FDA and Y2K
Companies that make FDA-regulated products continue to take preventive actions to ensure it will be a happy new year on Jan. 1, 2000. There are steps you can take, too.

Sugar Substitutes: Americans Opt for Sweetness and Lite
Foods sweetened with sugar are more popular than ever. But for people watching their waistlines, research shows that sweeteners such as saccharin and aspartame can help keep calories down as part of a diet and exercise program.

Taking Charge of Menopause
Though the transition that occurs when a woman's reproductive years end can be a jarring one, many women see the change as a new kind of freedom, especially with the variety of treatments available to ease menopausal symptoms.

How to Spot Health Fraud
Unwary consumers spend billions annually on bogus health products that promise to treat everything from dandruff to diabetes. Here are some tips to keep you on your guard.

Social Phobia's Traumas and Treatments
Entertainer Donny Osmond is just one of more than 10 million who suffer from a crippling fear of public embarrassment. Behavior therapy can help, along with a newly approved drug.
Unique Flu Drug Sends Symptoms Packing

A first-of-its-kind inhaled drug can reduce the time it takes flu sufferers to recover from their fevers, headaches, muscle aches, coughs, and sore throats.

FDA approved the drug Relenza (zanamivir) in July to treat adults and adolescents aged 12 and over with flu types A and B. These types are responsible for flu epidemics and cause most symptoms.

It is the first anti-viral drug approved to treat influenza since the agency approved Flumadine (rimantadine) in 1993.

Clinical studies showed that for the drug to be effective, patients needed to start treatment within two days of the onset of symptoms. The drug seemed to be less effective in patients whose symptoms weren’t severe or didn’t include a fever.

Relenza is a powder that is inhaled twice a day for five days from a breath-activated plastic device called a Diskhaler. Patients should get instruction from a health-care practitioner in the proper use of the Diskhaler, including a demonstration when possible.

Relenza has not been shown to be effective—and may carry risk—in patients with severe asthma or a lung condition called chronic obstructive pulmonary disease. Some patients with mild or moderate asthma experienced bronchospasm (marked by shortness of breath) after using Relenza. Anyone who develops bronchospasm should stop taking the drug and call their health-care provider. Patients with underlying respiratory disease should have a fast-acting inhaled bronchodilator available when taking Relenza.

The clinical trials of Relenza, some of which were done in Europe and the Southern Hemisphere, involved more than 1,000 patients with influenza type A and about 120 who had influenza type B. The drug’s safety and effectiveness have not been established for influenza prevention.

Relenza is marketed by Glaxo Wellcome Inc., Research Triangle Park, N.C.

Quickness, Ease Are Pluses With New Pneumonia Test

A new urine test that can detect the pneumonia-causing bacterium *Streptococcus pneumoniae* in 15 minutes has been approved by FDA.

Approved in August, the Binax test can help doctors diagnose pneumonia more quickly than in the past and begin antibiotic treatment sooner.

The test is done by dipping a swab into a urine specimen and inserting it into the test device. A positive result indicates that the patient most likely has pneumococcal pneumonia, but the health professional should also review a patient’s symptoms to rule out other possible causes of pneumonia.

According to FDA, the Binax test is much easier to use than conventional methods for diagnosing pneumonia, which primarily use saliva and mucus or blood, and can be lengthy, complex, and sometimes unreliable.

In studies conducted by the manufacturer, Binax Inc., Portland, Maine, the test was found to be 93 percent accurate in detecting *S. pneumoniae* when testing urine samples from 373 patients known to have pneumococcal pneumonia, and 78 percent accurate when testing urine from 215 patients with typical symptoms of pneumonia who may not have had the disease. Test results were not reliable in people who had been vaccinated for pneumonia within the previous five days.

Child vaccine linked to bowel obstruction ... Vaccinations against rotavirus, the leading cause of diarrhea in children, have been temporarily halted after a surveillance system run by the national Centers for Disease Control and Prevention and FDA linked the vaccine’s use in infants to a rare bowel obstruction known as intussusception. FDA approved the vaccine, RotaShield, in 1998 for infants as young as 6 weeks of age to protect against rotavirus infection. Twenty-five cases of bowel obstruction were reported within three to seven days after children were vaccinated, which prompted the investigation.

Symptoms of bowel obstruction include persistent vomiting, bloody stools, black stools, and abdominal distention. To report suspected intussusception cases, call the Vaccine Adverse Event Reporting System at 1-800-822-7967 (24 hours a day), or use the form on the Internet at www.cdc.gov/vaer.htm.
Doggie flea product is a danger to cats ... Some flea and tick products labeled only for use on dogs can be fatal to cats, cautions a report by the U.S. Pharmacopeia’s Veterinary Practitioners’ Reporting Program. Certain "spot-on" products, which contain the active ingredient “concentrated permethrin,” are intended only for dogs and can be highly toxic to cats. The report cautions cat owners to read flea and tick product labels carefully. (Journal of the American Veterinary Medical Association, July 1999)

Calcium does a body good ... Americans are facing a serious shortage of calcium, say experts from the University of Colorado and Creighton University. Nutrition professors told attendees at a calcium nutrition meeting that three out of four Americans do not get enough calcium, starting in childhood. This is an important finding, now that the benefits of calcium may extend beyond the bones to include lowering blood pressure and preventing colon cancer, experts say. (Journal of the American Veterinary Medical Association, July 1999)

Don’t go for the burn ... Sunbathers don’t head indoors until they start to burn, say researchers who studied time spent in the sun by 87 French and Swiss college students. Half of the students used sunscreen with a protection factor of 10 and the other half sunscreen with a factor of 30. The students were not told which lotion they received. Users of the stronger sunscreen spent 25 percent more time in the sun, the study found. Researchers concluded that sunscreens tend to encourage prolonged sun exposure because they delay sunburn, which helps explain why previous studies have linked sunscreen use with higher skin cancer rates. (Journal of the National Cancer Institute, August 1999)

Rules Governing Prescription-Drug Commercials Now Final

Television and radio ads promoting prescription drugs directly to consumers are not expected to change much under an FDA guidance recently finalized.

As in a 1997 draft version, the final guidance issued in August states that broadcast ads should ordinarily provide a toll-free telephone number and Internet address where consumers can get more information. Ads also should refer consumers to their health-care providers and to product brochures or print advertisements.

The approach aims to give people more information about a drug even if they are sensitive about their privacy.

Consumers can view the guidance document and find responses to frequently asked questions about direct-to-consumer drug advertising by visiting FDA’s Website at www.fda.gov/cder/guidance/index.htm and making a selection under “Advertising.” To comment on the final guidance, write to FDA’s Dockets Management Branch (HFA-305), 5630 Fishers Lane, Rockville, MD 20852.

On-line Sales of Rx Drugs To Get Closer Scrutiny

As part of a crackdown on illegal prescribing and selling of drugs over the Internet, FDA is teaming up with other federal and state agencies to identify and take action against sites that break the law.

Under federal and state laws, a patient generally must be examined physically by a licensed health-care practitioner before receiving a prescription drug for the first time. The patient then has the prescription filled by a registered pharmacist in a licensed pharmacy that meets state practice standards.

Reputable on-line drug companies can offer consumers a convenient service while complying with these laws. But an increasing number of Websites—based both in the United States and abroad—sell potent drugs without valid prescriptions or meaningful interaction with a health-care professional. Often sales are based only on a buyer’s answers to a questionnaire. Patients who use these services risk adverse side effects, dangerous drug interactions, and harm from contaminated, counterfeit or outdated drugs.

FDA’s enforcement plan includes:
• making Internet monitoring a higher priority and taking criminal or civil actions if needed
• cooperating with other agencies for more effective enforcement
• educating consumers about the risks of illegal Internet drug sales.

FDA urges consumers to avoid buying drugs from Websites that are not registered with search engines, that offer to prescribe drugs without a physician-patient relationship, that sell unapproved medicines or require linking to another site to buy the drug, and that don’t provide a U.S. phone number and address.

1-800-RXDRUGS
www.rxdrugs.com

FDA Consumer / November-December 1999 / 3
Updates (continued)

New Drug to Treat Recurring Brain Cancer

Some adult brain cancer patients now have another option for treating their disease.

The oral treatment temozolomide (Temodar) was approved by FDA in August to treat a form of brain cancer called anaplastic astrocytoma in patients who relapsed following initial treatment with radiation and chemotherapy.

Temozolomide was granted accelerated approval, a process FDA applies to some drugs for serious or life-threatening conditions. In a single study of the drug, tumors resistant to previous chemotherapy with two other drugs partially shrank and disappeared in 7 out of 54 patients. The most common side effects of temozolomide included headaches, nausea, vomiting, fatigue, and low blood counts.

At least 18,000 new cases of brain cancer are diagnosed each year in the United States, a figure which represents about 2 percent of all adult cancers. More than 50 percent of brain cancer cases are tumors that can cause severe disabilities such as motor dysfunction, seizures, and vision abnormalities.

As a condition of approval, FDA is requiring the manufacturer, Schering-Plough Corp., Madison, N.J., to further study the drug’s effects on patients’ survival or quality of life.

Blood Donor Restrictions Urged for Former U.K. Visitors

Certain former visitors to the United Kingdom should not be blood donors in the United States, according to a new guidance issued by FDA.

The new restrictions, issued in August, are a precautionary step designed to reduce the theoretical risk of transmitting a fatal degenerative disease called new variant Creutzfeldt-Jakob disease (nvCJD). The disease has been linked to the disease bovine spongiform encephalopathy, often referred to in the popular press as BSE or “mad-cow disease.”

New variant CJD has been found almost exclusively in the United Kingdom, which includes England, Scotland, Wales, Northern Ireland, the Isle of Man, and the Channel Islands. No cases of BSE or nvCJD have been identified in the United States.

FDA’s guidance to blood establishments (like a similar guidance issued by Canada’s health ministry) asks blood centers to exclude potential donors who have spent six or more cumulative months in the United Kingdom between Jan. 1, 1980, and Dec. 31, 1996. Also excluded are donors who have received non-U.S.-licensed insulin from cows or other injectable products made from cattle in countries with documented cases of BSE.

While no evidence exists to suggest that nvCJD can be transmitted by blood, blood products, or injectable products made from cattle, studies are under way to evaluate these possibilities.

FDA’s new guidance also will no longer recommend that blood centers withdraw from use plasma derivatives from donors at risk for or who have been diagnosed with classic CJD, which has not been found to be transmitted by blood or blood products. The agency’s previous guidance recommended that blood centers permanently defer these donors and that the blood centers immediately retrieve, quarantine and destroy any blood products or plasma derivatives from them.

FDA expects blood centers to implement the guidance by early 2000. For a complete copy of the guidance, go to www.fda.gov/cber/guidelines.htm on FDA’s Website.

Keeps on ticking ... People with implanted heart devices, under normal conditions, are not at risk when exposed to electronic detection systems, say researchers from the Indiana University School of Medicine and two other medical organizations. In a study of 170 people, the implanted heart devices were triggered when the subjects lingered in the detection system. But researchers say the interaction was minor and no one was harmed. Just as a precaution, however, experts say implant patients should not linger more than 15 seconds within anti-theft or airport security machines. (Circulation, July 1999)
Coming soon: FDA Science Forum ... To see how FDA determines which foods, drugs, biologics, and medical devices are safe and effective enough to make it to the marketplace, the agency, along with co-sponsors Sigma Xi and the American Association of Pharmaceutical Scientists, invites consumers, health professionals, industry, and the general public to attend the 2000 FDA Science Forum Feb. 14 and 15 at the Washington Convention Center in Washington, D.C. FDA Commissioner Jane Henney, M.D., and top scientists from FDA and around the world will address emerging issues in the safety of FDA-regulated products. To register, call (703) 548-3000 or go to www.aaps.org/edumeet/fdasfindex.html on the Internet.

FDA Bans Colloidal Silver Products, Cites Lack of Data
Under a rule recently finalized by FDA, drug products containing colloidal silver or silver salts are not recognized as safe and effective. These products, labeled to treat a wide variety of illnesses in adults and children, including AIDS, cancer, syphilis, scarlet fever, shingles, herpes, and pneumonia, have caused some people's skin to take on a permanent blue-gray discoloration.

FDA concluded that colloidal silver products (suspensions of silver particles in a gelatinous base) are misbranded because adequate directions cannot be written to allow consumers to use them safely. These products are also misbranded, FDA said, when their labeling falsely suggests that there is substantial scientific evidence to establish that they are safe and effective for their labeled uses. (For an enforcement action involving colloidal silver, see page 36.)

The FDA final rule, which was published in the Aug. 17 Federal Register and became effective Sept. 16, requires that any colloidal silver product intended to be used as a drug will have to be approved by FDA under the agency's new drug application procedures before being marketed.

New Number for Food Information ... FDA's toll-free Food Information Line has a new number: 1-888-SAFEFOOD (1-888-723-3366). The information line is open 10 a.m. to 4 p.m., Eastern time, Monday through Friday.

