MEDWATCH
ON LOOKOUT FOR
MEDICAL PRODUCT
PROBLEMS
Dietary Supplements: Making Sure Hype Doesn’t Overwhelm Science
Most vitamin and mineral supplements pose no safety concerns. But the risks of many other dietary supplements, such as herbs, animal gland extracts, and amino acids, are a mystery—which FDA is trying to solve.

MEDWatch on Lookout for Medical Product Problems
FDA replaced five forms with one, simplifying reporting about adverse reactions and other problems with products it regulates. Products causing problems will come off the market faster under MEDWatch—and that means increased safety for consumers.

Radiation Continuing Concern with Fluoroscopy
The technology that was used to x-ray children’s feet in shoe stores until its potential harm became known has made a comeback in modern medicine. FDA and professional organizations are working to minimize its risks.

Choosing a Treatment for Uterine Fibroids
Twenty percent of American women under 50 have noncancerous growths in their wombs, commonly known as fibroids. They are the reason for about one-third of all hysterectomies in this country. But now doctors—and women—are examining other treatments.

Surprising Sources for New Foods
New foods are coming from some surprising sources, such as cottonseed and a plant whose oil was once used to lubricate steam engines. To harvest these products, pioneering researchers have had to tackle some tough problems.

On the Teen Scene: Cosmetics and Reality
Ads promise romance! popularity! beauty! if you use their blushers, lipsticks, creams, shampoos, and other cosmetics. What do these products really deliver?
First Alzheimer’s Drug Approved

The first drug specifically for treating symptoms of Alzheimer’s disease was approved by FDA last Sept. 9. The drug is Cognex (tacrine hydrochloride).

Alzheimer’s disease, which affects an estimated 4 million Americans, causes progressive loss of memory, judgment, and ability to reason.

In two controlled trials, Cognex provided a small but clinically meaningful benefit for some patients with mild to moderate Alzheimer’s disease. The trials showed that the drug is superior to a placebo, based on results of tests designed to assess memory and reasoning ability, and on an overall assessment of function by a trained clinician.

Cognex can cause mild liver toxicity that is reversible if treatment is withdrawn promptly. The drug’s labeling recommends an escalating dosing regimen with frequent blood tests to identify patients sensitive to the drug. Patients who have mild liver toxicity can often continue taking a lower dose, or stop and then resume therapy at a lower dose. Other side effects include nausea, vomiting, diarrhea, and rash.

Since February 1992, a treatment IND has allowed more than 7,400 patients to receive the drug while the controlled clinical studies were being completed.

An advisory panel recommended approval in March 1993. Cognex is manufactured by Warner-Lambert Co. of Morris Plains, N.J.

(For more information, see “Despite New Clues, Alzheimer’s Mystery Remains Unsolved” in the March 1992 FDA Consumer.)

Manufacturers Must Track Some Medical Devices

Life-supporting and permanently implantable medical devices must now be tracked from manufacture through distribution to the user, according to an FDA final rule published in the Aug. 16, 1993, Federal Register.

The rule, mandated by the Safe Medical Devices Act of 1990, requires manufacturers of 17 implants and five devices to keep a record of patients who receive products such as heart valves or breathing monitors so that they can be contacted if problems develop that could threaten patient health or life.

“Tracking [these products] will help save lives by making it possible to get in touch quickly with people who have faulty devices,” said FDA Commissioner David A. Kessler, M.D.

As of Aug. 29, manufacturers must track the products so that, if necessary, they can provide FDA with names of patients and locations of devices within 10 working days. The tracking system will have to be maintained for the useful life of the device, with the data and function of the system audited periodically.

No specific method of tracking is required as long as the manufacturer’s chosen method adequately ensures collection of information from patients or health-care facilities.

Medical products covered by the rule include: vascular graft implants, ventricular bypass devices, implantable pacemaker pulse generators, cardiovascular permanent pacemaker electrodes, annuloplasty rings, replacement heart valves, automatic implantable cardioverter-defibrillators, tracheal implants, implantable cerebellar stimulators, implantable diaphragmatic- phrenic nerve stimulators, implantable infusion pumps, breathing frequency monitors, continuous ventilators, DC-defibrillators and paddles, silicone inflatable breast implants, silicone gel-filled breast implants, silicone gel-filled testicular implants, silicone gel-filled chin implants, silicone gel-filled angel chik reflux valves, electromechanical infusion pumps, jaw implants, and inflatable penile implants.

Other devices will be subject to tracking in the future, as necessary to protect public health.
Epilepsy Drug Approved

The first new epilepsy drug treatment in more than 10 years received FDA approval July 29.

Felbatol (felbamate) can control certain epileptic seizures in adults and a rare form of epilepsy in children.

"[Felbatol] provides a new weapon against the debilitating effects of epilepsy," says FDA Commissioner David A. Kessler, M.D. "For those struggling to live with uncontrolled epilepsy, it offers the prospect of a more normal life."

A disorder marked by sometimes violent seizures, epilepsy affects about 2 million people in the United States. Many seizures cannot be controlled with existing drugs.

Felbatol decreases the frequency of partial seizures that start in a localized part of the brain, including those that progress into more generalized grand-mal seizures. For adults, Felbatol appears to be effective alone or combined with other anti-epileptic drugs.

Trials also showed the treatment to be safe and effective when used with other drugs in children 2 years and older with Lennox-Gastaut syndrome. This disorder affects about 50,000 children in the United States and is characterized by multiple types of seizures, mental retardation, and resistance to existing drugs.

Side effects with Felbatol include abdominal pain, dizziness, and vomiting. To help decrease side effects, doctors can adjust dosages of other anti-epileptic drugs used with Felbatol, as instructed in product labeling.

Clinical development of felbamate began in 1982 as part of the anti-convulsant program at the National Institutes of Health. An FDA advisory committee unanimously recommended the drug's approval in December 1992.

Wallace Laboratories, Cranbury, N.J., makes Felbatol.

Refrigerate Fresh Garlic Mixes

Homemade and commercially prepared chopped garlic-in-oil, garlic-in-butter, and garlic-in-margarine mixes should be kept refrigerated, warns FDA. Left at room temperature, the mixes may cause potentially fatal botulism food poisoning.

Botulism symptoms include blurred or double vision, speech and breathing difficulty, and progressive paralysis.

FDA knows of no recent illness associated with the mixes, but is concerned that consumers or people who prepare food in hospitals and nursing homes may be unaware of the products' potential hazard. FDA issued a similar warning in March 1989, when three persons were hospitalized in New York with botulism poisoning after eating a commercially prepared garlic-in-oil mix that had been stored at room temperature despite a "Keep Refrigerated" statement on the label.

FDA requires commercial mixes to contain specific levels of additives that inhibit microbial growth, usually acidifying agents such as phosphoric or citric acid. As a double protection, such mixes must be labeled with a warning to store them in the refrigerator. Manufacturers may not rely solely upon refrigeration for safety.

Since the protective additives used in commercial mixes are not generally available for homemade mixes, FDA discourages consumers from preparing spice-in-oil, spice-in-margarine, or spice-in-butter recipes for extended storage. Consumers should refrigerate all such products and immediately discard any product suspected of being spoiled or stored unrefrigerated.

Clostridium botulinum bacteria are widespread in the environment and may be found on various kinds of produce, including garlic, but their spores are harmless in an oxygen environment. However, in an oxygen-free, low-acid environment, the spores can proliferate and produce a toxin. FDA studies have shown that garlic-in-oil mixtures can support Clostridium bacterial growth and toxin production even when very few spores are present.
**Defibrillator Device Changes Need for Open-Chest Surgery**

A medical device approved by FDA Aug. 26 eliminates the need for open-chest surgery when a defibrillator is implanted. The device is called the Endotak Lead System, and is manufactured by Cardiac Pacemakers Inc., of St. Paul, Minn. It is approved for use with the firm’s automatic cardioverter defibrillator pulse generator, with which it was tested in clinical trials.

An implanted defibrillator monitors heart rate and, if it detects an extreme irregularity such as heart fibrillation (quivering) or a heart attack in progress, it delivers a strong electrical shock directly to the heart. Until now, defibrillator implantation required open-chest surgery to attach the lead wires that deliver the shock onto the heart muscle. The new device consists of a lead system that can be threaded to the heart through a vein under the collarbone. This technology is already used for pacemakers.

The Endotak system is approved for use in people at high risk of sudden death because they have chronic, recurring or prolonged abnormal heart rhythm, usually as a result of coronary artery or heart muscle disease. Many of these people may already have had a heart attack brought on by an abnormal heartbeat.

FDA based its approval on results of the manufacturer’s two-year clinical study of the Endotak Lead System implanted in 400 patients at high risk of heart attack. In the study, 1,815 shocks were delivered in 1,369 instances of rapid heart rhythm or heart attack. In more than 90 percent of the episodes, a single shock corrected the problem.

FDA is requiring the firm to keep track of all patients implanted with the lead system and check for unexpected problems.

**Warner-Lambert Brings Facilities into Compliance**

Warner-Lambert Company is bringing its drug testing practices and facilities into compliance with current good manufacturing practice regulations (GMPs) under a consent decree between FDA and the company announced last August. In the decree, a U.S. District Court judge in New Jersey entered a permanent injunction against the company and its officials.

Since December 1992, 14 Warner-Lambert drugs have been recalled for failure to comply with GMPs and product quality standards. None of the recalled products posed a critical health risk.

Warner-Lambert has agreed that:
- Independent experts will certify laboratory and facility compliance with GMPs.
- Laboratory personnel will be trained to be fully qualified to perform their assigned duties.
- Outside experts will certify that manufacturing processes comply with GMPs.
- Expert certification or compliance plans to correct deficiencies will be approved by FDA for medically necessary products not otherwise available.

