selenium food additive regulations by increasing the permissible level of selenium in animal feeds and by eliminating the requirement for an analysis of each premix batch; and, as a manufacturer in the food industry, the petitioner asserted it had been adversely affected. The petitioner asserted that FDA’s actions had been in error, lacked an adequate explanation of underlying reasons, and failed to address the petitioner’s arguments.

DISPOSITION: The government moved to dismiss the action on the ground that this petition was premature in light of the petitioner’s pending request for reconsideration at FDA. The court granted FDA’s motion to dismiss the action, finding that the order under review did not meet the standard for reviewability. The court noted that judicial review might be sought after FDA had issued a final order disposing of the petitioner’s pending motion for reconsideration. (Misc. No. 984; S.J. No. 13)
One of the most frustrating things about having arthritis is not being able to do things as easily as you used to. Like opening a jar, buttoning your shirt, reaching in the upper cabinet or starting your car.

Fortunately there are hundreds of small, inexpensive devices you can use to help keep your independence. At the same time, you are protecting your joints against further damage.

The Arthritis Foundation knows lots of ways to keep arthritis from affecting your lifestyle. Contact your local chapter or call toll-free 1-800-283-7800.