Detectors find swallowed metal ...
Hand-held metal detectors are just as accurate as x-rays in finding coins and other metallic objects swallowed by children, according to a recent study. Not only that, they're cheaper and radiation-free. Teams of investigators scanned 176 subjects suspected of having swallowed a metallic object. In most cases the object was detected. While coins may pass uneventfully into the stomach, coins that become lodged in the esophagus can cause complications and possibly death if not detected early. (Archives of Pediatric and Adolescent Medicine, August 1999)

Another tick-borne bacteria detected in people ...
For the first time, researchers at the University of Minnesota have detected in humans a tick-borne bacterial infection that was thought to sicken only dogs. Evidence does not suggest that dogs are spreading the potentially deadly ehrlichiosis, which is similar to Lyme disease. But the ticks bite both humans and dogs and may be jumping from one to the other. (New England Journal of Medicine, July 1999)
Preparing for the New Millennium

By Carol Lewis
In June 1997, FDA began alerting regulated industry to the potential for problems with computer-controlled, date-sensitive products ...

The millennium “bug”: you can’t catch it, but if you’re a patient or are caring for one, you may be wondering if it could affect medical products such as drugs or devices. The good news is, it appears that all industries regulated by the Food and Drug Administration—drugs, medical devices, blood products, foods, and veterinary medicines—are well prepared for the turn of the century.

Also known as the Year 2000 problem or, more commonly, the Y2K computer glitch, the “bug” is the potential inability of some computerized systems and software applications to correctly recognize or process dates after 1999. The roots of the Y2K problem began years ago in early computer programming. To reduce memory requirements, programmers used two numbers for the year—for example, “63” would mean “1963.” Without modifications, those programs might recognize “00” as “1900,” rather than “2000,” resulting in anything from inconvenience to a serious malfunction.

FDA’s Responsibility

FDA first began addressing the Y2K issue in 1996. At that time, the agency took steps to ensure that its own computers would be ready for the transition to the year 2000 by checking mission-critical systems and correcting any problems. This past June, a third party completed a thorough independent process, which verified that those systems would properly function in the year 2000 and beyond.

While many manufacturers of FDA-regulated products depend on computers, computer chips, or software for their products to function or to enable production, very few products depend critically on date-related information to function properly. FDA’s normal regulatory processes, which include comprehensive manufacturing standards for drugs and devices, help assure consumers that all products are safe and available. For example, under these standards, manufacturers of drugs and devices are responsible for ensuring that their production processes function properly and for checking their computerized processes to be sure that they will not be disrupted by any Y2K problems. To date, there is every indication that manufacturers of medical products are well prepared for the millennium and that there will be an adequate supply of safe and effective medicines and devices available to American consumers.

In June 1997, FDA began alerting regulated industry to the potential for problems with computer-controlled, date-sensitive products through a series of letters, speeches, public appearances, meetings, workshops, and guidance documents. FDA advised manufacturers of their responsibilities to make corrections—either by fixing the problems, telling their customers not to use certain products, or providing information on how the products could be modified to avoid problems. In a further effort to alleviate any potential risks associated with Y2K problems, the agency provided specific recommendations to manufacturers regarding the steps necessary to identify and address Y2K issues, and requested they put back-up plans in place to ensure that business processes would continue uninterrupted.

At the same time, the agency asked manufacturers to submit product information on biomedical equipment to help FDA uncover potential Y2K problems before they became public health concerns. To give the general public, government agencies, and the healthcare and research communities one comprehensive source of publicly available information on the Y2K compliance status of medical devices and scientific laboratory equipment, FDA established a year 2000 information page on its Website (www.fda.gov). A special Federal Year 2000 Biomedical Equipment Clearinghouse database also was established, in collaboration with the Department of Veterans Affairs, in January 1998, located at www.fda.gov/cdrh/yr2000/year2000.html.

“While we’ve received good information and cooperation from our regulated industries, we have taken the additional step of checking that information independently,” says William K. Hubbard, FDA senior associate commissioner for Policy, Planning and Legislation. Hubbard, a senior official leading FDA’s Y2K effort with regard to regulated industry, adds, “We have confirmed that our industries are well prepared for the turn of the year.”

To continue to raise awareness about Y2K problems, FDA is conducting educational outreach through:
• the Internet at www.fda.gov (select “Year 2000”)
• a hot line number, 1-888-INFO-FDA (1-888-463-6332) (select first option)
• partnerships with key organizations and associations
• a national media campaign
• routine field inspections that checked Y2K compliance efforts.

In addition, FDA has established an Emergency Operations Center to assist industry and interested individuals in preparing for Y2K.

Other organizations are supporting the agency’s efforts as well. In February 1999, the American Hospital Association (AHA) conducted a national survey of over 2,000 hospitals on their Y2K readiness. Although one-third admitted they might not be completely compliant, they reported that systems directly related to patient care would be.

“Our outreach efforts will be even more critical now with those few at-risk hospitals that think they could potentially have problems in their operations,” says Fred Brown, AHA chairman. Brown, who is also a member of the Senior Advisor’s Group to the President’s Council on Year 2000 Conversion, adds, “Hospitals will be pre-
"We believe that the pharmaceutical industry has taken the steps necessary to ensure that a steady supply of medicine will continue to be available prior to and immediately after the start of the year 2000."

—Janet Woodcock, M.D., FDA

pared because it’s an issue of patient safety.” AHA continues to work with FDA to ensure that hospitals obtain the information they need to achieve total Y2K compliance.

Year 2000 and Medical Devices

The vast majority of medical devices sold in the United States will not be affected by the Y2K problem, according to Thomas B. Shope, Ph.D., special assistant to the director, Office of Science and Technology in FDA’s Center for Devices and Radiological Health (CDRH), “because they are not computerized or do not use dates.” Only about 2,000 of the nation’s approximately 13,500 medical device manufacturers make products that are the type that might be controlled by a computer and could be sensitive to Y2K problems. These include radiation therapy treatment planning systems, hemodialysis machines, some clinical laboratory systems, and some ultrasound systems.

Although most devices are regulated by CDRH, FDA’s Center for Biologics Evaluation and Research (CBER) regulates blood bank software. Blood bank software is used for many different tasks within a blood bank, such as tracking donors who are deferred from donating. In January 1998, CBER posted the industry guidance document “Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products” on FDA’s Website. The guidance provides specific recommendations to industry for evaluating the impact of Y2K on computer and software systems used in manufacturing blood products and for assisting in evaluating problems. FDA has been in contact with the manufacturers of blood bank software and has no information to suggest that these products will not function properly in the year 2000.

Technically fixing Y2K problems, according to Shope, is fairly straightforward. But the complexity of many systems and their dependent components often makes it tedious and time-consuming to implement. Most manufacturers have already identified solutions and provided upgrades for these types of devices and have notified their customers (hospitals and other health-care facilities) of their availability.

Shope suggests users of home devices that rely on personal computers for record keeping, such as certain sophisticated glucose monitors, contact the health-care provider who prescribed or recommended the device for information on the product’s Y2K status. Consumers may also contact a device’s manufacturer for additional information. Most personal computers built since late 1996 are Y2K compliant, but the Federal Trade Commission says it is important to verify this.

In the same June 1997 letter sent to thousands of medical device manufacturers reminding them of their responsibilities to assess their products, FDA also recommended specific actions to ensure the continued safety and effectiveness of these devices. For previously and currently manufactured medical devices, for example, manufacturers were advised to conduct hazard and safety analyses to determine whether device performance could be affected by the date change. For future medical device premarket submissions, manufacturers of devices whose safe operation could be affected were required to demonstrate that the products could perform date recording and computations properly.

Additionally, FDA initiated a study of the Y2K readiness of potentially high-risk medical devices such as the radiation treatment planning system. A number of manufacturers were asked to undergo voluntary assessment to check their procedures and records and to validate any Y2K corrections they made. While the study had not been completed at press time, all available data indicated that these manufacturers were diligently and successfully preparing for the turn of the year.

Impact of Y2K on Pharmaceutical Operations

Consumers may have questions about the effect Y2K will have on the availability of their prescription drugs. FDA has been working closely with the pharmaceutical industry to help ensure an adequate supply of medicines.

Specifically, the agency surveyed over 4,200 domestic and foreign prescription and over-the-counter drug manufacturers, bulk drug manufacturers, distributors, repackers, and medical gas manufacturers, as well as 1,576 licensed biologics manufacturers and registered blood establishments. In its program, FDA has focused its efforts, both in surveying and auditing, on priority firms, which are defined as sole source, orphan, and top 200 prescribed drug manufacturers and licensed biologics manufacturers of vaccines, therapeutic products, allergenic products, viral marker test kits, and large blood organizations. Approximately 97 percent of the priority drug companies and 88 percent of the priority biologics companies have responded to the survey. The results of the survey show that over 90 percent of all priority companies will have completed all necessary steps to prepare for the year 2000 by Nov. 1, 1999. The audit results to date confirm the results of the survey, and the audit activities are continuing with the goal of auditing all priority firms. FDA has checked closely with firms reporting readiness dates late in the year and will take appropriate action to help ensure continued availability of their products.

The Pharmaceutical Research Manu-
Common Misconceptions About Y2K

I need to replace the medical devices I use at home before Jan. 1, 2000.
Anyone with at-home medical devices should contact the health-care provider who prescribed or recommended the device for information on its Y2K status. Consumers may also contact the manufacturer for additional information.

My pacemaker will stop working on Jan. 1, 2000.
Pacemakers and other implanted devices will not fail on Jan. 1, 2000, because they do not require the current date to operate safely and effectively. However, there are a few older models of pacemaker programmers used by physicians to monitor and adjust pacemakers that could be affected. Physicians who are using these programmers will be contacted by the manufacturer and advised on how to correct any potential problems.

It's probably a good idea to stock up on food in case there's a shortage.
There is no need to store extra food. Consumers should know that any problems resulting from Y2K should be minimal and manageable. All research shows that both manufacturers and retailers are confident that food will be safe and available to consumers on Jan. 1, 2000, and beyond. Shopping patterns suggest that, on average, consumers purchase food items on a weekly basis, which typically covers weekly meals and monthly household and personal needs. As long as these normal shopping behaviors continue, food shortages will not happen.

The Food Marketing Institute, which represents food retailers and wholesalers in the United States and around the world, says typically, most stores have some level of “safety stock” of nonperishable items in back rooms and warehouses at any given time, which is more than adequate for the new year. But the institute says, “households should always be stocked with basic, over-the-counter products” such as toilet paper, candles, batteries, and matches.

There won't be enough drugs to go around.
An FDA survey of the drug industry showed that Y2K computer concerns would not affect the supply or availability of drug products unless consumers begin to stockpile drug products as a result of unfounded Y2K concerns. The agency found that industry has taken steps to ensure a steady supply of drugs. In addition, government agencies and organizations within the pharmaceutical industry supply system (including manufacturers, distributors, pharmacies, hospitals, physicians, and insurers) have been working together to prepare for the year 2000 and its potential impact on the supply of pharmaceuticals so that consumers will not have difficulty getting prescriptions refilled. (See "Managing Your Pharmacy Needs.")

—C.L.
Very few FDA-regulated products depend critically on date-related information to function properly.

Manufacturers of America (PhRMA) also conducted a survey, which indicated that Y2K preparations were under way early and that companies would spend the rest of the year continuing to check and re-check internal systems and work with external business partners to further minimize the risk of a significant Y2K systems-related failure.

"We believe that the pharmaceutical industry has taken the steps necessary to ensure that a steady supply of medicine will continue to be available prior to and immediately after the start of year 2000," says Janet Woodcock, M.D., director of FDA’s Center for Drug Evaluation and Research. "Consumers can be sure that FDA will continue to take any action necessary to help assure that their medications will be obtainable." And Woodcock adds, "Be prudent and sensible in preparing for the year 2000. Patients should maintain their normal five- to seven-day supply of medications and essential products."

The Availability of Safe Foods

Even though many of the food processes in the United States are in some way controlled by computers, the majority of food products will not be affected by the date change. The food industry has carefully looked at the equipment used to process foods and found that it does not necessarily rely on date-sensitive microchips to help ensure product safety. In those cases where date sensitivity is an issue, such as in the labeling of foods to indicate “sell by” or “use by” dates, the food industry has made, or is in the process of making, operations meet the Y2K requirements.

FDA held a roundtable discussion on the safety and availability of foods, which was attended by representatives of the national food trade organizations, who represent the vast majority of firms that manufacture, distribute and sell food in the United States. The meeting results echoed the Y2K readiness of the

Managing Your Pharmacy Needs

FDA’s Center for Drug Evaluation and Research recommends the following guidelines for users of prescription drugs to follow in refilling medications and preparing for pharmacy needs as the turn of the century approaches:

- Refill medications when a five- to seven-day supply remains. The supply system is resilient and can correct any issue that might arise within five to seven days. Local pharmacists will be within easy access of a substantial supply of pharmaceuticals.
- Keep a list of prescription and nonprescription medications you and your family are currently taking.
- Create a personal health record for you and your family. Document important medical information. If you need emergency medical treatment, this information can be very useful.
- Carry your current insurance card with you.
- Remember to inform your physician and pharmacist if your insurance coverage will change at the end of the year.
- Speak with your local pharmacists or doctor if you have questions about your medication supply.