FDA will ensure compliance by continuing to inspect Warner-Lambert’s six plants and examine records on manufacturing and testing methods. According to the decree, FDA may require Warner-Lambert to recall any product not meeting standards or to stop manufacturing and distributing any product not complying with GMPs or not conforming with its approved application.

Warner-Lambert must pay any damages resulting from violations of the injunction and the agency’s costs associated with this continuing oversight.

**New Warnings Required For OTC Antacids, Laxatives**

The labeling for nonprescription antacids, laxatives, and antidiarrheals will have to carry new or expanded warnings about possible interactions with other drugs, according to FDA final rules published in the Aug. 26, 1993, Federal Register. In that same Federal Register, FDA proposed new warning statements for sleep aids and antiemetics (drugs that treat nausea and vomiting).

Labels on antacids that contain aluminum currently warn that the products should not be used when a person is taking...
the oral form of the prescription antibiotic tetracycline. The new labeling, required by Feb. 28, 1994, will advise consumers that if they are taking any prescription drug they should consult a health-care professional before taking these antacids.

Laxative and antidiarrheal products containing water-soluble gums or bulking agents have the potential for swelling and blocking the throat or esophagus if they are taken without adequate fluid. Between 1970 and 1992 there were at least 199 cases of esophageal obstruction and eight cases of asphyxiation associated with these products or OTC weight-control products containing these ingredients. There were 18 deaths. In March 1992, FDA banned from the market virtually all weight-control products containing water-soluble gums. Beginning Aug. 26, 1994, remaining products will be required to carry a warning statement about the possible danger.

The proposed warning for sleep aids and antiemetics states: "Do not take this product, unless directed by a doctor, if you have breathing problems such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland." However, the current label warning against the use of these products by asthma patients would be deleted, at the recommendation of an FDA advisory committee.

FDA Commissioner David A. Kessler, M.D., advised consumers to read label directions and warnings on all OTC medications:

"Although these drugs are available without prescription, many of them carry the potential for interaction with other over-the-counter or prescription drugs, overdose, or adverse effects on people with certain existing medical conditions. The new label requirements and proposals are designed to provide consumers with added information they need to use these products safely."

Supplemental Test Licensed For Hepatitis C

A test that augments existing hepatitis C screening methods by helping to verify positive readings is now available. FDA licensed the test last June 22.

Current screening techniques have cut the risk of acquiring the hepatitis C virus from the blood supply to less than 1 in 3,300. But these blood screens can sometimes yield a "false positive" reaction—a test result that may not reflect a true infection.

The new test, called the RIBA HCV 2.0 Strip Immunoblot Assay, helps verify such readings by giving additional information based on production of antibodies to the virus. Several population groups have participated in clinical trials of the test. Among them are healthy donors, hemophiliacs, intravenous drug abusers, kidney dialysis patients, hepatitis C patients, and patients whose specimens repeatedly tested positive.

There are 170,000 new cases of hepatitis C in the United States each year, according to a 1991 estimate by the national Centers for Disease Control and Prevention. In half these cases, origins are unknown. But CDC attributes 25 percent to intravenous drug abuse and 18 percent to sexual and household contact. Fewer than 5 percent of cases can be linked to blood transfusions.

Chiron Corporation, Emeryville, Calif., manufactures the new test, and Ortho Diagnostic Systems, Inc., Raritan, N.J., will distribute it.

Claims for OTC Antifungals, Hemorrhoid Drugs Unproven

Effectiveness claims for over-the-counter scalp and nail antifungals and the use of a yeast ingredient in OTC hemorrhoidal drugs are prohibited by final rules FDA published in the Sept. 2, 1993, Federal Register. A proposed rule published at the same time declares docusate salts to be safe and effective for OTC laxatives.

A final rule, effective March 2, 1994, prohibits claims that OTC topical antifungals effectively treat fungal infections of the scalp and fingernails. From a review of
submitted clinical data, FDA determined there is not adequate information to prove effectiveness. Products include Fungi-nail, Pro Clearz, and Lee's Anti-fungal Nail Treatment.

Another final rule prohibits use of live yeast cell derivative (LYCD) in OTC hemorrhoidal products until it is proved effective. FDA concluded the two submitted studies did not adequately support claims that LYCD effectively treats hemorrhoidal symptoms such as pain, itching, burning or irritation, and swollen tissue caused by inflammation.

Manufacturers must remove anti-hemorrhoidal claims specifically attributed to LYCD, and companies marketing LYCD must reformulate their products using proven ingredients. Products affected include Preparation H, Formulation R, and Prompt Relief. The rule will take effect Sept. 2, 1994.

FDA also published a proposed rule to declare docusate salts a safe and effective active ingredient in OTC laxatives. Docusate salts include docusate sodium, docusate calcium, and docusate potassium.

In 1975, an FDA advisory panel recommended that docusate salts be recognized as safe and effective, but in 1985, concern was raised that docusate sodium might cause birth defects. As a result, the final decision was deferred.

After reexamining the data and considering new information, FDA concluded that docusate salts are safe and effective as OTC laxatives. Among the more than 50 marketed products containing docusate salts are Colace, Correctol, Dialose, Doxidan, Doxinate, and Feen-a-mint.

Three Sentenced for ‘Fountain of Youth’ Scheme

A man, his sister, and her husband were recently sentenced to prison for conspiracy and other felonies involved in operating an international black market in unapproved "Fountain of Youth" drugs.

Judge Earl B. Gilliam sentenced David Halpern, his sister, Frances H. Wellgood, and brother-in-law, Edward Sollisch, in the U.S. District Court for the District of San Diego last April 6 for smuggling 15 tons of unapproved drugs into the United States. Halpern, who masterminded the scheme, was sentenced to two years in prison and three years supervised release. Wellgood and Sollisch were each sentenced to eight months in prison and three years supervised release. Each was ordered to pay a special assessment of $150, and Sollisch was fined an additional $2,000.

Using sham companies and mail drops registered in fictitious names, the conspirators had been illegally importing "Fountain of Youth" drugs from Germany and England since at least 1983. They sold millions of dollars worth of drugs to thousands of customers in 43 states, Canada, Guam, and the Virgin Islands. The drugs were promoted as a cure for ills ranging from depression to diabetes, and rheumatoid arthritis to radiation damage, as well as treatment for various physical and psychological problems related to the aging process.

The three basic types of drugs in the scheme included cell therapies, procaine hydrochloride derivatives, and sexual tonics. (See “Family Indicted for Fountain of Youth Fraud” in the July–August 1992 FDA Consumer.)

Two Free Pubs Available

A backgrounder on FDA’s new practice of charging pharmaceutical manufacturers user fees and a safety brochure on ground meat and poultry are newly available free from the agency.

“User Fees” describes the user fee structure and waivers provided by the Prescription Drug User Fee Act of 1992 and ex-
 plains how FDA plans to use the money collected to shorten review time of certain new drug and biologic applications.

“A Consumer Guide to Safe Handling and Preparation of Ground Meat and Ground Poultry” (FDA 93-2269) discusses how to properly handle, store, clean, and cook ground meat and poultry, including cold storage times and internal temperatures for safe cooking.

To order single copies of the backgrounder or brochure, write to FDA, HFE-88, 5600 Fishers Lane, Rockville, MD 20857. To order two to 100 copies of the brochure, write to FDA, HFI-40, at the same address, or fax your order to (301) 443-9057. Please order the backgrounder by title and be sure to give the brochure’s publication number.

**Correction**

“Sunscreen Labeling to Warn Against Danger from the Sun,” in the Updates section of the September 1993 *FDA Consumer*, incorrectly states that proposed labeling requirements for sunscreen and suntan products appear in the May 2, 1993, *Federal Register*. The correct publication date is May 12, 1993.

---

**Consumer Forum**

**Prune Sketch**

We are writing on behalf of our client Sunsweet Growers Inc. of Yuba City, California, to express concern about the use of a sketch of our client’s product in the *FDA Consumer* magazine of May 1993 . . . at page 16 [“Starting This Month; Look for ‘Legit’ Health Claims on Foods”].

The sketch is obviously a copy of our client’s packaging and its Sunsweet and sunburst design trademark. The FDA did not request permission to use the copy. Had it done so, our client would have refused.

Our concern in this matter is that you have created and used an imperfect copy of our client’s product and that, if you wish to depict our client’s marks and packaging in the future, you first seek its consent. We also ask that you publish a notice acknowledging that the packaging depicted in your article is an imperfect copy of the packaging of Sunsweet Growers Inc. and may not be republished.

John K. Uilkema
Limbach & Limbach

Ed. replies: The drawings of typical foods allowed to bear health claims were intended to be generic. It was not apparent to us at the time that the prunes sketch too closely resembled Sunsweet’s packaging. We apologize for any problems this may have caused Sunsweet. The sketch, which is an imperfect copy of the packaging of Sunsweet Growers, Inc., may not be republished. We have replaced it in reprints.

**AccuMeter Info Corrected**

In the Updates section of the June 1993 issue of *FDA Consumer*, incorrect information was reported on the AccuMeter, the first over-the-counter cholesterol measuring device to receive FDA clearance. Cholesterol results are not obtained by comparing the color of the measurement strip to a color guide. Instead, the test is actually read much like a thermometer . . .

The test result is obtained by reading the height of the peak, not its color, and comparing it to a result chart that converts height to cholesterol concentration . . .

Alison C. Pal
Clinical & Regulatory Affairs
ChemTrak, manufacturer of Cholestrac & AccuMeter
Sunnyvale, Calif.

*FDA Consumer* welcomes comments from readers. Send letters to: Editor, *FDA Consumer*, HFI-40, 5600 Fishers Lane, Rockville, MD 20857.
Dietary Supplements
When it comes to dietary supplements, consumers have the right to expect safety and to have information about products they choose so they know what they're getting, according to the Food and Drug Administration.