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• Keep a list of prescription and nonprescription medications you and your family are currently taking.
• Create a personal health record for you and your family. Document important medical information. If you need emergency medical treatment, this information can be very useful.
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• Remember to inform your physician and pharmacist if your insurance coverage will change at the end of the year.
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food industry in general. The industry also reported that over the years, its experience with food processing and distribution problems due to natural disasters has provided them with contingency plans applicable to potential but unexpected Y2K computer-based malfunctions.

“The food supply system typically includes a 60-day inventory,” says John A. Koskinen, Assistant to the President and Chair, President’s Council on Year 2000 Conversion.

The council created a Food Supply Working Group, led by the U.S. Department of Agriculture, to oversee those involved in producing and distributing the nation’s food supply and to raise awareness about potential Y2K problems and possible solutions.

FDA also looked at specific foods that have significant importance to a large segment of the population. For example, infant formula manufacturers voluntarily provided FDA with written summaries of their preparations for the millennium rollover. FDA review of this information concluded that the infant formula manufacturing industry has undertaken very specific assessment, renovation, and verification activities to minimize disruption and ensure the safety and availability of its products.

What the Data Are Telling Us

FDA believes that the information received to date confirms the agency’s original expectation that Y2K problems with regulated products will not be significant or widespread because manufacturers have taken appropriate actions.

“Through the hard work of many involved in this effort, including those in the agency as well as in the private sector,” says FDA Commissioner Jane E. Henney, M.D., “we hope to make January 2000 simply business as usual.”

Carol Lewis is a staff writer for FDA Consumer.

For More Information

FDA has Y2K information for both industry and consumers on its Website. Go to www.fda.gov and click on “Year 2000,” or call the hotline at 1-888-INFO-FDA (1-888-463-6332) and select option one. Other Websites with information on Y2K issues relevant to health care and public health include:

Government Sites and Hot Line Numbers:

Department of Health and Human Services
Federal Trade Commission
1-888-USA-4Y2K (1-888-872-4925)
U.S. Department of Agriculture
Centers for Disease Control and Prevention
Health Care Financing Administration
Veterans Health Administration
President’s Council on Year 2000 Conversion
1-888-USA-4Y2K (1-888-872-4925)

Other Sites

Food Marketing Institute
(202) 429-8238
American Hospital Association
“Sugar in the morning, sugar in the evening, sugar at suppertime ...”

The lyrics of that old song go a long way toward describing the cravings of many Americans. A bowl of sugary breakfast cereal may be followed by a mid-morning donut, a lunch time soda, ice cream at supper, and, in between, snacks of pudding, pie or pastry. Not to mention all the goodies that are part of Valentine’s Day, Halloween, and the year-end holiday season. It all adds up to one massive national sweet tooth.

So much so that the average American eats the equivalent of 20 teaspoons of sugar a day, according to figures from the most recent federal Continuing Survey of Food Intakes by Individuals (1994–1996). Nearly 60 percent of this intake, says the trade group The Sugar Association, is from corn sweeteners, used heavily in sodas and other sweetened drinks. Another 40 percent is from sucrose (table sugar), and a small amount comes from other sweeteners, such as honey and molasses.

There’s nothing unusual about craving sweets, experts say. Humans naturally have an appetite for sugary things. But in excess, sugary foods can take a toll. Large quantities add up to surplus calories, which can contribute to weight gain. In order to lose weight, the total calories from foods, especially those with lots of calories from sugars as well as fats, must be decreased and physical activity increased. As a result, many consumers seeking to control their weight have turned to sugar substitutes as one way to help lower the daily calorie count without having to give up their favorite foods.

“Anything that can help people cut back on [excess] calories is good,” says Adam Drewnowski, Ph.D., director of nutritional science at the University of Washington. He emphasizes that weight loss is complex and can’t be attributed to any one food product. But existing studies, some of which he has conducted, show that sugar substitutes can help certain people maintain a weight loss. Because sugar substitutes, also called artificial sweeteners, are many times sweeter than sugar, it takes much less of them to create the same sweetness. The resulting calorie count of the amount used is negligible.

According to a 1998 survey by the Calorie Control Council, 144 million American adults regularly consume low-calorie, sugar-free products such as artificially sweetened sodas and desserts. The Food and Drug Administration has approved four sugar substitutes—saccharin, aspartame, acesulfame-K, and sucralose—for use in a variety of foods. At least three other sweeteners are under FDA review but had not been approved at press time.

Two approved sugar substitutes, saccharin and aspartame, have been the subject of ongoing controversy that, in the case of saccharin, dates back more than 20 years. Questions still linger about whether saccharin may cause cancer in humans, and though the sweetener is still widely used, it carries a label that warns of its potential risks.

Aspartame has come under fire in recent years from individuals who have used the Internet in an attempt to link the sweetener to brain tumors and other serious disorders. But FDA stands behind its original approval of aspartame, and subsequent evaluations have shown that the product is safe. A tiny segment of the population is sensitive to one of the sweetener’s byproducts and should restrict intake. However, the agency...
Foods containing saccharin must carry a label (above) saying that the sweetener is linked to cancer in laboratory animals. In addition to saccharin, a wide range of other sweetener choices is available (right), including aspartame, fructose, and newer products such as acesulfame potassium.

continually monitors safety information on food ingredients such as aspartame and may take action to protect public health if it receives credible scientific evidence indicating a safety problem.

Other organizations give aspartame and the other approved sugar substitutes a thumbs up. For example, the American Heart Association endorses their use by diabetics and those on weight-loss diets. The American Diabetes Association calls sugar substitutes “free foods” because they make food taste sweet, but they have essentially no calories and do not raise blood sugar levels.

More Than a Century of Use

The granddaddy of all sugar substitutes is saccharin. Discovered in 1879, it was used during both world wars to sweeten foods, helping to compensate for sugar shortages and rationing. It is 300 times sweeter than sugar.

An early attempt to ban saccharin came in 1911 when a board of federal scientists called the artificial sweetener “an adulterant” that should not be used in foods. This same board later decided to limit saccharin just to products “intended for invalids,” a restriction that was lifted after World War I began.

In 1958, Congress passed the Food Additives Amendment to the Food, Drug, and Cosmetic Act, which required premarket approval from FDA for food additives developed after 1958. This requirement did not apply to ingredients “generally recognized as safe,” or GRAS. Saccharin was considered GRAS, so it remained on the market.

FDA began reviewing hundreds of GRAS substances—including saccharin—in the early 1970s to ensure that the latest scientific information continued to back up their safety. Studies in 1972 and 1973 of rats fed saccharin raised concerns about the sweetener’s role in causing bladder cancer, but data analysis later suggested that impurities, not saccharin, may have caused the tumors.

Then in 1977, a Canadian study that looked specifically at the role of impurities—and of other suspected tumor causes, such as parasites in test animals—showed convincingly that saccharin itself was causing bladder cancer in rats. That same year, FDA proposed to ban saccharin for all uses except as an over-the-counter drug in the form of a tabletop sweetener. At the time, saccharin was the only available alternative to sugar.

The FDA proposal prompted a public outcry, fueled in part by media reports that the test rats were fed the equivalent of as many as 800 diet sodas a day. Congress responded by passing the Saccharin Study and Labeling Act, which placed a two-year moratorium on any ban of the sweetener while additional safety studies were conducted. The law also required that any foods containing saccharin must carry a label that reads “Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals.” Congress has extended the moratorium several times, most recently renewing it until 2002.

Saccharin has remained on the market and continues to have a fairly large appeal as a tabletop sweetener, particularly in restaurants, where it is available in single-serving packets under trade names such as Sweet’n Low. Because it has a good shelf life, saccharin is used widely in fountain sodas, and its stability at high temperatures makes it an option for sweetening baked goods, unlike aspartame, which degrades when heated.
Saccharin also is favored economically because it can be made inexpensively.

But given saccharin’s continuing tentative status, should consumers use it?

“We know for certain that it causes cancer in animals,” says Andrew Laumbach, Ph.D., consumer safety officer in FDA’s Office of Premarket Approval. He acknowledges, however, that animal studies do not always predict the behavior of a substance in the human body.

The National Cancer Institute states in its “Cancer Facts” documents that “epidemiological studies do not provide clear evidence” of a link to human cancer. Regina Ziegler, Ph.D., an NCI epidemiologist, says, “Typical intakes of saccharin at normal levels for adults show no evidence of a public health problem.”

The government’s National Toxicology Program has kept saccharin on its roster of “anticipated carcinogens,” though it periodically considers “de-listing” the sweetener based on available safety evidence.

In the late 1970s FDA and NCI conducted a population-based study of saccharin’s role in causing bladder cancer in humans and found that “in general,” people who used the sweetener had no greater risk of bladder cancer than the population at large. However, the study found “suggestive evidence” that heavy saccharin users—defined as those using six or more servings of the sweetener a day—may have an increased risk. Laumbach says that for consumers who use saccharin, the key to a lower risk may be moderation, as is the case with many foods that can cause problems when eaten in excess. Other health groups, including the American Medical Association, the American Cancer Society, and the American Dietetic Association, agree that saccharin use is acceptable.

The Aspartame Controversy

While questions about saccharin may persist, the safety of another artificial sweetener, aspartame, is clear cut, say FDA officials. FDA calls aspartame, sold under trade names such as NutraSweet and Equal, one of the most thoroughly tested and studied food additives the agency has ever approved. The agency says the more than 100 toxicological and clinical studies it has reviewed confirm that aspartame is safe for the general population.

This message would not necessarily be apparent to consumers surfing the Internet, especially those who use Web-based search engines to find information about sugar substitutes or artificial sweeteners. Websites with screaming headlines and well-written text attempt to link aspartame consumption to systemic lupus, multiple sclerosis, vision problems, headaches, fatigue, and even Alzheimer’s disease. One report distributed nationally over e-mail systems claims that aspartame-sweetened soft drinks delivered to military personnel during the Persian Gulf War may have prompted Gulf War syndrome.

No way, says FDA, along with many other health organizations such as the American Medical Association. David Hattan, Ph.D., acting director of FDA’s division of health effects evaluation, says there is no “credible evidence,” to support, for example, a link between aspartame and multiple sclerosis or systemic lupus. Some Internet reports claim that patients suffering from both conditions went into remission after discontinuing aspartame use. “Both of these disorders are subject to spontaneous remissions and exacerbation,” says Hattan. “So it is entirely possible that when patients stopped using aspartame they might also coincidentally have had remission of their symptoms.”

It is true, says Hattan, that aspartame ingestion results in the production of methanol, formaldehyde and formate—substances that could be considered toxic at high doses. But the levels formed are modest, and substances such as methanol are found in higher amounts in common food products such as citrus juices and tomatoes.

Other circulating reports claim that two amino acids in aspartame—phenylalanine and aspartic acid—can cause neurotoxic effects such as brain damage.

“This is true in certain individuals and in high enough doses,” says Hattan. He explains that a very small group of people who have the rare hereditary disease phenylketonuria, estimated at 1 in 16,000 people, are sensitive to phenylalanine. These “phenylketonurics” have about 4 to 7 percent of the acceptable daily intake the agency has set for the sweetener.

Still other reports attempt to link aspartame to seizures and birth defects. Regarding seizures, Hattan cites animal and human studies showing that the sweetener neither causes nor enhances the susceptibility of seizures. Aspartame also has been evaluated for its potential to cause reproductive effects or birth defects. Again, researchers found no evidence, even in test animals fed the sweetener at doses much higher than those to which humans would be exposed.

Approved in 1981, aspartame is 180 times sweeter than sugar. It is used in products such as beverages, breakfast cereals, desserts, and chewing gum, and also as a tabletop sweetener. In 1996, a study raised the issue that aspartame consumption may be related to an increase in brain tumors following FDA’s approval of the sweetener in 1981. But analysis of the National Cancer Institute’s database on cancer incidence showed that cases of brain cancers began increasing in 1973—well before aspar-
Internet surfers may find screaming headlines and sensational text attempting to link aspartame to numerous health problems. But FDA officials say the product is safe, though a tiny segment of the population is sensitive to one of aspartame’s byproducts.

tame was approved—and continued to increase through 1985. In recent years, brain tumor frequency has actually decreased slightly. NCI currently is studying aspartame and other dietary factors as part of a larger study of adult brain cancer.

Other Sweetener Choices

FDA also has approved two other artificial sweeteners, acesulfame potassium and sucralose, both of which are available in products such as fruit drinks and gelatin desserts.

Acesulfame Potassium: First approved in 1988 as a tabletop sweetener, acesulfame potassium, also called Sunett, is now approved for products such as baked goods, frozen desserts, candies, and, most recently, beverages. More than 90 studies verify the sweetener’s safety. About 200 times sweeter than sugar and calorie free, acesulfame potassium often is combined with other sweeteners. One major beverage maker mixes acesulfame potassium with aspartame to sweeten one of its diet sodas. Worldwide, the sweetener is used in more than 4,000 products, according to its manufacturer, Nutrinova. Acesulfame potassium has excellent shelf life and does not break down when cooked or baked.

Sucralose: Also known by its trade name, Splenda, sucralose is 600 times sweeter than sugar. After reviewing more than 110 animal and human safety studies conducted over 20 years, FDA approved it in 1998 as a tabletop sweetener and for use in products such as baked goods, nonalcoholic beverages, chewing gum, frozen dairy desserts, fruit juices, and gelatinis. Earlier this year, FDA amended its regulation to allow sucralose as a general-purpose sweetener for all foods. Sucralose tastes like sugar because it is made from table sugar. But it cannot be digested, so it adds no calories to food. Because sucralose is so much sweeter than sugar, it is bulked up with maltodextrin, a starchy powder, so it will measure more like sugar. It has good shelf life and doesn’t degrade when exposed to heat. Numerous studies have shown that sucralose does not affect blood glucose levels, making it an option for diabetics.

Sugar Alcohols: Though not technically considered artificial sweeteners, sugar alcohols are slightly lower in calories than sugar and do not promote tooth decay or cause a sudden increase in blood glucose. They include sorbitol, xylitol, lactitol, mannitol, and maltitol and are used mainly to sweeten sugar-free candies, cookies, and chewing gums. FDA classifies some of these sweeteners as “generally recognized as safe” and others as approved food additives.

Other “natural sweeteners” are available, but these are variations of table sugar and contain about the same amount of calories. These products include honey, molasses, evaporated cane juice, rice syrup, barley malt, and fructose.

Another product, stevia, is derived from a South American shrub. Though it can impart a sweet taste to foods, it cannot be sold as a sweetener because FDA considers it an unapproved food additive. “The safety of stevia has been questioned by published studies,” says Martha Peiperl, a consumer safety officer in FDA’s Office of Premarket Approval. “And no one has ever provided FDA with adequate evidence that the substance is safe.” Under provisions of 1994 legislation, however, stevia can be sold as a “dietary supplement,” though it cannot be promoted as a sweetener.

Three other sugar substitutes are currently under FDA review. One of them, cyclamate, was marketed in the 1960s, but FDA banned it in 1970 after evidence emerged linking it to bladder cancer. Subsequent studies have failed to verify that link, so FDA is considering a petition to reapprove cyclamate. The other sweeteners under review are neotame and alitame.

Though sugar substitutes have a long history of controversy, the Calorie Control Council says Americans are continually searching for good-tasting, low-calorie products as part of a healthy lifestyle. Market surveys show that calorie-conscious consumers want more low-calorie foods and beverages. And though artificially sweetened products are not magic foods that will melt pounds away, they can be, experts say, a helpful part of an overall weight control program that includes exercise and other dietary factors.

John Henkel is a staff writer for FDA Consumer.
“I was 40 when I first started having night sweats,” says Patti Shields, 42, of Birmingham, Ala. “I’d wake up in the middle of the night, and even though the air conditioner was running full blast, I’d be covered in sweat.”

Shields is talking about menopause, the rite of passage that signals the end of a woman’s reproductive years. “Those night sweats—and the other symptoms I began to notice—suddenly made me feel old. One day I’m a young woman in her prime, and the
Medical scholars dispassionately define menopause as "the cessation of menstruation." For women, it is much more than that. Because menopause marks the end of fertility, many women see it as a time of freedom from menstrual periods and pregnancy.

"Women shouldn't think of menopause as a death sentence," says Holly Richter, M.D., assistant professor of medical/surgical gynecology at the University of Alabama at Birmingham. "It is a transition from a healthy reproductive life to a healthy nonreproductive life. If women see themselves not just as a uterus, but instead look at themselves as a whole person, this nonreproductive life can be as fulfilling as their reproductive years."

Menopause is the result of ovarian failure, which sounds ominous, but is actually a normal part of aging. Over time, the ovaries gradually lose the ability to produce estrogen and progesterone, the hormones that govern the menstrual cycle. Estrogen can also protect against several health threats, most notably heart disease and osteoporosis. Loss of these hormones, especially estrogen, causes hot flashes and other symptoms associated with menopause.

In the United States, the average age of natural menopause—defined as one year without a menstrual period—is 51, but some women reach menopause in their 40s, and a few in their 60s.

Menopause before age 40 is considered premature menopause. There can be several causes, including genetics or autoimmune disorders, and a medical evaluation is needed.

Induced menopause can occur at any age due to surgical removal of the ovaries or damage to ovaries from treatments such as chemotherapy or radiation.

The Journey Begins
Menopause is a gradual process, says Richter, a journey that takes years to navigate. Most women notice their bodies are changing by their mid-30s. Hormone fluctuations cause disruptions in the menstrual cycle, such as lighter or heavier bleeding, and longer, shorter or skipped periods.

As ovarian function decreases, hormone production becomes erratic and digina can become inflamed and irritated from a high alkaline content, a condition called "atrophic vaginitis."

• **Urinary tract changes**—Thinning of the lining of the urethra and weakening of surrounding pelvic muscles may lead to more frequent urination, frequent bladder infections, painful urination, sudden urinary urgency, and frequent urination during the night. Urinary incontinence may also become a problem.

• **Loss of libido**—In addition to losing their ability to secrete estrogen, the ovaries no longer produce testosterone—the hormone responsible for sex drive in both men and women. Some women's bodies may produce the tiny amount needed through the adrenal glands. Many women, however, lose all testosterone, and with it their sex drive.

• **Emotional changes**—Irritability, mood swings, anxiety, and depression are frequently the result of fluctuating hormones.

• **Formication**—This bizarre symptom, the feeling that ants are crawling over the skin, occurs in about 20 percent of women, according to Lois Jovanovic, M.D., in her book *A Woman Doctor's Guide to Menopause.*

These changes may continue up to three years following a woman's last menstrual period, a time known as the "climacteric."

Long-Term Health Risks
Since women today live an average of 35 years longer than they did 150 years ago, scientists have only recently come to understand the long-term outcomes of living without the protective effects of estrogen. Ongoing studies have confirmed these effects, and women should be aware of them in order to avoid serious health risks.

Cardiovascular disease is the leading killer of American women. Before
menopause, estrogen appears to help women maintain a healthy balance between LDL (bad) and HDL (good) cholesterol, making them six times less likely to experience a heart attack than men age 50 and younger, according to Jovanovic. Once estrogen is no longer present, LDL levels rise, and atherosclerosis (narrowing of the arteries) occurs. After menopause, a woman’s risk for heart disease is about the same as a man’s.

Estrogen also protects a woman against osteoporosis, the bone disease that affects 50 percent of American women over 60. In osteoporosis, bones become brittle and are easily fractured. It is the cause of the distinctive hump noticed in some elderly women and of dangerous hip fractures—the twelfth leading cause of death in the United States.

A 1996 study, reported in the medical journal The Lancet suggests estrogen protects against Alzheimer’s disease, as well. The study showed that patients with Alzheimer’s were significantly less likely to have taken estrogen following menopause (7 percent versus 18 percent). Additionally, the study found that four of seven Alzheimer’s patients taking daily estrogen improved on mental test scores.

“It’s predicted that the number of Americans with Alzheimer’s will double in the next 30 years—affecting up to 14 million people. It’s a major health issue for women, and the fact that estrogen may help prevent the disease is an important finding,” says Richter.

Other health risks associated with the loss of estrogen include increased risk for ovarian and colon cancer, periodontal (gum) disease and tooth loss, and cataract formation.

When menopause symptoms begin, a woman should see her doctor to rule out pregnancy or serious health problems such as uterine cancer. A blood test to assess estrogen status also should be performed.

The most reliable test measures the level of follicle stimulating hormone (FSH), a hormone that is secreted by the pituitary gland to stimulate estrogen production. Levels of 30 to 40 milli International Units per milliliter (MIU/mL) or above means a woman has reached menopause. A level in the teens or 20s means there is still partial ovarian function.

If the ovaries are still functioning, many physicians prescribe low-dose contraceptive pills, which regulate periods and alleviate other symptoms. Because contraceptives can mask menopausal changes, a yearly FSH test should be performed beginning at age 50 to assess ovary status.

“Once a woman reaches menopause [and ovaries no longer function], we discontinue the contraceptives and consider other options,” Richter says.

Replacing Estrogen

Estrogen replacement therapy (ERT) is an effective treatment for menopausal symptoms and has been approved for this use since the 1940s. During the 1980s, ERT also received approval by the Food and Drug Administration for preventing osteoporosis. When taken for many years, ERT reduces the risk of wrist, hip and spine fractures by 50 to 75 percent.

Its health benefits don’t stop there. Numerous studies suggest possible effectiveness in prevention of heart disease, Alzheimer’s, and other menopause-related conditions. In fact, a study published in the Feb. 1999, issue of The Lancet cited research revealing that postmenopausal women who use ERT have a 30 to 50 percent lower death rate than those who do not.

Currently ERT is available in pill and transdermal (skin) patch form. Different regimens and dosages are available. Health status and personal choice determine which is best. Because estrogen causes the buildup of endometrial tissue, and may increase the risk of cancer, a woman who still has her uterus must also take a progestin, which causes the excess tissue to shed.

Progestins can be taken either cyclically or continuously. In the cyclical regimen, estrogen is taken daily and progesterone is added for 12 to 14 days of each month. Several days after progesterone is stopped, a woman will usually experience a short period.

Monthly bleeding can be lessened by

Because menopause marks the end of fertility, many women see it as freedom from menstrual periods and pregnancy.
Taking a low dose of progestin with estrogen every day.

ERT may increase the risk for uterine cancer, blood clots, or gallbladder disease. Many studies have evaluated the possibility of increased breast cancer risk, but results are conflicting. Women taking ERT should perform monthly breast self-exams, says Richter, and have yearly mammograms after age 50.

Side effects associated with ERT include weight gain, bloating, breast tenderness, and nausea.

The hormones available for ERT are derived from two sources. Premarin (conjugated estrogens), the oldest and still the most widely prescribed estrogen, is derived from pregnant horse urine. It is approved for both symptom relief and prevention of osteoporosis.

Other ERTs are plant-derived, and several are available in both pill and patch form. One of the newest to receive FDA approval is Cenestin (synthetic conjugated estrogens, A), which is synthesized from soy and yam extracts. "Cenestin is approved for the relief of vasomotor symptoms such as hot flashes," says Lisa Rarick, M.D., director of FDA's division of reproductive and urologic drug products. "There have been no trials on osteoporosis prevention yet."

Other plant-derived estrogens approved for menopausal symptoms include Alora (estradiol), Climara (estradiol), FemPatch (17-beta-estradiol), Menest (esterified estrogens), Ortho-est (estropipate), Vivelle (estradiol), and Ogen (estropipate). Estrace (estradiol), Estraderm (estradiol), and Estratab (esterified estrogens) are plant-based estrogens approved for both menopausal symptoms and osteoporosis prevention. Estrogen/progesterone combinations are available in either patch or pill form.

Relief from vaginal atrophy can be attained with a variety of FDA-approved vaginal creams containing estrogen, such as Estrace (estradiol), Ortho Dienestrol (diestrol), Ogen (estropipate), and Premarin (conjugated estrogens). Estrin (17-beta-estradiol), a vaginal ring, also is available. The ring is inserted into the upper vagina, where it provides a consistent low dose of estrogen for three months. Since only a small amount of the hormones provided by the ring and creams is absorbed into the system, they are not believed to increase the risk for endometrial or breast cancer. Estradiol rings do not alleviate symptoms such as hot flashes, and are not believed to provide protection against menopause-related diseases such as osteoporosis and heart disease.

**Estrogen Alternatives**

In 1997, FDA approved Evista (raloxifene), a drug that mimics estrogen's protective effects on the bones and heart. Clinical studies show that this drug, one of a new class called selective estrogen receptor modulators (SERMs), increases bone density and reduces levels of LDL, or "bad" cholesterol. But it does not cause the endometrial buildup or breast changes that may increase cancer risk. It does carry the risk of blood clots and is not effective for menopausal symptoms such as hot flashes. More studies are in progress to determine the long-term effects and efficacy of Evista and other SERMs.

Micalcin (calcitonin) and Fosamax (alendronate) are two drugs FDA has approved for treating osteoporosis. Micalcin is effective in women who are not candidates for HRT and who are at least five years postmenopausal and are suffering from osteoporosis. Available as a nasal spray, it has been found to increase bone density.

Fosamax reduces the activity of the cells that cause bone loss and thereby increases the amount of bone present. Both drugs can cause side effects, making a consultation with a physician essential.

Some women may prefer to "let nature take its course" and choose not to take prescription hormones. Others turn to alternative remedies touted to relieve menopausal symptoms and protect against related diseases.

One type of foods being extensively researched are "phytoestrogens." These are natural compounds similar in chemical structure to estrogen that may produce estrogen-like effects in menopausal women.

Of these compounds, the isoflavones found in soy protein seem to be the most promising. Studies being conducted at Wake Forest University Baptist Medical Center in Winston-Salem, N.C., show the phytoestrogens in soy protein to be just as effective as Premarin in monkeys at limiting the formation of atherosclerosis, a major cause of heart disease. Additionally, women who added 20 grams of soy protein to their diets reported less intense menopausal symptoms, such as hot flashes and night sweats.

"We believe soy may offer many of the benefits of estrogen replacement therapy without the risks," says study leader Greg Burke, M.D.