"Without the proper safety data," however, says Michael Taylor, FDA deputy commissioner for policy, "the agency has no way to ensure that many consumers taking supplements won't be at risk."

FDA is responsible under the Federal Food, Drug, and Cosmetic (FD&C) Act for ensuring that manufacturers of foods, including dietary supplements, provide safe ingredients for their products as well as accurate, complete labeling that is truthful and not misleading.

**Defining a Dietary Supplement**

The Nutrition Labeling and Education Act of 1990 (NLEA), which amended the FD&C Act, refers to dietary supplements of "vitamins, minerals, herbs, or other similar nutritional substances."

As commonly consumed, dietary supplements in the marketplace—in the form of capsules, tablets, liquids, or powders—include vitamins; essential minerals; protein; amino acids; botanicals such as ginseng and yohimbe; extracts from animal glands; garlic extract; fish oils; fibers such as acacia and guar gum; compounds not generally recognized as foods or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-aminobenzoic acid, and rutin; and mixtures of these ingredients.

The Council for Responsible Nutrition, a trade organization for supplement manufacturers, reports that in 1991 some 40 percent of American adults took vitamin supplements, and retail sales for over-the-counter nutritional products totaled several billion dollars.

Most vitamin and mineral supplements usually pose no safety concerns for the general population. Scientists generally know more about these nutrients than about ingredients used in other types of dietary supplements. And, most vitamin and mineral products are accurately labeled for content and are offered at moderate potencies.

"Our main concerns," Taylor says, "are with the array of other products that have unsubstantiated safety—such as amino acids and herbs and other botanicals. We know very little about some of these products' ingredients."

**Diet and Disease**

Recent attention to a possible effect of diet in reducing the risk of certain diseases has raised new safety issues about how FDA should regulate dietary supplements. Growing scientific support for such benefits and increased consumer interest in improving health through diet provided much of the impetus for provisions of the NLEA to allow health claims for foods. (See "Starting This Month: Look for 'Legit' Health Claims on Foods" in the May 1993 FDA Consumer.)

But, because manufacturers believed FDA would limit claims on their supplements under the NLEA, they conducted a rigorous consumer campaign to get Congress to limit FDA's authority.

"They wanted us to adopt a more relaxed standard for claims on supplements than Congress had adopted for conventional foods," Taylor says.

When the Dietary Supplement Act of 1992 became law on Oct. 29, 1992, a year's moratorium was imposed on implementation of the NLEA with respect to supplements. But it called for FDA to propose NLEA-based labeling rules for supplements by June 15, 1993, which the agency did (see "FDA's Proposals"), and to issue final rules in December.

In October, FDA published a proposed rule on allowing a health claim on foods, including supplements, that are good sources of folic acid. The claim would discuss the link between folic acid intake by women of childbearing age and a reduced risk of neural tube birth defects in newborns. The agency also proposed amending its food additive rule for folic acid and standard of identity to require the addition of folic acid to "enriched" grain products.

FDA is working with manufacturers and scientists on other potential health claims—such as a claim associating antioxidant vitamins like vitamin C with a reduced risk of cancer and other diseases.

**Potentially Unsafe Supplements**

While FDA is open to exploring new evidence on the relationships between diet and disease, Taylor says, the agency is concerned that increased attention to these
relationships will increase the potential for wider use of possibly unsafe supplements (such as amino acids for bodybuilding) and for development of more untested products. Safety and misleading labeling are prime concerns. FDA is not proposing to regulate dietary supplements as drugs. But if a supplement makes drug claims or contains a substance already regulated as a drug, then consumers deserve to have information about the product’s safety and effectiveness, as they do for drugs.

“FDA certainly does not regulate personal choice or the practice of medicine,” Taylor says. “But we know that many supplements are sold in drug-like formulations and potencies, yet they haven’t been subjected to the safety controls of FDA’s drug approval process.”

Lori A. Love, M.D., Ph.D., director of the clinical research and review staff in FDA’s Center for Food Safety and Applied Nutrition, cites as an example white willow bark, which contains a substance the body metabolizes into acetylsalicylic acid, aspirin’s active ingredient.

Firms market this botanical as an ingredient in products for children’s use. However, unlike labeling for aspirin, labels for these products do not carry the FDA warning that children and teenagers should not use these products if they have symptoms of chickenpox or influenza, because such use has been associated with Reye syndrome, a rare, but serious illness. In fact, Love says, a number of these products are labeled “aspirin free.”

Levels of natural constituents in herbs sometimes vary greatly. The concentration of a constituent, for instance, varies with the part of the plant it comes from, growth stage at harvest, and processing and dilution during manufacture. Some ingredients in herbal products naturally contain chemicals that are harmful, such as certain alkaloids.

In other words, “natural” doesn’t necessarily mean “safe.”

Substances in supplements that have raised safety issues include:

- **Chaparral**—After learning of five cases of chaparral-related acute toxic hepatitis, FDA warned against consuming this herb, and manufacturers voluntarily removed

---

**FDA’s Proposals**


In announcing the proposals, FDA Commissioner David A. Kessler, M.D., said, “FDA’s goal is simple: We want people to have access to products that are safe, and we want to assure consumers that claims made about the health and nutritional benefits are truthful.”

Among these proposals are the following:

- Special rules for nutrition labeling would apply to dietary supplements of vitamins or minerals. (Nutrition labeling for products consisting of herbs or other nutritional substances would be like that for conventional foods.)
- Vitamin and mineral nutrition labeling would be in a “Nutrition Facts” panel (see facing page) that is as similar as possible to the conventional foods panel. (See “‘Nutrition Facts’ to Help Consumers Eat Smart” in the May 1993 FDA Consumer.)
- If a supplement bears a nutrient content claim, an adjacent referral statement would direct consumers to the nutrition panel.
- If a claim uses either the term “free” or “low,” the wording would have to make it clear the claim is true for all products of that type—for example, instead of “brand X, a fat-free vitamin C supplement,” the claim would read “brand X vitamin C, a fat-free supplement.”
- Supplements, including those for infants and children under 2, could be labeled with the term “sugar free” and its synonyms, such as “sugarless,” “no sugar,” and “trivial source of sugar.”
- The term “more” could be used in a claim if a product has 10 percent more of the Daily Value of a nutrient than the food to which it’s being compared.
- For health claims, supplements would be subject to the same scientific standard and procedures that are required for conventional foods. (See “Starting This Month: Look for ‘Legit’ Health Claims on Foods,” in the May 1993 FDA Consumer.)
- Supplements would be exempt from the conventional foods requirement that, to bear health claims, products must contain 10 percent or more of the Daily Value of the nutrients vitamin A, vitamin C, iron, calcium, protein, or fiber.

—D.F.
This proposed nutrition labeling panel for vitamin and mineral dietary supplements would help consumers make informed choices and understand how individual nutrients fit into the total daily diet. It closely resembles the panel used for conventional foods.

**Nutrition Facts**

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>1 tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amount Per Serving</strong></td>
<td>%Daily Value</td>
</tr>
<tr>
<td>Vitamin A 5000 I.U. (50% as Beta Carotene)</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin C 60 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin D 400 I.U.</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin E 30 I.U.</td>
<td>100%</td>
</tr>
<tr>
<td>Thiamin 1.5 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Riboflavin 1.7 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Niacin 20 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B₆ 2 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Folate 0.4 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B₁₂ 6 mcg</td>
<td>100%</td>
</tr>
<tr>
<td>Biotin 0.03 mg</td>
<td>10%</td>
</tr>
<tr>
<td>Pantothenic Acid 10 mg</td>
<td>100%</td>
</tr>
</tbody>
</table>

"Serving Size" would be expressed as a unit, such as a teaspoonful, tablet or packet (or units, such as "two tablets").

Number of "Servings Per Container" also would be given, beneath the serving size line, when this number is not in the product's net quantity of contents declaration. Liquid or powder products would always have to declare this number because their net quantity would be in weight measures, such as ounces or grams, not serving size unit measures.

"Amount Per Serving" indicates the basis on which the nutrition information is presented. Nutrient names and quantitative amount by weight would be listed.

When products are to be used by infants, children under 4, or women who are pregnant or nursing, the "% Daily Value" heading would state the intended group.

"% Daily Value" (when appropriate) would show how the listed nutrients fit into the overall daily diet.
Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA regulates dietary supplements as foods, as long as no drug claims are made for them. The FD&C Act includes provisions to ensure that foods are safe and their labels are truthful and not misleading.

The Proxmire Amendment of 1976, introduced by then Sen. William Proxmire, D-Wis., restricts FDA’s authority to limit supplement potency and the composition of most multi-nutrient products, except for safety reasons. It prohibits the agency from deeming a vitamin or mineral a drug solely because of potency.

When products are marketed for therapeutic use, FDA regulates them through its Center for Drug Evaluation and Research. The FD&C Act defines “drugs” as products intended to diagnose, cure, mitigate, treat, or prevent disease, or non-food products intended to affect the structure or a function of the body.

Between November 1990 and June 1993, FDA took actions against 188 products perceived as dietary supplements on grounds that they made unsubstantiated claims about serious medical conditions.

---D.F.

How Supplements Are Regulated

most products containing chaparral from the market. Promoters claim chaparral slows aging, “cleanses” the blood, and treats skin problems—all unproven claims.

- Comfrey—Since 1985, at least seven cases of liver disease, with one death, have been associated with oral use of products made from this leafy plant. Comfrey contains pyrrolizidine alkaloids. People who ingest even small amounts of these alkaloids for a prolonged time may be at risk for developing cirrhosis of the liver. Comfrey is sold as teas, tablets, capsules, tinctures, medicinal poultices, and lotions.

- Germanium—Use of this nonessential element for a long time may cause serious, irreversible kidney damage and has resulted in death. Germanium products are promoted as so-called “health promoting” elixirs or as an “electronutrient” for uses such as neutralizing heavy metal toxicity. There is no evidence of effectiveness.