The benefits of soy protein first drew interest when studies showed that in Asian countries, where diets are high in soy, both the incidence of breast cancer and the heart disease mortality rate are four times lower than in the United States. In addition, Asian women report fewer hot flashes and night sweats during menopause. These women get about 30 to 50 milligrams of isoflavones daily, the levels found in half a cup of soy milk or tofu.
Health experts say a diet that includes calcium-rich foods such as low-fat dairy products and broccoli can help reduce the health risks associated with menopause.

In 1998, FDA proposed allowing health claims about the role soy protein may play in reducing the risk of heart disease on the labels of foods containing soy protein. Studies show that 25 grams of soy protein per day may lower blood cholesterol levels.

Be Prepared
Making some lifestyle changes can help women increase longevity and avoid the health risks associated with menopause. The American Heart Association recommends limiting total fat intake to no more than 30 percent of calories, cholesterol to no more than 300 milligrams daily, and salt to no more than 3,000 milligrams daily. The association also recommends eating lean meats, low-fat dairy products, and at least five servings of fruits and vegetables daily. (See “Eating for a Healthy Heart” on FDA’s Easy Reader Website at www.fda.gov/opacom/lowlit/englowl.html.)

In addition to a heart-healthy diet, exercise that includes cardiovascular and weight-bearing workouts is good for the heart and bones. The action of muscle on bone helps to increase bone density, so exercises such as weight training, running, walking, or jogging are important. Check with a doctor before beginning an exercise program.

"Preparing for the change of life is essential, since women are living one third or more of their lives in menopause," says Richter. "Together with their physicians they can minimize the associated health risks and help sustain a good quality of life throughout their nonreproductive years."

Lynne L. Hall is a writer based in Birmingham, Ala.

For More Information
The National Women's Health Information Center 1-800-994-WOMAN (1-800-994-9662) www.4woman.gov

The North American Menopause Society P.O. Box 94527 Cleveland, OH 44101 1-800-744-5342 www.menopause.org


American Heart Association 1-800-242-8721 www.americanheart.org

Shape Up America! www.shapeup.org
How To Spot Health Fraud

You don’t have to look far to find a health product that’s totally bogus—or a consumer who’s totally unsuspecting. Promotions for fraudulent products show up daily in newspaper and magazine ads and TV “infomercials.” They accompany products sold in stores, on the Internet, and through mail-order catalogs. They’re passed along by word-of-mouth.

And consumers respond, spending billions of dollars a year on fraudulent health products, according to Stephen Barrett, M.D., head of Quackwatch Inc., a nonprofit corporation that combats health fraud. Hoping to find a cure for what ails them, improve their well-being, or just look better, consumers often fall victim to products and devices that do nothing more than cheat them out of their money, steer them away from useful, proven treatments, and possibly do more harm than good.

“There’s a lot of money to be made,” says Bob Gatling, director of the program operations staff in the Food and Drug Administration’s Center for Devices and Radiological Health. “People want to believe there’s something that can cure them.”

FDA describes health fraud as “articles of unproven effectiveness that are promoted to improve health, well being or appearance.” The articles can be drugs, devices, foods, or cosmetics for human or animal use.

FDA shares federal oversight of health fraud products with the Federal Trade Commission. FDA regulates safety, manufacturing and product labeling, including claims in labeling, such as package inserts and accompanying literature. FTC regulates advertising of these products.

Because of limited resources, says Joel Aronson, team leader for the nontraditional drug compliance team in FDA’s Center for Drug Evaluation and Research, the agency’s regulation of health fraud products is based on a priority system that depends on whether a fraudulent product poses a direct or indirect risk.

When the use of a fraudulent product results in injuries or adverse reactions, it’s a direct risk. When the product itself does not cause harm but its use may keep someone away from proven, sometimes essential, medical treatment, the risk is indirect. For example, a fraudulent product touted as a cure for diabetes might lead someone to delay or discontinue insulin injections or other proven treatments.

While FDA remains vigilant against health fraud, many fraudulent products may escape regulatory scrutiny, maintaining their hold in the marketplace for some time to lure increasing numbers of consumers into their web of deceit.

How can you avoid being scammed by a worthless product? Though health fraud marketers have become more sophisticated about selling their products, Aronson says, these charlatans often use the same old phrases and gimmicks to gain consumers’ attention—and trust. You can protect yourself by learning some of their techniques.

The following products typify three fraudulent products whose claims prompted FDA to issue warning letters to the products’ marketers, notifying them that their products violated federal law. Two of the products also were added to FDA’s import alert list of unapproved new drugs promoted in the United States. Products under import alert are barred from entry onto the U.S. market.

Take a look at these products’ promotions. They are rife with the kind of red flags to look out for when deciding whether to try a health product unknown to you.

Paula Kurtzweil is a member of FDA’s public affairs staff.
Tip-Offs to Rip-Offs

Product No. 1: Pure emu oil

FDA determined that a pure emu oil product marketed to treat or cure a wide range of diseases was an unapproved drug. Its marketer had never submitted to FDA data to support the product's safe and effective use.

One Product Does It All

"... extremely beneficial in the treatment of rheumatism, arthritis ... infections ... prostate problems, ulcers ... cancer, heart trouble, hardening of the arteries, diabetes and more. ..." "completely eliminating the gangrene ..." "... antibiotic, pain reliever ... ."

Be suspicious of products that claim to cure a wide range of unrelated diseases—particularly serious diseases, such as cancer and diabetes. No product can treat every disease and condition, and for many serious diseases, there are no cures, only therapies to help manage them.

Cancer, AIDS, diabetes, and other serious diseases are big draws because people with these diseases are often desperate for a cure and willing to try just about anything.

Quick Fixes

"... eliminates skin cancer in days! ..."

Be wary of talk that suggests a product can bring quick relief or provide a quick cure, especially if the disease or condition is serious. Even with proven treatments, few diseases can be treated quickly. Note also that the words "in days" can really refer to any length of time. Fraud promoters like to use ambiguous language like this to make it easier to finagle their way out of any legal action that may result.

Personal Testimonials

"Alzheimer’s Disease!!! My husband has Alzheimer. On September 2, 1998 he began eating 1 teaspoon full of ... Pure Emu Oil each day. ... Now (in just 22 days) he mowed the grass, cleaned out the garage, weeded the flower beds, and we take our morning walk again. It hasn’t helped his memory much yet, but he is more like himself again!!"

Personal testimonies can tip you off to health fraud because they are difficult to prove. Often, says Reynaldo Rodriguez, a compliance officer and health fraud coordinator for FDA’s Dallas district office, testimonials are personal case histories that have been passed on from person to person. Or, the testimony can be completely made up.

"This is the weakest form of scientific validity,” Rodriguez says. “It’s just compounded hearsay.”

Some patients' favorable experiences with a fraudulent product may be due more to a remission in their disease or from earlier or concurrent use of approved medical treatments, rather than use of the fraudulent product itself.
Product No. 2: Over-the-counter transdermal weight-loss patch

FDA issued a warning letter to the marketer of the weight-loss product described here because it did not have an approved new drug application. Because of the newness of the dosage form—skin-delivery systems—FDA requires evidence of effectiveness, in the form of a new drug application, before the product can be marketed legally.

‘Natural’

“Healthy, simple and natural—way to help you lose and control your weight.”

Don’t be fooled by the term “natural.” It’s often used in health fraud as an attention-grabber; it suggests a product is safer than conventional treatments. But the term doesn’t necessarily equate to safety because some plants—for example, poisonous mushrooms—can kill when ingested. And among legitimate drug products, says Shelly Maifarth, a compliance officer and health fraud coordinator for FDA’s Denver district office, 60 percent of over-the-counter drugs and 25 percent of prescription drugs are based on natural ingredients.

Also, any product—synthetic or natural—potent enough to work like a drug is going to be potent enough to cause side effects.

Time-Tested or New-Found Treatment

“This revolutionary innovation is formulated by using proven principles of natural health based upon 200 years of medical science.”

Usually it’s one or the other, but this claim manages to suggest it’s both a breakthrough and a decades-old remedy. Claims of an “innovation,” “miracle cure,” “exclusive product,” or “new discovery” or “magical” are highly suspect. If a product was a cure for a serious disease, it would be widely reported in the media and regularly prescribed by health professionals—not hidden in an obscure magazine or newspaper ad, late-night television show, or Website promotion, where the marketers are of unknown, questionable or nonscientific backgrounds.

The same applies to products purported to be “ancient remedies” or based on “folklore” or “tradition.” These claims suggest that these products’ longevity proves they are safe and effective. But some herbs reportedly used in ancient times for medicinal purposes carry risks identified only recently.

Satisfaction Guaranteed

“... Guarantee: If after 30 days ... you have not lost at least 4 pounds each week, ... your uncashed check will be returned to you ... .”

Here’s another red flag: money-back guarantees, no questions asked. Good luck getting your money back. Marketers of fraudulent products rarely stay in the same place for long. Because customers won’t be able to find them, the marketers can afford to be generous with their guarantees.
Product No. 3: Unapproved weight-loss product marketed as an alternative to a prescription drug combination

Meaningless Medical Jargon

"... Hunger Stimulation Point (HSP)

... thermogenesis, which converts stored fats into soluble lipids ...

"One of the many natural ingredients is inolitol hexanicontinate."

Terms and scientific explanations such as these may sound impressive and may have an element of truth to them, but the public "has no way of discerning fact from fiction," Aronson says. Fanciful terms, he says, generally cover up a lack of scientific proof.

Sometimes, the terms or explanations are lifted from a study published in a reputable scientific journal, even though the study was on another subject altogether, says Martin Katz, a compliance officer and health fraud coordinator for FDA's Florida district office. And chances are, few people will check the original published study.

"Most people who are taken in by health fraud will grasp at anything," he says. "They're not going to do the research. They're looking for a miracle."

FDA issued an import alert for a Canadian-made weight-loss product whose claims compared the product with two prescription weight-loss drugs taken off the market after FDA determined they posed a health hazard.

Promises of Easy Weight Loss

"Finally, rapid weight loss without dieting!"

For most people, there is only one way to lose weight: Eat less food (or fewer high-calorie foods) and increase activity.

Note the ambiguity of the term "rapid." A reasonable and healthy weight loss is about 1 to 2 pounds a week.

Paranoid Accusations

"Drug companies make it nearly impossible for doctors to resist prescribing their expensive pills for what ails you ...."

"It seems these billion dollar drug giants all have one relentless competitor in common they all constantly fear—natural remedies."

These claims suggest that healthcare providers and legitimate manufacturers are in cahoots with each other, promoting only the drug companies' and medical device manufacturers' products for financial gain. The claims also suggest that the medical profession and legitimate drug and device makers strive to suppress unorthodox products because they threaten their financial standing.

"This [accusation] is an easy way to get consumers' attention," says Marjorie Powell, assistant general counsel for the Pharmaceutical Research and Manufacturers of America. "But I would ask the marketers of such claims, 'Where's the evidence?' It would seem to me that in this country, outside of a regulatory agency it would be difficult to stop someone from making a claim."

Think about this, too: Would the vast number of people in the healthcare field block treatments that could help millions of sick, suffering patients, many of whom could be family and friends? "It flies in the face of logic," Barrett says on his Quackwatch Website.
Joining Forces to Fight Fraud

Health fraud isn’t confined to the United States only. It’s worldwide, and to help combat it in North America, the United States has joined with Canada and Mexico to share knowledge and coordinate enforcement activities related to fraudulent health products, services and devices.

In announcing their decision in December 1998 to adopt the Joint Strategies Agreement, the countries agreed to:

- share information on current trends in health fraud
- cooperate in detecting health fraud along borders
- share information about significant investigations in their country
- consider each others’ requests to investigate domestic activities and coordinate related enforcement activities
- develop and distribute joint consumer and business education messages about health fraud.

—P.K.

Consumers often fall victim to products that do nothing more than cheat them out of their money, steer them away from useful, proven treatments, and possibly do more harm than good.

The underlying rule when deciding whether a product is authentic or not is to ask yourself: “Does it sound too good to be true?” If it does, it probably isn’t true.

If you’re still not sure, check it out: “Look into it—before you put it in your body or on your skin,” says Reynaldo Rodriguez, a compliance officer and health fraud coordinator for FDA’s Dallas district office.

To check a product out, FDA health fraud coordinators suggest:

- Talk to a doctor or another health professional. “If it’s an unproven or little-known treatment, always get a second opinion from a medical specialist,” Rodriguez says.
- Talk to family members and friends. Legitimate medical practitioners should not discourage you from discussing medical treatments with others. Be wary of treatments offered by people who tell you to avoid talking to others because “it’s a secret treatment or cure.”
- Check with the Better Business Bureau or local attorneys generals’ offices to see whether other consumers have lodged complaints about the product or the product’s marketer.
- Check with the appropriate health professional group—for example, the American Heart Association, American Diabetes Association, or the National Arthritis Foundation if the products are promoted for heart disease, diabetes or arthritis. Many of these groups have local chapters that can provide you with various resource materials about your disease.
- Contact the FDA office closest to you. Look for the number and address in the blue pages of the phone book under U.S. Government, Health and Human Services, or go to www.fda.gov/ora/fed_state/dsfr_activities/dsfr_pas.html on the FDA Website. FDA can tell you whether the agency has taken action against the product or its marketer. Your call also may alert FDA to a potentially illegal product and prevent others from falling victim to health fraud.