- Guar gum—Now banned from use as an active ingredient in drugs, this complex carbohydrate that swells when wet has been used in weight-loss products to produce a feeling of fullness. One brand resulted in hospitalization of at least 10 patients and one death from a blood clot after surgery to remove a throat blockage. Guar gum can cause diarrhea, vomiting, bloating, and intestinal blockages.

- Jin Bu Huan—Unapproved labeling claims this Chinese herbal product is useful for relieving pain. After accidentally taking Jin Bu Huan, three preschool children were hospitalized this year in Colorado with life-threatening, very slow heart rates, depressed central nervous systems, and breathing difficulties. After intensive medical care, the children recovered.

- Ma huang—Products with Ma huang, derived from an evergreen plant, are under investigation following reports to FDA of serious adverse effects such as high blood pressure, rapid heart rate, nerve damage, muscle injury, psychosis, stroke, and memory loss. Ma huang is sold in products for weight control or boosting energy. These products often contain other stimulants, which, taken together, may increase the potential for adverse effects.

- Yohimbe—Yohimbe is a tree bark marketed in products for bodybuilding and “enhanced male performance.” Serious adverse effects—including kidney failure, seizures, and death—have been reported to FDA with products containing yohimbe and are currently under investigation.

Nutrients

Like other natural substances, even nutrients may be harmful at certain levels. With vitamins and minerals, there may be adverse effects from excessive potency of certain ingredients, or from contaminants or impurities in these products.

For example, says John Vanderveen, Ph.D., director of the Office of Plant and Dairy Foods and Beverages in the Center for Food Safety and Applied Nutrition, FDA discovered that some calcium supplements contained lead. “They had to be reformulated,” he says. “And some calcium supplements had excessive levels of vitamin D, which would have been toxic if taken continuously at this high intake.”

Although the margin of safety between the needed level and the toxic level is quite wide for some nutrients, Vanderveen says, it is very narrow for others, such as the mineral selenium.

The agency believes that problems with nutrients can be best handled by subjecting them to the same labeling requirements as other foods.

Known Risks

Some known risks of nutrients consumed at excessive potencies are:

- Folic acid—Intakes higher than 1 milligram a day may mask symptoms of vitamin B12 deficiency while pernicious anemia caused by the deficiency progresses undetected.
• **Iron**—As few as six high-potency iron tablets could seriously injure a child weighing 22 pounds or less. Iron is the most common cause of U.S. child poisoning deaths, causing about 2,000 poisonings a year, mainly in young children taking their mothers’ prenatal supplements.

• **Niacin**—High intakes can damage the liver and cause severe gastrointestinal problems.

• **Selenium**—High intakes can damage tissue, especially in tissues or organs where selenium concentrates. Toxicity depends on the chemical form and the selenium content of the foods eaten and has occurred with high intakes after a few weeks.

• **Vitamin A**—Continuous high intakes can cause headaches, liver damage (including cirrhosis), bone damage, diarrhea, and, during pregnancy, birth defects.

• **Vitamin B6**—High intakes can cause bone pain, muscle weakness, numbness, or other symptoms of nerve disorder.

• **Vitamin C**—Very high intakes can cause diarrhea and may cause urinary tract problems.

• **Vitamin D**—Continuous high intakes can cause kidney damage and bone deformity.

**Underreported Reactions**

Just because there haven’t been a lot of reports of adverse effects associated with use of dietary supplements doesn’t necessarily mean they’re safe. A person taking a supplement may not associate an adverse effect with it, especially if the individual also is taking one or more medications or is chronically ill. For example, muscle weakness or numbness caused by too much vitamin B6 might be ignored as a sign of conditions associated with aging. Or adverse effects may take time to develop, so that it’s difficult to link them with a specific supplement.

Sometimes, reactions may not be recognized unless large numbers of people are using the supplement. In 1989, for instance, the use of the essential amino acid L-tryptophan was associated with an outbreak of an illness called eosinophilia-myalgia syndrome (EMS), a serious connective tissue disorder. More than 1,500 EMS cases, including 38 deaths, have been associated with L-tryptophan ingestion.

All marketed products to which manufacturers had added L-tryptophan were recalled, except for specific medical foods or infant formula products, which require L-tryptophan to provide adequate nutrition. FDA issued an import alert to prevent importation of the raw material, except for those certain permitted uses.

Initial studies suggested that the cause of the outbreak was an impurity or other component in the product from a particular Japanese manufacturer. Today, however, the exact cause of EMS remains uncertain, despite intense research in this area.

“Cases of EMS, as well as a related illness, eosinophilic fasciitis, were associated with the use of L-tryptophan even before the 1989 EMS epidemic,” Love says. “And cases of EMS and related illnesses have occurred with the use of a compound [L-5-hydroxytryptophan] that’s similar to L-tryptophan, but not manufactured with the same fermentation process and, therefore, not associated with the same impurities.”

Thus, Love says, FDA believes the overall findings point to multiple factors, including L-tryptophan itself, as playing a role in the cause of EMS.

**Approaches to Safety**

FDA last June published a notice (along with the NLEA-based proposals) to solicit public comment and scientific data on the best approaches to ensuring the safety of dietary supplements, particularly amino acids and botanical products.

The notice summarized the report of FDA’s Dietary Supplements Task Force on alternatives for regulating supplement products. The task force made 20 recommendations, including stricter amino acid regulation, required good manufacturing practices for supplements, and stronger adverse reaction reporting requirements for supplements.

However, FDA Deputy Associate Commissioner for Regulatory Affairs Gary Dykstra, who headed the task force, points out, “Contrary to claims by FDA critics, we have no plans to close health food stores, and we aren’t going to take safe, properly labeled supplements off the market or make all supplements available only by prescription. The agency favors personal choice as much as possible within the constraints of the FD&C Act.”

Also included in the notice were findings by the Federation of American Societies for Experimental Biology, with which FDA had contracted to provide information on whether the use of amino acids in dietary supplements presents any particular safety concerns. The group found data to be inadequate to determine safe upper levels of use and advised that consumers not take amino acids except under responsible medical supervision.

FDA is evaluating these reports and other submitted data.

**Precautions**

For consumers who choose to take dietary supplements, FDA’s Love suggests these precautions:

• Be wary of unfounded medical claims for dietary supplements, and be sure to tell health-care providers about all supplements you take, including concentrations and amounts.

• Children, adolescents, older or chronically ill people, and women who are pregnant or are breast-feeding should not use high-potency supplements or those used for medicinal purposes unless they have responsible medical supervision.

• Keep supplements out of the reach of children.

Dixie Farley is a staff writer for FDA Consumer.
MEDWATCH

On Lookout for Medical Product Problems

by Kevin L. Ropp

MEDWATCH

No, it's not some new doctor show in this fall's TV line-up.

Unveiled last June 3, MEDWATCH is the Food and Drug Administration's new voluntary Medical Products Reporting Program for quickly identifying unsafe medical products on the market.

"Post-market surveillance is critical to our job of ensuring the safety of drugs, devices, and other FDA-regulated products," FDA Commissioner David A. Kessler, M.D., said in a May 4, 1993, address to health professional organizations.

"There is simply no way that we can anticipate all possible effects of a drug or device during the clinical trials that precede approval," he said. "A new drug application, for example, typically includes safety data on several hundred to several thousand patients. If an adverse event occurs in 1 in 5,000 or even 1 in 1,000 users, it could be missed in clinical trials. But it could pose a serious safety problem when the drug is used by many times that number of patients."

A recent example is Omniflox (temafloxacin), an antibiotic drug first marketed in the United States in February 1992. Less than four months after its introduction into the marketplace, Omniflox was withdrawn after FDA received about 50 reports of serious adverse events, including three deaths. These occurred during the first three months of the drug's use in this country. Side effects included dangerously low blood-sugar levels in older patients; excessive destruction of red blood cells that was frequently associated with renal failure; ab-
FDA had set up its own surveillance program to monitor adverse drug reactions in 1961 following another drug-related tragedy, birth defects caused by thalidomide.

"We were under investigation but had not been marketed," Anello explains. "By the time the problem was recognized, there were 10,000 cases of phocomelia—a congenital malformation where arms and legs are shortened or not developed," Anello explains. "By the time the problem was recognized, there were 10,000 cases of phocomelia worldwide. In the United States, the drug was under investigation but had not been marketed."

In an effort to avoid future tragedies, the World Health Organization and most industrialized countries, including the United States, implemented adverse reaction reporting systems.

The U.S. Congress passed the 1962 Drug Amendments to the Food, Drug, and Cosmetic Act, which required drug manufacturers to report to FDA all adverse drug events they became aware of that were associated with their products.

"That is why it is so crucial to keep an eye on a product once it is in general use," Kessler said in his address. "And the health professionals who use the products are indispensable to that process."

Avoidable Tragedies?

The first post-marketing surveillance program was established in 1954 by the American Medical Association following reports of aplastic anemia (a blood disorder) associated with the use of chloramphenicol, an antibiotic, according to Charles Anello, Sc.D., acting director of the Office of Epidemiology and Biostatistics in FDA's Center for Drug Evaluation and Research.

AMA's program, run by its Committee on Blood Dyscrasias, was expanded in 1961 to monitor all adverse drug events. The program was discontinued because of parallel efforts by FDA.

FDA had set up its own surveillance program to monitor adverse drug reactions in 1961 following another drug-related tragedy, birth defects caused by thalidomide, a sedative and hypnotic drug marketed in Europe for nausea during pregnancy.

"It turns out, that drug caused a condition called phocomelia—a congenital malformation where arms and legs are shortened or not developed," Anello explains. "By the time the problem was recognized, there were 10,000 cases of phocomelia worldwide. In the United States, the drug was under investigation but had not been marketed."

Patients who suspect they've had a serious adverse event after using a medical product should ask their physicians to call the medWatch hot line at (1-800) FDA-1088.
permanent damage, disability, and congenital anomaly. Congenital anomalies include birth defects, miscarriage and stillbirth, or birth with cancer or some other serious disease.

The identity of patients involved in medWatch reports is confidential and legally protected. The identity of the reporter may be shared with the manufacturer unless the reporter requests otherwise.

"Physicians should report when there is a suspicion that the drug or device may be related to a serious adverse effect; they are not expected to establish the connection or even wait until evidence seems compelling," Kessler wrote in a recent Journal of the American Medical Association article.

"On the other hand, the FDA does not want providers to report every adverse reaction observed; this would not be practical for the practitioner or useful to FDA," Kessler continued.

Problems should also be reported when there is concern about the quality, performance or safety of any medication or device. Product quality problems may occur during manufacturing, shipping or storage. These problems include contamination, defective components, poor packaging or product mix-up, questionable stability, and labeling concerns.

The agency's medWatch central unit receives all the reports initially. From there, it is determined what type of product is involved. Within one working day of receipt of a report, it is in the hands of the appropriate program in the center responsible for the particular product.

"We're currently receiving about 100,000 reports each year of adverse events with drugs," Anello says. "Several thousand of those are serious and unlabeled [not listed in the product labeling] reactions. Not every one of those reports establishes cause-and-effect relationships. We have a staff of epidemiologists who assess the causes [of the reaction] and also the public health importance of these reported adverse events."

Once an adverse event or product problem is identified, FDA can take any of the following actions:

- **Labeling Changes**—Adverse events of-
Vaccine Reporting

MEDWatch doesn’t include vaccines.

In 1986, Congress passed the National Childhood Vaccine Injury Act, requiring health-care practitioners and vaccine manufacturers to report serious adverse events with certain vaccines.

The Vaccine Adverse Event Reporting System (VAERS) began Nov. 1, 1990, collecting all vaccine reports for FDA and the national Centers for Disease Control and Prevention.

“In 1992, VAERS received 11,015 reports,” says John Nazario, FDA’s VAERS project officer. “Of those, 1,510 were serious.”

Congress passed the act after realizing litigation against manufacturers was driving up vaccine costs and motivating some companies to stop vaccine production, Nazario explained.

Anyone—consumers, parents, manufacturers, and health-care providers—can submit a VAERS form, but patients or their representatives are encouraged to also consult their doctors, Nazario says.

For a VAERS form or more information on reporting vaccine adverse events, call the 24-hour VAERS hot line at (1-800) 822-7967.

—K.L.R.

Sharing Information

Communicating FDA actions that resulted from MEDWatch reports to health professionals is another primary goal of the new program.

“Already we have about 70 health-care organizations that have signed up to be our partners,” Kennedy says. “They’re doing news and journal articles, distributing forms, publishing print ads, public service announcements—we’re really just getting into the phase where we would expect to see a real surge of reporting.”

These organizations have also agreed to help disseminate information about the safety actions the agency has taken.

FDA also reports back to health-care professionals through “Dear Doctor” and “Dear Health Professional” letters, FDA Medical Bulletin, and through press releases and journal articles.

“The plans are for us to provide whatever information comes out back to the health professional,” Kennedy says.

“We’re certainly not able to individualize responses, although if a significant problem is discovered, we might look back at the reports used in discovering the problem and write back to those who reported it.”

What Does MEDWatch Mean to You?

The MEDWatch program will provide different benefits to different people.

For health professionals, the MEDWatch program will help educate and inform practitioners of the need for adverse event reporting. It will also quickly correct product problems and remove defective or dangerous products from distribution.

But the greatest beneficiary will be the general public. “MEDWatch will help identify problems earlier so that we [FDA] can prevent the continued occurrence of that problem,” Kennedy says.

Simply put, MEDWatch is expected to make medical products safer for consumers by ensuring the safety of products on the market and enabling faster removal from the market of those that cause problems.

As Kessler told the health professionals, “What MEDWatch is all about is preventing illness and death. It is about someone in my family, in your family, someone anywhere in this country who will escape illness or even death because a health professional filed a report. And it is about every patient who will suffer because a report was not filed.”

Kevin L. Ropp is a staff writer for FDA Consumer.
In 1956, 7-year-old Steven Gold swallowed a penny. Fortunately, the coin journeyed through the boy's system without doing any harm. For a week, Steven's father, a doctor in general practice, followed the penny's path by placing his son behind his office fluoroscope screen. A fluoroscope is an x-ray device that provides images of internal body parts as they move. When an image appeared on the screen of Steven's insides, moving when he squirmed, the route of the penny could be seen, a little farther along each day.
A couple of generations ago, children visiting shoe stores were fascinated to see the bones of their feet through a fluoroscopy machine. This use was discontinued when scientists realized its potential for damage.

At that time, the fluoroscope was a standard piece of medical equipment in some offices of family physicians. If a patient came in with an arm dangling at an odd angle, for example, the fluoroscope could rapidly reveal whether the bone had been broken.

Fluoroscopes were also used for a short time in a very nonmedical setting—shoe stores. To determine shoe size, a fluoroscope would reveal the length and structure of foot bones, much to the delight of children who could see their skeletal toes wiggle.

Use of fluoroscopy in shoe stores was a rather frivolous application of ionizing radiation, a form of energy that has the potential to damage living tissue. "Fluoroscopy in shoe stores was stopped because it wasn't necessary to expose people to radiation when they wouldn't have much benefit. It was a sales ploy, with fairly high exposures," says Thomas Shope, deputy division director at the Center for Devices and Radiological Health at FDA.

In the 1960s, some doctors upgraded their fluoroscopic equipment with a device called an image intensifier. This produced brighter images, eventually allowing physicians to use lower doses. Many family physicians opted to send patients to radiologists or hospitals for x-rays. Meanwhile, fluoroscopy found diverse nonmedical applications, such as screening airport luggage for hidden metallic objects and detecting oil paintings hidden behind other paintings.

In fluoroscopy, as first observed by Ger-
A patient is positioned for a lower GI (gastrointestinal) series by fluoroscopy.

For an upper GI series, the patient is rotated to an upright position.

(Photo courtesy of GE Medical Systems Group)

man physicist Wilhelm K. Roentgen in 1895, x-rays strike a screen that is coated with a fluorescent material. Because the radiation is blocked more effectively by dense tissue, such as bone, than by soft flesh, the result is a dark shadow of bones on the screen, against a light background.

“Fluoroscopy was originally done with a fluoroscopic screen, which required that the radiologist sit in a darkened room until he became dark-adapted to see the image in the low light level. The x-ray image intensifying tube invented in the 1960s took the place of the screen,” says Shope.

In today’s fluoroscope systems, television or video cameras can be attached to the image intensifier tube. “The camera output can be digitized and sent through a computer, introducing computer processing capabilities such as image enhancement,” Shope adds. In cardiac catheterization, for example, a high-speed version of the technology called cinefluorography images the working heart and its blood vessels, once the physician has inserted the catheter using normal fluoroscopy.

Today, fluoroscopy’s ability to image moving internal body parts has found application in guiding invasive medical procedures. Snaking a catheter into an organ to biopsy a tumor is safer and may reveal more information if the image is observed with fluoroscopy, compared to the static images of other scanning technologies. For example, fluoroscopy is essential to cardiac catheterization, in which a catheter is inserted into a vein or artery and guided into the interior of the heart to assess blockage in the heart’s arteries. The fluoroscope allows the physician to see where the catheter is going. The catheter delivers a contrast agent or monitors physiological function. Fluoroscopy is also used to image the gastrointestinal (GI) tract in a test commonly called a “GI series.”

In fact, the upper GI series accounts for 42 percent of all fluoroscopy procedures. A patient drinks a chalky, milkshake-like concoction containing barium, which coats the esophagus and stomach. The barium absorbs the x-rays so that the lining of the upper digestive tract can be visualized. In a lower GI series, the patient receives a barium enema, which coats the intestines and rectum. A gap in the image in the stomach or small intestine could indicate an ulcer; bubbles in the normally smooth large intestinal lining may be abnormal growths.

Fluoroscopy can help patients regain lost functions. At Royal Prince Alfred Hospital in Sydney, Australia, fluoroscopy is being used to study throat movements in cancer patients who have had their larynxes (voice boxes) removed. This type of analysis helps physicians and speech pathologists identify and instruct individual patients on new ways to produce some sounds. And at Tel Aviv University in Israel, a fluoroscopically-guided catheter is used to clear women’s fallopian tubes of scar tissue that has been preventing conception. Some previously infertile patients have conceived within two months of treatment.

Fluoroscopy can improve the safety of other procedures. For example, blindly probing a tumor to remove cells for examination, some surgeons believe, can actually spread the disease by introducing cancer cells into the bloodstream. In an alternative technique, physicians at Wuesthoff Memorial Hospital in Rockledge, Fla., use a fluoroscope to guide a catheter in biopsy ing cancerous tissue from a hard-to-reach kidney. Know-
ing precisely which cell types are cancerous can aid a physician in choosing the most effective therapy.

Fluoroscopy is also useful in studying the esophagus. In a procedure called Maloney dilation, a tube is passed through constrictions in the esophagus to try to alleviate a persistent feeling of having a lump in the throat. Done blindly, the procedure is successful 80 percent of the time, but damages delicate throat tissues up to 2.2 percent of the time. Gastroenterologist Leslie E. Tucker, M.D., of Washington, Mo., reported in the American Journal of Gastroenterology on results in 145 patients treated for a constricted esophagus with a Maloney dilator and fluoroscopy. He found improved safety and efficacy over using a dilator alone. When both techniques were used, he reported, the rate of success rose to 96 percent, with no injuries.