—P.K.
hen his self-described “worst episode” of anxiety lay hold of him on stage in 1994, Donny Osmond was no fledgling entertainer. The singer-actor had been in the public spotlight for more than 30 years—four of those, starting when he was just 18, as co-host of a popular variety program with his younger sister, Marie.

“Once the fear of embarrassing myself grabbed me,” Osmond writes in his recent autobiography, Life Is Just What You Make It, “I couldn’t get loose. It was as if a bizarre and terrifying unreality had replaced everything that was familiar and safe. I felt powerless to think or reason my way out of the panic.”

At the time, Osmond was playing the lead character in the Andrew Lloyd Webber musical “Joseph and the Amazing Technicolor Dreamcoat.” “… I kept trying to remember the words,” he continues, “but they slipped through my fingers like mercury, defying me to try again. The
To avoid the frightening, panic-like reactions, people often rearrange their lives to sidestep their personal triggers.

harder I tried, the more elusive they became. The best I could do was to not black out, and I got through the show, barely, by telling myself repeatedly, "Stay conscious, stay conscious."

This was not garden-variety stage fright, Osmond explains. The entertainer who had confidently mixed with such stars as Bob Hope, John Wayne, Andy Griffith, Lucille Ball, Danny Thomas, and Farrah Fawcett, and who had won two celebrity auto races by driving his cars at speeds of up to 150 miles an hour, had become afraid—not just of humiliating himself during his shows, but of being scrutinized off-stage, as well, while doing things as mundane as returning merchandise to the store for a refund. The fear, Osmond says in his book, stemmed from the possibility of not always being in control of what happened to him. His mind would race: "What will I do? What will people think? Will I look stupid?"

As Osmond discovered, the condition that caused his foreboding panics had a name: social phobia. Also called social anxiety disorder, social phobia is an extreme fear of public embarrassment and being judged by others. The condition affects as many as 13 of every 100 Americans at some point in their lives, according to the Anxiety Disorders Association of America, making it the third most common psychiatric condition after substance abuse and depression.

To control his condition, Osmond learned techniques to manage his fears by changing his thought patterns. While many people address their social phobia with such psychological therapy alone, many others find medication helpful, either alone or coupled with psychotherapy. In May, Paxil (paroxetine hydrochloride) became the first drug approved by the Food and Drug Administration specifically for treating social phobia.

Way Beyond Butterflies

Social phobia is far different from the run-of-the-mill nervousness associated with stressful situations. It's the intensity of the fear that distinguishes the condition from the almost inevitable butterflies that most people feel when they are about to give a speech or go to an interview or even a party.

When people with social phobia perceive that others will judge their "performance" in a certain situation, their bodies undergo physical changes, which typically include profuse sweating, rapid heartbeat, shortness of breath, faintness, and blushing.

"In the more severe cases, people can have a panic-like reaction and become so overwhelmed with anxiety that they feel completely disoriented," says Jerilyn Ross, president of the Anxiety Disorders Association of America and a psychotherapist who has treated thousands of patients with social phobia, including Osmond. "Your fight-or-flight alarm system that warns you when there's danger goes off at the wrong time. You literally feel like you're losing control, you're going to do something stupid to embarrass yourself, you're going to die."

Una McCann, M.D., an associate professor of psychiatry at the Johns Hopkins University School of Medicine and former head of the anxiety disorders unit at the National Institute of Mental Health, admits that when she started at NIMH, even she underestimated the life-altering impact that social phobia could have. "My initial reaction toward social phobia was probably typical of most people's," McCann says. "I thought, 'What's that? That's a disorder?' Because everybody experiences anxiety in some social situations, like public speaking, large crowds, or being the center of attention, it really seemed like a pseudo-disorder to me at first. Until I met some patients. Then, I suddenly realized how unbelievably debilitating social phobia can truly be."

For Marissa Turner, now 27 years old, even visiting her own aunt used to trigger panic-type symptoms. "It was pretty hair-raising," says Turner. "Standing on my aunt's doorstep, I'd be hyperventilating, shaking, and feeling hot when it wasn't hot outside. I'd feel like I wanted to turn around and run a mile. My throat would constrict, and it felt like if I opened my mouth to talk it wouldn't make a sound."

To avoid the frightening, panic-like reactions, people often rearrange their lives to sidestep their personal triggers rather than endure the intense anxiety. "What we're talking about is an anxiety so severe that a person is unable to function, either socially, academically or occupationally," explains Thomas Laugheren, M.D., the team leader for FDA's psychiatric drug products group. "You hear of people who would turn down a promotion or quit their job rather than dealing with talking to groups of people. Other people are shut-ins because they fear being judged in almost any social interaction outside of their family."

It's not that these people are shy, necessarily. Turner, for example, craved social interaction. "I could list a million things I wanted to do, which my peers were doing, that I couldn't," Turner says. "I didn't date. I rarely went to parties, and when I did, I was very scared the whole time."

Turner's condition is referred to as "generalized" social phobia because her anxiety extended to a broad variety of
Her social phobia treated, Marissa Turner can now take pleasure in something she would have dreaded just a year ago: a social gathering at a café near her home.

settings. Some people with generalized social phobia become very anxious about activities as routine as eating in a restaurant, writing something down while someone is watching, or using a public restroom. As a group, those with generalized social phobia are less likely to graduate from high school and are more likely to rely on government financial assistance or have poverty-level salaries, McCann points out.

Other people have the more limited “specific” social phobia, meaning their fear is associated with just public speaking or another well-defined circumstance.

Combination of Causes

Scientists have not pinpointed the exact causes of social phobia, which tends to run in families and may affect women slightly more often than men. Studies suggest that both biological and psychological factors may contribute to the anxiety disorder.

Some scientists think social phobia is related to an imbalance of the brain chemical serotonin. Perhaps someone who is biologically predisposed to social phobia endures a triggering embarrassing event, Ross says. “I think we can all remember a time when we got up to talk, and the kids giggled because our skirt was up, or we forgot our line in a school play. At the moment it seemed like a traumatic experience, but for people who are biologically predisposed to social phobia, that experience can truly imprint itself on the brain as a traumatic event.”

Many unproblematic years can pass between such an event and the phobia rearing its head, Ross says. Social phobia can appear any time in one’s life, but typically shows up in the mid- to late-teens and can grow worse for a time after that, according to the Anxiety Disorders Association of America.

Turner has wrestled with her anxiety most of her life, but says that it “shot through the roof” as she neared adulthood. Like many fighting this war of
nerves, Turner tried to self-medicate with alcohol. Without medical help, she says, she would have relied increasingly on drinking to get her through social situations. Turner did finally seek medical help, but not, she says, until she felt like she “couldn’t cope with another day.”

Addressing the Anxiety

Turner’s doctor has prescribed the drug Paxil to ease the primary symptoms of her social phobia. This first drug approved by FDA for treating the condition is also approved to treat depression, obsessive compulsive disorder, and an anxiety condition called panic disorder. However, it is not approved for performance anxiety or shyness that does not rise to the level of social phobia.

Paxil is an effective treatment option for doctors to consider, says the agency’s Laughren, who adds that many patients will see improvement but not be cured of their anxiety altogether.

Turner says it has made a “really big difference” in her life. “Since I’ve started taking Paxil, I’ve been on top of my anxiety.”

People taking antidepressant drugs called “monoamine oxidase inhibitors” shouldn’t take Paxil. The drug should be used with particular caution in some other patients, such as those who are pregnant or nursing or who have a history of seizures, mania (emotional highs associated with bipolar disorder), or certain other medical conditions.

Besides Paxil, doctors sometimes prescribe certain antidepressants or other drugs—beta blockers and benzodiazepines, for example—to try to control the anxiety symptoms associated with social phobia. While these drugs have not been approved by FDA specifically for treating social phobia, doctors can legally prescribe them if they feel a patient will benefit.

Some patients with social phobia opt for a nondrug treatment approach instead of, or in addition to, medication.

Philip Lawson (not his real name) is one of those who wanted to overcome his social anxiety without drugs. As an agent representing athletes, authors, and other public figures, the 24-year-old Lawson is required not only to meet individually with his clients and others, but also to give speeches. He relished doing presentations in college, but since graduating—during interviews and on his job as a talent representative—he has battled an extreme fear of public speaking that’s brought on white-knuckle anxiety attacks.

At first, Lawson didn’t even want to accept that he had an anxiety disorder. “I’m the antithesis of someone you would expect to have a social problem. I planned my five-year high school reunion.” The colleagues in whom he confided about his anxiety reacted with astonishment: “I don’t believe it, you? Mister Outgoing Talk-to-Anybody?”

Yes, him, Lawson says. “When I had to give a presentation, I would either pretend to be unprepared or I’d say something really quick,” he explains. “The anxiety grew into one-on-one meetings with people, where I would feel like I was completely on the spot. You always assume that all the attention is on you, like a spotlight.”

Lawson’s low point, he says, was when he called in sick to work because he had to give a speech. “I can either face this,” he told himself, “or let it get worse and worse.” Rather than allowing his condition to spiral downward, Lawson worked with a psychotherapist, individually and in group sessions, to learn to face down his irrational fears. He participated in a standard, two-pronged approach to treating social phobia called “cognitive-behavioral therapy.”
Lecturer, educator and journalist William Lyon Phelps (1865-1943) told this story about his pre-speech jitters:

*Having to speak at a public dinner in Chicago, I found my place at that pillory of torment, the speakers' table; and there, seeing a magnificent man in evening dress, I gave him my name and grasped his hand with what cordiality I could command.*

"I'm the headwaiter, sir," he replied. "Shake hands again, old man," I cried. "You don't know how I envy you."

It’s a rare person who feels no anxiety before addressing a large group. But do you have true social phobia? Your answers to the following questions could help a health professional diagnose your condition.

**Are you troubled by:**
- an intense and persistent fear of a social situation in which people might judge you?
- fear that you will be humiliated by your actions?
- fear that people will notice that you are blushing, sweating, trembling, or showing other signs of anxiety?
- knowing that your fear is excessive or unreasonable?

**Does the feared situation cause you to:**
- always feel anxiety?
- go to great lengths to avoid participating in the feared situation?
- experience a “panic attack” during which you suddenly are overcome by intense fear or discomfort including any of these symptoms?
  - pounding heart
  - sweating
  - trembling or shaking
  - shortness of breath
  - choking
  - chest pain
  - nausea or abdominal discomfort
  - “jelly legs”
  - dizziness
  - feelings of unreality or being detached from yourself
  - fear of losing control or going crazy
  - fear of dying
  - numbness or tingling sensations
  - chills or hot flushes

Does all this interfere with your daily life? ●

**Sources:**
*Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition.

Anxiety Disorders Association of America

The first part of cognitive-behavioral therapy—the “cognitive” aspect—tries to correct people’s catastrophic perceptions of what others are thinking about them and what the real consequences are of a less-than-perfect performance. “Social phobia is a very self-focused illness,” explains McCann. “You might think that people see you blushing and trembling, when really, many of them are thinking about what they’re going to have for lunch.”

To help people put things in perspective, a therapist may ask, “What is going to be the consequence if you do have a panic?” McCann’s examples: “If you have a job interview and you blow it, so what? So you don’t get that job. But it was good practice. So you do flub a sentence. What is the worst thing that can happen? Somebody might chuckle, maybe they’ll rib you about it.”

For Osmond, cognitive therapy reinforced what his wife, Debbie, had told him over and over: If he wasn’t perfect, on-stage or off, people would like him nonetheless.

The “behavioral” aspect of therapy, typically undertaken at least partially in a group setting, gradually exposes people to the circumstances that can trigger their panic. It teaches them techniques to help them focus on the present reality rather than anticipating the imaginary dangers like “what if I lose control?” For example, people may learn to:
- expect the fear and accept rather than fight it
- focus on manageable things in the present—by paying attention to their breathing, for example, or counting backwards from 100 by threes, repeating an encouraging phrase to themselves (“What doesn’t kill me makes me stronger,” for instance), picturing themselves at the beach or another place they would like to be, or consciously rubbing their hand on a podium, chair, or other object.

By socializing or giving a speech surrounded by an empathetic group, people can practice using these techniques to (Continued on page 33)
Social phobia affects as many as 13 out of 100 Americans.

What doesn't kill me makes me stronger. What doesn't kill me makes me stronger. What doesn't kill me makes me stronger. 100, 97, 94, 91, 88, 85, 82, 79, 76, 73, 70, 67, 64, 61, 58, 55, 52, 49, 46, 43.
"You literally feel like you're losing control, you're going to do something stupid to embarrass yourself, you're going to die."

—Psychotherapist Jerilyn Ross

(Continued from page 31)

cope in the unnerving situation and give their confidence a boost. Speaking groups like Toastmasters might not be a sufficiently nurturing first step for those with social phobia, stresses Ross, who does encourage patients to join such groups once they conquer their paralyzing fear. "Toastmasters teaches you how to give an effective speech and deal with the normal fears and jitters," she says, "but it doesn’t teach you how to deal with the more pathological anxiety."