Researchers at the University of Vienna used fluoroscopy to visualize the esophagus in action. Wolfgang Schima and colleagues compared videofluoroscopy to manometry, a standard technique that measures pressure, in 92 patients who had difficulty swallowing. A manometer is inserted into the nose, threaded down to the stomach, then pulled back up to the lower esophagus. A microphone is placed externally on the patient’s throat, and as he or she swallows, abnormal pressure changes are recorded, providing diagnostic clues.

In the fluoroscopy-assisted procedure used by Schima, swallowing a pressure gauge is unnecessary. After drinking a barium-containing liquid, the patient swallows, first in an upright position, then lying down. A videofluoroscope records throat movements during swallowing. Later, radiologists review the videotape to see how the barium spreads as the patient swallows. Whereas conventional x-rays can identify a structural flaw in the esophagus, fluoroscopy reveals malfunction, such as a spasm that might cause the lump-in-the-throat sensation, or poor peristalsis (waves of muscle contraction) that stalls food. The Viennese researchers recommend that videofluoroscopy become a routine procedure for diagnosing a persistent lump-in-the-throat.

Safety Concerns

The greatest concern about fluoroscopy continues to be excessive radiation exposure. A single session for an invasive medical procedure can take an extended time, sometimes lasting more than an hour. FDA is currently analyzing the precautions that can be taken in the use of the technology.

“We are going to see an effort by the FDA and professional organizations such as the American College of Radiology to put a higher profile on encouraging education” of physicians in safe fluoroscopy operation, says J. Thomas Payne, M.D., chairman of the American College of Radiology’s Commission on Physics and Radiation Safety.

Since receiving a number of reports of alleged patient injury from long exposures to high-dose fluoroscopy, FDA has intensified efforts to minimize exposures, evaluate risks, develop ways to ensure safety of equipment and adequate training of operators, and identify situations in which prolonged exposures may occur. According to CDRH, two factors contribute to the potential public health concern about fluoroscopy. First is the increasing use of fluoroscopy to guide catheters, which requires longer exposure times and for which physicians other than radiologists may handle the x-ray equipment. Second, the increasing complexity and capabilities of some newer fluoroscopy systems require greater skill to operate.

Payne published a warning to users outlining how overexposure great enough to cause a severe radiation burn might occur. In 1974, when FDA established x-ray safety standards, most devices emitted 10 roentgen per minute. A roentgen (R) is a unit for the quantity of radiation emitted. Today, more efficient x-ray systems can produce 20 to 120 R per minute, a variation called “high-level control mode.”

Also, in 1967, when fluoroscopy was used for direct imaging rather than guiding catheters, exposure times were shorter. Payne describes a 100-minute-long procedure guided by fluoroscopy emitting 20 R per minute. That amounts to an exposure of 2,000 R, enough to cause a serious burn if delivered to one part of the body. To put that into perspective, most diagnostic x-rays use less than 1 R.

Such observations have alerted the medical community to take measures to enhance the safety of fluoroscopy. A recent workshop sponsored by the American College of Radiology in Herndon, Va., to address this issue produced some valuable recommendations. These include:

- instituting separate controls for regular- and high-exposure modes of operation, so a patient cannot inadvertently be given too high a dose
- developing “last image hold capability,” so that a physician finding a revealing view can “freeze frame” it, rather than continuing to expose the patient.

The dynamic nature of fluoroscopy makes it a valuable medical tool. Today, fluoroscopy—with proper controls—will continue to help doctors view the body’s insides in action.

Ricki Lewis is the author of textbooks on biology and human genetics.
Choosing a Treatment for UTERINE FIBROIDS

by Eleanor Mayfield

Uterine fibroids, one of the most common noncancerous gynecological conditions occurring in reproductive-age women, are estimated to affect more than 1 out of 5 women under 50 and account for 3 out of every 10 hysterectomies performed annually in the United States.

A fibroid, or myoma, is a noncancerous mass of muscle and connective tissue in the uterus (womb). No one knows what causes fibroids, but scientists believe their growth may be stimulated by the female sex hormone estrogen.

“A fibroid can be as small as a pinhead or as large as a watermelon,” says Gene Williams, M.D., a medical officer in the obstetrics and gynecological devices branch of FDA’s Center for Devices and Radiological Health. “It can cause no symptoms or a lot of symptoms. To the woman who has one, a fibroid may feel like a rock-hard bulge in the lower abdomen.”

Every year, about 175,000 American women—most of them 35 to 55—undergo hysterectomy, or surgical removal of the uterus, as treatment for fibroids. According to American College of Obstetricians and Gynecologists guidelines, a fibroid that makes a woman’s uterus bigger than it would be at 12 weeks of pregnancy, even if the woman is suffering no other symptoms, is an indication for a hysterectomy.

However, the practice of routinely recommending hysterectomy for fibroids has come under increasing scrutiny from both consumer organizations and doctors concerned about the high rate of hysterectomy in the United States. By age 60, more than a third of American women have had a hysterectomy, a rate higher than in any other Western country.

Blue Cross/Blue Shield of Illinois, in a study of all the hysterectomies performed in the state between 1987 and 1989, concluded that one-third were unnecessary. Most of the unnecessary surgeries, the insurer found, were performed for fibroids and other benign (noncancerous) conditions.

Options Increase

New medications and less-invasive surgeries have made more treatment options available to women whose fibroids cause them problems. A number of doctors interviewed for this article say the most important consideration in treating a fibroid should be how the patient feels about her condition and what level of intervention she is comfortable with.

“The physician should look objectively...
Fibroids are classified by their position in the uterus. Intramural fibroids, the most common type, grow inside the uterine wall. Subserous or subserosal fibroids grow outward from the uterine wall into the abdominal cavity. Submucous fibroids grow inward from the uterine wall, taking up space within the uterus itself. This type of fibroid is the most likely to cause symptoms of heavy, prolonged menstrual bleeding. A fibroid can be as big as 20 centimeters (nearly 8 inches) in diameter and can weigh more than 20 pounds.

Small fibroids usually cause few if any symptoms. But, as a fibroid grows larger, it may press on the bladder and the ureters, the pair of tubes that connect the bladder to the kidneys. Pressure on the bladder can cause urinary frequency; pressure on the ureters can lead to kidney and urinary tract infections. Fibroids can sometimes be a cause of miscarriages and infertility.

A woman with a moderate-to-large fibroid may also notice a protruding stomach and a sensation of heaviness in the abdomen. For many women, the most distressing symptom is prolonged, heavy bleeding at the time of their menstrual periods, as well as spotty vaginal bleeding outside of the normal menstrual cycle. Women who lose too much blood may become anemic.

Sometimes a fibroid develops a thin stalk “like a balloon on a string,” says David Barad, M.D., head of reproductive endocrinology at New York’s Montefiore Medical Center. This is called a pedunculated fibroid. In some cases, the stalk can become twisted, cutting off its own blood supply, and causing severe pain.

Fibroids tend to grow in spurts, with periods of rapid growth punctuated by periods of no or very slow growth. As a woman approaches menopause, a fibroid may begin to grow rapidly. After menopause, however, fibroids stop growing and may start to shrink.

—E.M.
at the patient’s symptoms, inform her of the treatment choices, and give her the autonomy to decide what she wants to do,” says David Barad, M.D., director of reproductive endocrinology and infertility services at Montefiore Medical Center, Bronx, New York, and an associate professor at the Albert Einstein College of Medicine.

“There are probably hundreds of thousands of women who have fibroids on their uteruses that don’t need to have anything done to them. At the other end of the spectrum, if a woman who has completed her family has a large fibroid that is causing distressing symptoms—like painful cramps, heavy menstrual bleeding, and anemia—she would be a candidate for hysterectomy.”

In the March 1993 issue of the American Journal of Obstetrics and Gynecology, Andrew J. Friedman, M.D., and Susan T. Haas, M.D., of Harvard Medical School, write that the recommendation for surgery when fibroids make a woman’s uterus larger than a 12-week pregnancy is based on three main concerns:

• Ovarian cancer might go undetected because the presence of a fibroid makes it difficult for the doctor to feel the ovaries during a pelvic examination.
• A rapidly growing fibroid may signal uterine cancer.
• A growing fibroid may produce more debilitating symptoms and add to the risks of surgery later on.

Friedman and Haas, advocating a less aggressive approach to fibroid treatment, respond to these concerns this way:

• The development of ultrasound (the use of high-frequency sound waves to produce an image of a part of the body) makes it possible to look at a woman’s ovaries even when a fibroid prevents a manual examination. In any case, ovarian cancer is rare before age 50, and most hysterectomies for fibroids are done on women ages 35 to 44.
• Ultrasound and magnetic resonance imaging can be used to screen for uterine cancer, also rare in women under 50.
• Studies of hysterectomies done because of fibroids have not shown that removing a larger uterus poses a greater risk of surgical complications. “Watchful waiting” and treatment of problematic symptoms with medication or minimally invasive surgery may be just as effective as hysterectomy.

Exploring Drug Therapy

Many doctors prescribe drugs chemically similar to gonadotropin releasing hormone (GnRH) to treat fibroids. GnRH, produced by the pituitary gland, stimulates the production of estrogen. The drugs, known as GnRH analogs, block release of the hormone, thereby preventing the production of estrogen. These drugs, which include leuprolide (Lupron), nafarelin (Synarel), and goserelin (Zoladex), are approved by FDA to treat endometriosis in women and prostate cancer in men. Although FDA has not approved these drugs for treatment of fibroids, as with other approved medications, doctors may prescribe them if in their professional judgment a patient will benefit from them.

“Placing a woman on these drugs creates a false menopause,” says Lisa Rarick, M.D., a medical officer in the division of metabolism and endocrine drug products.
The development of endoscopes, lasers, and electrosurgical devices has led to new, less-invasive surgical techniques to remove fibroids. An endoscope is a thin fiberoptic tube that surgeons insert into the body. It can transmit an image to a television-like screen. Specialized endoscopes for viewing the abdominal cavity are called laparoscopes. Endoscopes designed to view the inside of the uterus are known as hysteroscopes. A laser is a device that uses a thin, intense light beam to "cut" or vaporize tissue, while electrocautery devices use electricity to destroy tissue by applying heat.

These devices can be combined in several ways to perform a variety of procedures. Some devices combine the visualization and surgical functions in one instrument, such as the hysteroscopic resectoscope, which consists of a hysteroscope with an electrosurgery device built into it. This device is often used to remove submucous fibroids, the type most likely to cause symptoms of heavy menstrual bleeding (see "Fibroid Types").

The most appropriate procedure for each patient will depend on factors such as the size and position of the fibroid, the severity of symptoms, and future childbearing plans. Hysterectomy, by removing the uterus, makes it impossible to become pregnant or carry a baby.

Endometrial ablation, in which an electrosurgical device is used to remove the lining of the womb, may be recommended if a woman's major fibroid-related symptom is heavy, debilitating menstrual bleeding. This procedure also makes pregnancy impossible.
In 1983, Diane Trent (not her real name), 42, began experiencing pain on the left side of her abdomen during her monthly period. Then she began to have extremely heavy periods lasting as long as two weeks. She went to see her gynecologist, who performed a pelvic examination and told her she had a fibroid in her uterus. The doctor recommended a hysterectomy.

Trent requested an ultrasound examination, which showed that the fibroid was about 7 centimeters (2 1/4 inches) in diameter. She decided she only wanted to undergo a hysterectomy as a last resort and asked her doctor if there was a less drastic option.

In response, the gynecologist performed an endometrial biopsy, which showed no cancer, and a dilation and curettage (D&C), a procedure that involves dilating the cervix (neck of the womb) and scraping the uterine lining. The D&C stemmed Trent’s heavy bleeding for a while. But after a few months the problem recurred. At times, she says, the bleeding “was so disabling that I couldn’t go to work.” Because the fibroid was pressing on her bladder, she had to urinate frequently.

Many women in Trent’s situation would have opted for a hysterectomy. Instead, Trent consulted a reproductive endocrinologist, who agreed to monitor the fibroid’s growth.

After three years, it had grown to 10 centimeters (4 inches) in diameter—about the size of a grapefruit. Her new doctor now recommended a hysterectomy.

“My feeling was that this was not life threatening and I didn’t know what the long-term outcome of surgery would be,” Trent says. “I decided I would rather put up with some discomfort that I knew would go away eventually.” So she found another specialist who was willing to continue monitoring the fibroid.

The mass did not enlarge during the next five to six years. Trent is now 52. Since she reached menopause about two years ago, the fibroid has shrunk slightly. She continues to have an ultrasound examination every year. Her doctor says the fibroid should keep shrinking slowly, but it will never disappear completely.

Lisa Rarick, M.D., a medical officer in FDA’s Center for Drug Evaluation and Research, says Trent’s experience illustrates that the “best” treatment for a fibroid may be what the patient is most comfortable with.

“The issue is whether you can live with the symptoms. It’s very individual. It depends how uncomfortable you are and how you feel about having surgery.”

—E.M.
Surprising Sources
For New Foods

by Bill Wagner

America has, for a long time, literally been a fertile field for the development of new food.

The American Indians first cultivated and then gave to the world two of its most basic food crops, corn and potatoes. Other crops first grown by Native Americans include manioc, which became a staple in parts of Africa, as well as the American sweet potato, peanuts, squashes, tomatoes, pumpkins, and others.

Early American food pioneers include George Washington Carver and Luther Burbank, who both worked in the late 19th and early 20th centuries. Carver came up with scores of new uses for the peanut and the sweet potato. Burbank developed all sorts of flowers, vegetables, grains, grasses, and fruits, including the grapefruit.

Today’s food pioneers may not be as well known, but they exist. The new foods they’ve set on our tables include edible cottonseed, canola oil, scores of soybean products—and the revival of the almost extinct American chestnut. The Food and Drug Administration has a responsibility to see that these “new” foods are as safe as those already on the market.

Cottonseed

Credit for increased use of cottonseed products should go to Woodrow Rogers, a West Texas farmer, according to both the Texas Food and Fiber Commission and Texas Monthly magazine. The 78-year-old Rogers started his search for a commercially viable edible cottonseed 30 years ago.

He maintains that cottonseed oil has been a human food for more than 100 years, ever since scientists figured out how to remove gossypol, a toxic hormone it contains.

“Texas A & M had already bred out the gossypol long before I started,” Rogers says. “But you have to keep in mind that cottonseed is a byproduct. The main value of cotton is for the fiber. The Texas A & M strain wasn’t commercially attractive. The plant was spindly, it was hard to grow, and the quality of the cotton fiber was poor.”

Despite the bleak prognosis, Rogers was hopeful: “The new Texas A & M strain was there for anyone to run with.” He did, starting with the first plants kept in a greenhouse on his Waco farm to avoid cross-pollination from nearby conventional cotton. After succeeding in growing the new cotton plants in the greenhouse, Rogers tackled growing them outdoors. Workers lying on a platform pulled by a slow-moving tractor plucked out plants that had the black dot of the gossypol gland.

“Every time we found a strain we liked, it took another seven years to make it commercially acceptable,” he says. “Strains on the market containing the gossypol gland are all insect-, disease-, weather-resistant, and quick maturing. Ours had to perform as well as they did to compete.”

It took Rogers three more years to patent the new seed, LG 86. FDA didn’t require special tests, but the modified cottonseed product had to meet existing requirements adopted some years earlier, according to Robert L. Martin, supervisory consumer safety officer in FDA’s division of petition control. Martin explains that the regulation governing modified cottonseed products intended for human con-
sumption requires that the kernels be heated to 250 degrees for five minutes, and be identified as additives on the label with the words “glandless cottonseed.”

According to Betty Alford, Ph.D., Department of Nutrition and Food Sciences, Texas Women’s University, “Edible cottonseed is being called ‘the new staff of life.’ It contains more than four times the protein of wheat. But, more importantly, it contains all nine of the essential amino acids the human diet requires.”

Cultivation of cotton goes back to the dawn of civilization along the Nile in Egypt. Canola, another significant new food, has only been around a few decades.

**Canola**

Andy Thostenson, founder of Spectrum Crop Development Corp., Ritzville, Wash., a canola expert, explains the plant that canola comes from (which looks like a mustard plant) has been grown for centuries in Central Europe under its original name of rapeseed.

Long recognized as the premier marine steam engine lubricant, rapeseed was first grown in Canada during World War II when European supplies were cut off. But the war’s end and the replacement of steam engines with diesels eliminated the need for rapeseed oil as a lubricant.

In addition, although it was used as a food in Canada and Europe, research on the long-term use of rapeseed oil as a human food was disturbing. In 1970, European researchers linked the erucic acid present in rapeseed oil with heart disease. The Canadian government announced it would quite likely end all rapeseed production unless these health concerns were addressed. By this time, two Canadian scientists were working to lower the erucic acid level.

The interest of Baldur Steffanson, Ph.D., University of Manitoba, and Keith Downey of the Agriculture Canada Research Station in Saskatoon was more than academic. Canadian farmers knew how to grow rapeseed, the crop thrived there, and it could wean the prairie provinces from their historic and often financially disastrous reliance on the boom or bust world wheat market.

The two scientists worked independently, but in consultation with one another. With thousands of rapeseed varieties to analyze, Downey and Steffanson saved considerable time by borrowing a novel and highly effective tool from another discipline: gas chromatography.

The petroleum industry’s gas chromatography equipment was adapted to analyze the fatty acid composition of vegetable oils, which permitted 30 to 40 samples to be tested daily. “Using the old distillation method, it would have taken several lifetimes to locate the right genetic material,” Steffanson said.

Steffanson and Downey announced in 1974 the development of the new rapeseed oil, in which the erucic acid had been replaced by oleic acid, a type of monounsaturated fatty acid. Then came a new name. According to Thostenson, canola is a contraction of “Canadian oil.”

“It came onto the U.S. market at just the right time,” says Thostenson, “just when everyone was concerned about saturated fats, and canola oil was the lowest.”

During its first few years in the U.S. market, canola wasn’t called canola—and it wasn’t called rapeseed oil, either. It was called low erucic acid rapeseed oil (LEAR) and affirmed as generally recognized as safe (GRAS) by FDA in 1985. FDA also stated that the name “canola” could be used, but not without the words “low erucic acid rapeseed oil” or the abbreviation, “LEAR.”

The Canola Council of Canada didn’t like the term LEAR, preferring canola as more descriptive and better known. It petitioned FDA for permission to use canola all by itself.

FDA agreed in 1988 that canola alone could appear on the label for canola. Procter & Gamble became one of the primary marketers of canola in this country.

On the question of canola oil’s claiming the lowest percentage of saturated fat of the vegetable oils, FDA oil expert, David Firestone, Ph.D., senior research chemist, division of pesticides and industrial chemicals, says: “I wouldn’t say canola has the lowest amount of saturated fat of any vegetable oil, but it’s certainly true of the edible oils available on the market.”

Monounsaturated fats and polyunsaturated fats are not associated with the increased risk of heart disease to the same extent as saturated fat, present in animal products and some plant sources such as coconut oil, palm kernel oil, palm oil, and cocoa butter. Other products with high amounts of monounsaturates include olive oil and high-monounsaturated forms of sunflower seed and safflower oils.