Behavioral therapy homework assignments can include making presentations in a real-life environment. "It’s not just going for those 12 or so weeks," McCann says. "You have to go through a little pain and have the failures to get your improvements."

Osmond’s "homework" included a trip with Ross to the local shopping center to buy, and the next day return, a shirt. At the mall, he tracked his panics on a scale of 1 to 10 while practicing his coping tricks. "Now, the entire time I was in the mall," he writes, "my panic never went down to 0, but anything under 5 or so, I could cope with."

To this day, Lawson isn’t entirely without anxiety, either, but says the quality of his life has improved significantly. "I went from calling in sick to now at least being able to get up in front of a group of people. I’m able to have one-on-one meetings with people without feeling terribly nervous. I try not to take myself so seriously."

Combined with her Paxil treatment, cognitive behavioral therapy contributed to Turner’s progress, too. Paxil, she says, "calmed my nerves and elevated my mood enough that I could use all the cognitive behavioral therapy techniques I’d learned."

Taking Control

Up to 80 percent of those treated for social phobia say they’ve gotten their anxiety under control, according to the Anxiety Disorders Association of America. Yet a recent study reveals that treatment delays of 10 years or more are common among adults with the condition. Some reasons people cited for not being in treatment: a fear of what others might think, a belief that the anxiety could be controlled without professional help, and uncertainty about where to go.

But despite such hesitations, medical experts and individual sufferers alike urge people to seek out help for this real and treatable condition. Turner: "The real me has been hidden for all these years. It’s like a big, dark curtain was around me all that time, and I’m just now poking my head out. I want people to know they don’t have to suffer. Life can be enjoyable."

As for Osmond, when his mind starts racing, he no longer thinks "what if I lose control?" Now, writes Osmond, he says to himself, "If I lose control, I know what to do."

Tamar Nordenberg is a staff writer for FDA Consumer.

For tips on what will help those with the anxiety disorder, contact one of the following organizations for more information, including the names of qualified therapists in your area.

Anxiety Disorders Association of America
11900 Parklawn Drive, Suite 100
Rockville, MD 20852
301-231-9350
www.adaa.org

American Psychiatric Association
1400 K St., N.W.
Washington, DC 20005
(202) 682-6000
www.psych.org/public_info/phobias.html

National Institute of Mental Health
Room 15C-05
5600 Fishers Lane
Rockville, MD 20857
1-888-826-9438
www.nimh.nih.gov/anxiety/
Something Fishy About This Site

Selecting fish for dinner can be a daunting process. There are so many possibilities. If you decide on, say, snapper, should you choose Gray, Lane, Pacific, Caribbean Red, Silk, or Yellowtail? What's the difference?

And how do you know that what the store calls snapper is really snapper? FDA's Center for Food Safety and Applied Nutrition has helped take some of the guesswork out of seafood shopping at www.cfsan.fda.gov/~frf/rfeO.html.

High-resolution photos and descriptions of 96 fish types, as well as photos of marketed forms such as fillets and steaks, are all part of the center's on-line Regulatory Fish Encyclopedia. Developed to help regulatory officials, seafood marketers, and consumers identify fraudulent fish substitutions and inferior products, the encyclopedia also serves nicely as a crash course in the family of fish.

Tracking Your Fruits and Veggies

Sure, you've heard that "5 a day" is the minimum number of fruits and vegetables you should eat to promote good health. But how do you keep track of all these foods and where they fit in your lifestyle? With the "5-a-day calculator." At saday.nci.nih.gov, you fill in the average number of fruits and vegetables you've eaten every day over the last six months, and you include the average number of minutes spent daily on exercise. Add in the answers to four more questions about diet and exercise and presto! Your own personal tracking chart shows where you are and where you should be regarding a healthy lifestyle. The site also has recipes and tips on how to eat more nutritious foods and boost physical activity. The National Cancer Institute and the national Centers for Disease Control and Prevention run the site.

Preventing the Worst Ears of Your Life

Thirty million Americans are exposed to dangerous levels of noise daily, and 10 million have already suffered irreversible hearing damage, according to the National Institute on Deafness and Other Communication Disorders (NIDCD). Much of this exposure and damage can be prevented, and you can find out how on the "Wise Ears!" Website at www.nih.gov/nidcd/health/wise/coalition.htm. Helpful pages include a fact sheet on how we hear and how hearing loss is caused by noise. You'll also find pages on "How Loud Is Too Loud," which matches noise levels with common sounds that can be harmful, and "Ten Ways to Recognize Hearing Loss." NIDCD operates the site in cooperation with the National Institute for Occupational Safety and Health.

What Are the Latest Drug Products?

With new drug treatments coming on the market all the time, it can be hard to keep up with just what the newest approved products are. By going to www.fda.gov/cder/approval/, you can get a heads up with an alphabetical listing of drugs FDA has approved over the last two years. The list gives the manufacturer, date of approval, and, in many cases, a description of how the drug is intended to be used. One note: Some of the newer approved products may not yet be available.
Pharmacy Chief Turns Medicine Thief

by Tamar Nordenberg

The former director of pharmacy at New York City’s renowned Columbia-Presbyterian Medical Center is serving out a year-and-a-day prison sentence for selling cancer medicines and other prescription drugs he had stolen from the hospital’s pharmacy.

Harry Morelli, 54, of Putnam Valley, N.Y., illegally sold prescription drugs to drug wholesalers from about 1985 to 1993, according to evidence gathered by the Food and Drug Administration’s Office of Criminal Investigations. Morelli admitted to at least 45 transactions, for which he got $3,000 to $4,000 each.

“It was not a crime of need but a crime of greed,” says Stewart Magee, special agent in charge of OCI’s New York field office, which investigated the case.

A former pharmacy school classmate of Morelli’s who had bought some stolen drugs from Morelli in the past and was himself under FDA investigation in 1997 told FDA special agents in March of that year about Morelli’s thefts. The former classmate-turned-informant said that, for at least seven years, Morelli had stolen expensive drugs from the hospital pharmacy to sell to drug wholesalers and kept 50 percent of the drugs’ wholesale value for himself.

An FDA-enforced law called the Prescription Drug Marketing Act prohibits the wholesale distribution of prescription drugs by unlicensed sellers. This measure of accountability is meant to prevent consumers from getting potentially mislabeled, subpotent, expired, counterfeit, or otherwise low-quality drugs.

With the informant’s help, OCI in June 1997 set up three undercover buys of Morelli’s stolen prescription drugs, including the antidepressant Prozac (fluoxetine hydrochloride), the fertility drug Fertinex (urofollitropin), and the cancer drugs Lupron (leuprolide acetate) and Taxol (paclitaxel).

Each time, Morelli agreed to send prescription drugs to the informant’s fictitious business, and the informant would in return pay Morelli about half of the drugs’ wholesale value. The informant gave Morelli the address of a Miami mailbox store where FDA had an undercover mailbox, and Morelli sent to that address boxes containing packages of cancer and AIDS drugs, as well as some antibiotics.

In a recorded telephone conversation with the informant, Morelli called the breast cancer drug Taxol the “hottest item around here.” He said he had stashed away 30 vials of it and placed an order for another shipment that wouldn’t be easily traced back to the pharmacy at the hospital, which is acclaimed for its cancer treatment. The wholesale value per vial of the Taxol was $500, according to the OCI case agent who investigated Morelli.

“He resold only very expensive items with a lot of value in a small package,” says the case agent. The estimated wholesale value of one shipment of 2,000 Prozac pills Morelli sent the informant, for another example, was over $4,800.

At least once, OCI found, Columbia-Presbyterian bought from a wholesaler drugs that Morelli had previously stolen from the hospital.

Faced with the government’s evidence of his illegal drug sales, Morelli pleaded guilty in April 1998 to the wholesale distribution of drugs without a license.

In sentencing Morelli in September 1998, District Judge Allen Schwartz of the U.S. District Court for the Southern District of New York in Manhattan said the pharmacist had abused his position of trust at the pharmacy and jeopardized the lives of cancer patients who took the resold drugs.

In addition to his prison sentence, the court ordered Morelli to pay a $30,000 criminal fine, $58,000 compensation to Columbia-Presbyterian Hospital, and about $9,000 reimbursement to FDA for the cash the agency laid out for the undercover buys. Morelli also gave up his license to practice pharmacy.

Tamar Nordenberg is a staff writer for FDA Consumer.
Ozone Generators Generate Prison Terms for Couple

by Paula Kurtzweil

“Show us the data,” FDA advised a Florida man and his wife who continued to market an unapproved medical device despite FDA warnings to stop. So, when they failed to heed FDA’s advice, a federal judge in Florida decided to show them the door—to prison.

Kenneth R. Thiefault and his wife, Mardel Barber, formerly of Jupiter, Fla., were sentenced in the U.S. District Court for the Southern District of Florida in March to prison terms that together total more than eight years and fines that add up to more than $100,000. They illegally distributed ozone generators, devices that turn oxygen into ozone, by claiming that the devices could cure a variety of diseases, including cancer and AIDS. FDA has never approved ozone generators or ozone gas for treating any medical conditions.

They continued to sell the unapproved medical devices, even after FDA informed them several times that FDA approval was necessary to market medical devices or medical gas in this country. This would require the submission of scientific data to support the devices’ safety and effectiveness.

Proponents of medical ozone generators believe ozone can kill viruses and bacteria in the body. While ozone is used as a germicide in the cleaning of manufacturing equipment, FDA is not aware of any scientific data that supports the safety or effectiveness of ozone generators for treating medical conditions. In fact, the agency believes that at the levels needed to work effectively as a germicide, ozone could be detrimental to human health.

“These devices keep popping up,” says Bob Gatling, a biomedical engineer and director of the program operations staff in FDA’s Center for Devices and Radiological Health. “We always tell their makers”: ‘Show us some data,’ but no one ever pursues it.”

FDA’s knowledge of Thiefault’s involvement in ozone generators dates to at least 1990, when Thiefault was interviewed during an FDA criminal investigation of one of Thiefault’s associates. This associate was later prosecuted and imprisoned for, among other things, manufacturing and selling ozone generators for treating medical conditions. After release from prison, he returned to making and distributing ozone generators for treating medical conditions but fled the country before he could be prosecuted again.

In April 1990 and January 1991, Thiefault acknowledged in an FDA-obtained written affidavit that medical ozone generators needed to be approved by FDA before they could be marketed. He also wrote that his interest in ozone generators was limited to ozone’s “antiviral and antibacterial capabilities in relationship to water for dairy cows, swimming pools and spas.”

Thiefault’s activities came to FDA’s attention again, in January 1993, when officials with Florida’s Comptroller’s Office shared evidence they obtained.
during a state securities fraud investigation of Thiefault with FDA’s Office of Criminal Investigations. State investigators found that one room in Thiefault’s former Lake Park, Fla., home served as a medical treatment center, housing a variety of devices, including a frequency generator on which various frequencies were labeled with the names of diseases. At the high end of the frequencies was “AIDS,” followed in descending order by “cancer,” “syphilis” and “constipation.” This evidence suggested that the business Thiefault operated out of his home, Kanzyme Laboratories, was an unlicensed medical practice.

In early 1993, OCI special agents began to collect evidence, and in July, OCI executed a search warrant at Thiefault’s Lake Park home, seizing various records and documents and the generators themselves.

With these pieces of evidence, OCI agents learned that:

• Since 1988, Thiefault had been buying components and making ozone generators, selling them for about $4,800 each to customers across the country.
• Each ozone generator, contained in a silver metal case, included a medical-grade humidifier and a medical-grade oxygen cylinder with a label that said the cylinder had been converted from medical to industrial grade. The cylinder was fixed into place with Velcro straps and had on the outside of it tubing that could be used to attach urinary catheters.
• Thiefault presented himself as a scientist and clinical researcher in a promotional videotape. He is not a doctor and lacks a scientific background.
• Thiefault did not have any bank, credit or charge accounts. Instead he funneled proceeds from the ozone generators—estimated to be $1 million—through his wife and other individuals’ financial accounts.
• Thiefault and his wife touted ozone as a treatment for many diseases, ranging from AIDS and cancer to herpes, hepatitis and gangrene. In the videotape, Thiefault says, “Ozone will cure almost any disease.”
• Product literature recommended several ways to administer the ozone: by catheter into the rectum, vagina or ear; by breathing in through the nose or mouth; or by absorption through the skin, accomplished by standing naked in a body bag into which ozone is blown.

In addition, OCI special agents learned that since 1988, Thiefault also had been selling illegal drug products called K Z Enzyme, Kanzyme, and Kanzyme II. These products have never been approved by FDA for treating any diseases.

As he did with the ozone generators, Thiefault touted K Z Enzyme and Kanzyme as cures for many diseases. According to promotional literature and Thiefault, the products were plant extracts. FDA laboratory analysis showed that each product contained about 10 percent dissolved substances, such as sugars, amino acids, acetic acid, chloride, phosphate, sulfate, and nitrate. The rest was a combination of water and alcohol.

Kanzyme II was colloidal silver, also an unapproved drug (see page 5 of this issue). Thiefault promoted and sold it as an accompaniment to ozone therapy for treating cancer. Product literature claimed the product replaced the body’s store of silver, a substance lacking in cancer patients. However, FDA is not aware of any scientific studies that support this claim.

OCI’s investigation, complemented by a multi-year IRS investigation, led in 1998 to a seven-count indictment against Thiefault and Barber. FDA-related charges focused on the couple’s involvement with ozone generators and not the unapproved drugs because the devices appeared to be their main business thrust—and source of income, according to OCI.

Following a two-week trial, in November 1998, a federal jury found Thiefault and Barber guilty of mail fraud, wire fraud, and distribution of an ozone generator. They also were found guilty on one count of impeding the IRS.

For illegally selling ozone generators, Thiefault was sentenced to six and a half years in prison, fined $100,000, and ordered to pay $14,400 in restitution. His wife was sentenced to two years and nine months in prison and fined $60,000.

Thiefault and Barber also were ordered to help the IRS compute their back taxes and pay the money due. The judge also banned both from dealing in securities, telemarketing, direct mailings, and nationwide advertising.

Thiefault is now in federal prison in Minnesota. His wife is in federal prison in California. Following their prison terms, they also will serve three years of supervised release.

Paula Kurtzweil is a member of FDA’s public affairs staff.
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 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 the Office of the Chief Counsel, Food and Drug Administration.

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SEIZURE ACTIONS

Food/Contamination, Spoilage, Insanitary Handling

PRODUCT: Peeled shrimp, frozen, 124 cases more or less, at Tampa, Fla. (M.D. Fla.); Civil Action No. 95-12-CIV-T-21(E).
CHARGED 1-5-95: While held for sale, after shipment in interstate commerce, at Americold Cold Storage, Inc., stored to the account of Crystal Cove Seafood Corp., the articles of food were adulterated in that they consisted in whole or in part of a decomposed substance by reason of the presence therein of decomposed shrimp—402(a)(3).
DISPOSITION: Pursuant to a default judgment, the articles were destroyed. (F.D.C. No. 67037; S. No. 94-681-943; S.J. No. 1)

PRODUCT: Peeled shrimp, quick frozen, 86 cases more or less, at Tampa, Fla. (M.D. Fla.); Civil Action No. 95-129-CIV-T-23(B).
CHARGED 1-30-95: While held for sale, after shipment in interstate commerce, at Seaboard Cold Storage, Inc., stored to the account of Crystal Cove Seafood Corp., the articles of food were adulterated in that they consisted in whole or in part of a decomposed substance by reason of the presence therein of decomposed shrimp—402(a)(3).
DISPOSITION: Pursuant to a default judgment, the articles were destroyed. (F.D.C. No. 67053; S. Nos. 94-681-944/945; S.J. No. 2)

PRODUCT: Shrimp, frozen, 695 cases, at Los Angeles, Calif. (C.D. Calif.); Civil Action No. 95-129-CIV-T-25(B).
CHARGED 10-30-97: While held for sale, after shipment in interstate commerce, at Los Angeles Cold Storage, in Los Angeles, Calif., the article of food was adulterated in that it consisted in part of a decomposed shrimp substance by reason of the presence therein of decomposed shrimp—402(a)(3).
DISPOSITION: The government filed and was granted a motion for summary judgment that sought the condemnation, forfeiture and destruction of the shrimp. This was appealed to the Ninth Circuit but was subsequently dropped. The article of food was destroyed. (F.D.C. No. 67209; S. No. 97-768-223; S.J. No. 3)

Medical Devices

PRODUCT: Dry Heat Sterilizers, 29 cases, at Mecklenberg County, N.C. (W.D. N.C.); Civil Action No. 3:95CV1-H.
CHARGED 1-9-95: This was a seizure of dry heat sterilizers and steam sterilizer autoclaves. The devices, located at D.A. Kadan Co., in Mecklenberg County, N.C., were adulterated in that they had been classified under 21 U.S.C. Section 360(f) as class III devices, and there were no approved premarket approval applications in effect pursuant to 21 U.S.C. Section 360(j)(g)—501(f)(1)(B).
DISPOSITION: The articles were destroyed. (F.D.C. No. 66911; S. No. 93-700-673; S.J. No. 4)

DEFENDANT: TPLC, Inc., doing business as Telectronics Pacing Systems ("Telectronics"), a corporation, and James W. Dennis, an individual, at Miami Lakes, Fla. (S.D. Fla.); Civil Action No. 95-1075.
CHARGED 5-19-95: While held for sale, after shipment of one or more of their components in interstate commerce, at Telectronics, in Miami Lakes, Fla., and Englewood, Colo., the articles of device, implantable cardiac pacemakers and pacemaker leads, were adulterated in that the methods, facilities or controls used to manufacture, process, pack, label, and hold such devices did not conform to and were not operated and administered in conformity with current good manufacturing practice regulations—501(h).
DISPOSITION: Pursuant to a consent decree of permanent injunction, Telectronics shut down its operation until the Food and Drug Administration found that they were in compliance with the Food, Drug, and Cosmetic Act. The company has since sold its pacemaker operations to St. Jude. (F.D.C. No. 67050; S. No. Doc. 95-711-341; S.J. No. 5)

Drugs/Human Use

PRODUCT: Anthocaine Injection 2%, 8000 mL vials, at Arcadia, El Monte, and Irwindale, Calif. (C.D. Calif.); Civil Action No. 95-0810.
CHARGED 2-8-95: While held for sale, after shipment of one or more of their components in interstate commerce, at An-
PRODUCT: Jogging PRODUCT: An Article of Drug, 480 cases, more or less, each case containing 6/64 bottles, labeled in part: Jogging PRODUCT: Immune Serum Globulin for IV Use, A/D...

PRODUCT: Immune Serum Globulin for IV Use, A/D...

PRODUCT: L’Aprina (Topical Aspirin), 20 unlabeled cases, at Chantilly, Va. (E.D. Va.); Civil Action No. 98-1453-A.

CHARGED 2-26-99: While held for sale, after shipment of one or more of its components in interstate commerce, at Radix Group International (doing business as AEI Customs Brokerage Services), in Miami, Fla., the article of drug was misbranded in that its labeling failed to bear adequate directions for use for—502(f)(1).

DISPOSITION: Final default judgment of forfeiture was granted and the article was destroyed. (F.D.C. No. 67260; S. No. DOC 27719/27722; S.J. No. 8)

PRODUCT: Oxygen, at Wichita, Kan. (D. Kan.); Civil Action No. 98-1292-MLB.

CHARGED 8-17-98: While held for sale, after shipment of one or more of their components in interstate commerce, at Brown Welding Supply, in Wichita, Kan., the articles of drug were adulterated in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice to ensure that such drugs met the safety requirements of the Food, Drug, and Cosmetic Act and had the identity and strength, and met the quality and purity characteristics, which they purported and were represented to possess—501(a)(2)(B). The articles, Nitrous Oxide USP and Medical Air USP, were misbranded in that their labels failed to bear an accurate statement of the quantity of the contents—502(b)(2).

DISPOSITION: The articles were reconditioned. (F.D.C. No. 67236; S. No. 98-688-713; S.J. No. 10)

INJUNCTION ACTIONS

DEFENDANT: Ackrad Laboratories, Inc., a corporation, and Bernard Ackerman, an individual, at Cranford, N.J. (D. N.J.); Civil No. 95-CV-6149.

CHARGED 12-4-95: While held for sale, after shipment in interstate commerce, at Ackrad Laboratories, Inc., in Cranford, N.J., the articles of device (catheter irrijet syringes) were adulterated in that the methods used in and the facilities or controls used for their manufacture, packing, storage, or installation were not in conformity with current good manufacturing practice regulations—501(h).

DISPOSITION: A consent decree of permanent injunction was entered Dec. 6, 1995. The firm came into initial compliance as specified in the decree in 1996. The consent decree is still in place and the district office continues to monitor the firm’s compliance. (Inj. 1349; S. No. 94-675-214; S.J. No. 11)

DEFENDANT: K & K Merchandising Group, Inc., and Stuart J. Kerzner, at New York, N.Y. (S.D. N.Y.); Civil No. 97Civ0461.

CHARGED 1-22-97: This case was a civil action for injunctive relief and monetary penalties brought by the United States...
of America, against defendants K & K Merchandising Group, Inc. (K & K), and its principal officer, Stuart J. Kerzner, as a result of defendants’ repeated violations of the Radiation Control for Health and Safety Act, 21 U.S.C. Section 360hh et seq. (incorporated into the Food, Drug, and Cosmetic Act), and the regulations promulgated thereunder. The defendants imported into the United States and introduced into commerce two shipments of a total of 38 television receivers (Sony models 220-240v KPR-S53MN1/2 and 220-240V KPR-S46MN1/2), which did not comply with all applicable performance standards in that they did not bear a certificate of compliance as required by 21 U.S.C. Section 360kk(a)(1), 21 C.F.R. Section 1010.2(b) (1996), and 21 C.F.R. Section 1005.3 (1996)—538(a)(1). The defendants refused to permit Food and Drug Administration ("FDA") inspectors to have access to K & K’s premises, or to inspect K & K—538(a)(3). The defendants delivered television receivers to distributors or dealers without certifying that they conformed to all applicable performance standards, as required by 21 U.S.C. Section 360kk(h) and 21 C.F.R. Section 1010.2 (1994)—538(a)(5). Lastly, the defendants failed to submit reports required pursuant to 21 U.S.C. Section 360(n)(b)—538(a)(4).

DISPOSITION: A default judgment against K & K was entered Oct. 21, 1997, enjoining it from: (a) importing into the United States any electronic products that do not comply with all applicable performance standards or that lack certification to that effect; (b) failing or refusing to permit FDA to inspect records that the defendants are required to establish and maintain, or make available such records for FDA inspection in accordance with 21 U.S.C. Section 360mm; (c) failing or refusing to file reports required by 21 U.S.C. Section 360nn(b) and 21 C.F.R. Sections 1002.10, 1002.11 and 1002.13; and (d) failing to furnish to the distributor or dealer at the time of delivery of electronic products, a certificate that the products conform to all applicable performance standards, in accordance with 21 U.S.C. Section 360kk(h). (Inj. 1338; S. No. 94-644-622; S.J. No. 12)


CHARGED 4-7-95: While held for sale, after shipment of one or more of their components in interstate commerce, at Mira, Inc., in Waltham, Mass., articles of an ophthalmic device were adulterated in that the methods used in and the facilities and controls used for the manufacture, packing and storage of the Cryo probe and the Imex implant did not conform to and were not in conformity with good manufacturing practice regulations—501(h).

DISPOSITION: All articles of device in possession or control of the defendants, except those devices that were brought into compliance, were destroyed at the defendants’ expense. (Inj. 1373; S. No. 94-658-653; S.J. No. 13)

DEFENDANT: Producer’s Peanut Co., Inc., a corporation, and James R. Pond Sr., an individual, at Suffolk, Va. (E.D. Va.); Civil No. 2:95CV256.

CHARGED 3-15-95: On March 21, 1995, a consent decree of permanent injunction was entered against the defendant. This statutory injunction was brought to enjoin the defendants from the manufacturing, processing, packing, labeling, storing, and holding for sale of peanut butter, a food within the meaning of 21 U.S.C. Section 321(f), after one or more of its components had been shipped in interstate commerce, and from introducing and delivering for introduction into interstate commerce such peanut butter. This peanut butter manufacturer had a long history of violation involving sanitation. Past inspections revealed gross insanitary conditions, including insects in peanuts being processed into peanut butter, insects in and around peanut butter processing equipment, accumulations of product residue and static material on processing equipment, and ineffective cleaning and sanitation procedures. While held for sale after shipment of one or more of its components in interstate commerce at Producer’s Peanut Company, Inc., in Suffolk, Va., all articles of food were adulterated in that they were prepared, packed and held under insanitary conditions whereby they might have become contaminated with filth—402(a)(4).

In 1998, after an inspection had revealed relatively few inspecational observations, defense counsel sought to have the injunction lifted.

DISPOSITION: The Food and Drug Administration conducted another inspection, decided that the company was sufficiently in compliance, and a motion to vacate the permanent injunction was granted on March 5, 1999. (Inj. 1376; S. No. 94-703-691; S.J. No. 14)

DEFENDANT: Henry H. Vechery, an individual, doing business as May’s Seafood, and Joyce A. Krantz, an individual, at New Orleans, La. (E.D. La.); Civil Action No. 97-3873.

CHARGED 12-16-97: While held for sale after shipment in interstate commerce at May’s Seafood, in New Orleans, La., the article of food (crab meat) was adulterated in that the crab meat had been prepared, packed or held under insanitary conditions whereby it might have become contaminated with filth—402(a)(4).

DISPOSITION: A consent decree of permanent injunction was entered April 21, 1998, and under that decree, the defendants were enjoined from processing crab. The consent decree allowed the firm to continue to operate as a live crab receiving dock. (Inj. No. 1417; S. No. 96-763-647; S.J. No. 15)
Every day, 3000 new kids will become regular smokers. One out of every three will die from it.

Will it be him?

Will it be her?

Will it be yours?

Selling cigarettes or chewing tobacco to children is illegal. For a reason.

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