**Grains**

In the past several years, there have been a number of new food uses in the United States for grains. Soy foods, especially tofu (curdled soy milk), have been around for centuries in Asia, and arrived here with the first Chinese immigrants during California’s gold rush days, according to William Shurtleff, author and owner of a soy foods business in Lafayette, Calif. Tofu, he adds, has been produced in San Francisco for more than 100 years.

According to Shurtleff, the demand for tofu and other soy foods rose with the increasing influx of Asian immigrants. As
chestnuts are coming back. With only 3 percent fat, chestnuts are good in our diets.”

—Michael Kelly, owner of Chestnut Hill Nursery in Austin, Texas
A sea of cosmetics crowds the drugstore shelves, luring you with claims of romance, popularity and beauty. To be happy, you must use these products! Or so the advertisers would have you believe.

Do they work? Will you be the most beautiful, the most successful, and the most radiant person if you use these products? Where does the hype end and the help begin?

Cosmetics are defined in the Federal Food, Drug, and Cosmetic Act as "articles (other than soap) intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body’s structure or functions.”
If, while trying to decrease the oily shine on your face, you make your skin overly dry, or if you’re spending a lot of time outdoors in very cold weather, you may want to use a moisturizer. “Teens really should only use a water-based moisture lotion labeled ‘non-comedogenic,’ which means it doesn’t clog pores,” says Dr. Barry Leshin, M.D., associate professor of dermatology at the Wake Forest School of Medicine. “Heavier oil-based moisturizers can cause acne cosmetica—an [acne-like] skin condition directly attributed to the use of cosmetics.”

The following are all considered cosmetics:
- skin care creams, lotions, powders
- perfume, cologne, toilet water
- makeup (lipstick, foundation, blush)
- nail polish, polish remover, cuticle softener
- hair coloring preparations
- deodorants
- shaving cream, aftershave, skin conditioner
- shampoo (except dandruff shampoos)
- bath oils and bubble bath
- mouthwash and toothpaste (with whiteners it is considered a drug)

**Skin Care**

Cosmetics can’t work miracles, but they can help keep your skin clean and looking moist and soft. They also can temporarily close pores, plump up skin to make it appear smoother, and give you a rosy glow or blush.

Many cosmetic products are designed to protect the skin of people over 30 against dryness and the accompanying wrinkles. But these aren’t the concerns of most teens. The biggest skin problem for most teenagers is acne. Some studies show that all adolescents have acne to some degree because when puberty hits, your skin starts secreting more oil. This contributes to blackheads and pimples, which cause your pores to stretch a little bit. Although acne cannot be avoided simply by washing your face, the oils on the surface of your skin can be diminished by frequent washing with cleansers made for that purpose. And there are many treatments available for acne both in over-the-counter and prescription strengths (see “Acne Agony” in the July-August 1992 FDA Consumer).

**Ingredients**

What cosmetics can or cannot do for your complexion is determined by the ingredients of the cosmetics and your own complexion. Cosmetics contain ingredients from nature and from the laboratory. Some work well for cleaning, others are good for lubricating—and some don’t do very much at all.

It’s a good idea to read the labeling on cosmetics to find out what the product contains. Some ingredients, such as alcohol and mineral oil, are fairly common. Others seem more unusual and may require some explanation. Here are some examples.
- **Liposomes**: Microscopic sacs manufactured from natural or synthetic fatty substances which include phospholipids (components of cell membranes). When properly mixed with water, phospholipids can “trap” any substance that will dissolve in water or oil. Manufacturers say that liposomes act like a delivery system, depositing product ingredients into the skin. When the liposomes “melt,” the ingredients, such as moisturizers, are released.
- **Aloe vera**: A plant from the lily family, aloe vera in large amounts has anti-irritant properties. Although it’s an ingredient in many skin lotions, it would take much more aloe vera than most products contain for the anti-irritant properties to work.
- **Vitamins**: Foods containing vitamins A, D, E, K, and some of the B complex group are necessary in diets to maintain healthy skin and hair but, according to Dr. Leshin, “There is no evidence that vitamins or other additives are advantageous when applied to the skin.”

**Allergies**

Overuse of some cosmetics can cause allergies and other skin problems (see “Cosmetic Safety More Complex Than at First Blush,” in the November 1991 FDA Consumer). Ingredients such as fragrance and preservatives can cause allergic reactions in some people. Skin reactions, which doctors call contact dermatitis, should be taken seriously. (See “Contact Dermatitis: Solutions to Rash Mysteries” in the May 1990 FDA Consumer.) Even if you’ve used a cosmetic for years with no problems, you can develop an allergic reaction as you become sensitized to one or more of the ingredients.

Some cosmetics are labeled “allergy-tested” or “hypoallergenic,” but products with these claims don’t always offer a solution to cosmetic allergies. “Hypoallergenic” means only that the manufacturer feels that the product is less likely to cause an allergic reaction. Before placing this claim on the label, some companies conduct tests, and others simply don’t include perfumes or other common problem-causing ingredients in their products. The claim “dermatologist-tested” on
Cosmetic Safety

Serious problems from cosmetic use are rare, but sometimes problems arise with specific products. FDA warned consumers last February about the danger of using aerosol hairspray near heat, fire, or while smoking. Until hairspray is fully dry, it can ignite and cause serious burns. Injuries and deaths have occurred from fires related to aerosol hairsprays.

Another problem can occur with aerosol sprays or powders: If they are inhaled, they can cause lung damage.

The most common injury from cosmetics is from scratching the eye with a mascara wand. Eye infections can result if eye scratches go untreated. Such infections can lead to ulcers on the cornea, loss of lashes, or even blindness. To play it safe, never try to apply mascara while riding in a car, bus, train, or plane. Sharing makeup can also lead to serious problems. Cosmetics become contaminated with bacteria the brush or applicator sponge picks up from the skin—and if you moisten brushes with saliva, the problem is much more severe. Washing your hands before using makeup will help prevent exposing the makeup to bacteria.

Artificial nails can be a source of problems, especially when not applied correctly. Artificial nails must be completely sealed because any space between the natural nail and the artificial nail gives fungal infection an opportunity to begin. Such infections can lead to permanent nail loss.

Sleeping while wearing eye makeup can cause problems, too. If mascara flakes into your eyes while you sleep, you might awaken with itching, bloodshot eyes, and possibly infections or eye scratches. To avoid eye infections or injury, remove all makeup before going to bed.

Other safety tips are:

- Keep makeup containers closed tight when not in use.
- Keep makeup out of the sunlight to avoid destroying the preservatives.
- Don't use eye cosmetics if you have an eye infection such as conjunctivitis (pink eye), and throw away any makeup you were using when you first discovered the infection.
- Never add any liquid to a product unless the instructions tell you to.
- Throw away any makeup if the color changes or an odor develops. Preservatives can degrade over time and may not be able to fight bacteria.

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

■ The National Mammography Quality Assurance Advisory Committee was established by FDA July 6, according to an Aug. 5 final rule. The committee will advise the agency on: quality standards and regulations for mammography facilities and for organizations accrediting the facilities, regulations on sanctions, procedures for monitoring standards compliance, a mechanism to investigate consumer complaints, and reporting new developments in breast imaging. (FR Aug. 5)

■ Safe handling instructions for raw meat and poultry products will soon appear on the label, according to a USDA Food Safety and Inspection Service interim final rule that took effect last Oct. 15. To prevent food-borne illness caused by bacterial and parasitic contaminants, the new label lists instructions for safely storing raw meat and poultry, preventing cross-contamination, cooking raw products, and handling leftovers. (FR Aug. 16)

■ Uncured meat patty regulations went into effect last Sept. 1. The new regulations, issued Aug. 2 by USDA’s Food Safety and Inspection Service, specify heat-processing, cooling, handling, labeling, and storage requirements for hamburgers, Salisbury steaks, breaded and battered chopped veal steaks, beef patties, and pork sausage patties. The regulations were issued to reduce the incidence of E. coli, salmonellosis, and listeriosis outbreaks associated with improper cooking, handling and storage of those products. (FR Aug. 2)

■ Certain drug labeling controls have been revised to reduce the frequency of mislabeling and recalls, according to an FDA final rule that took effect last Aug. 3. The rule defines the term “gang-printed labeling,” specifies conditions for the use of such, exempts from some requirements manufacturers that use automated 100 percent labeling inspection systems, and requires manufacturers to identify filled drug containers they have set aside for future labeling. (FR Aug. 3)

■ Nominations for 16 public advisory committees in FDA’s Center for Drug Evaluation and Research (CDER) are being accepted. Nominees must have research or clinical experience appropriate for the committee to which they are nominated. For information on consumer nominations, contact Phyllis Weller, Office of Consumer Affairs (HFE-20), FDA, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-5006. For information on other nominations, contact Adele S. Seifried, CDER (HFD-9), FDA, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-5455. (FR Aug. 26)

■ The 1993 FDA Almanac is now available. The Almanac provides data that show how the agency fulfilled its regulatory mandates in the past year and its impact on public health. The Almanac costs $19.50 for paper copies and $9 for microfiche. To order, request document number PB93-213726 from National Technical Information Services, 5285 Port Royal Road, Springfield, VA 22161; telephone (703) 487-4650.

■ An updated pesticide residues in food database is available. “Enhancement of the Pesticide Residues Information System” contains more than 500,000 analyses for residues of 329 pesticides in over 100,000 fresh fruits and vegetables and processed foods. To order the two-volume report, call or write National Technical Information Services, 5285 Port Royal Road, Springfield, VA 22161; telephone (703) 487-4650. Request document number PB93-209013 for volume one and PB93-209021 for volume two. Volume one costs $17.95; volume two costs $44.50. (FR Aug. 4)
A Tumwater, Wash., man convicted of lacing Sudafed 12-hour capsules with cyanide in an attempt to kill his wife and collect her $700,000 insurance policy was sentenced to life in prison without possibility for parole. Two other persons died as a result of the attempt.

Judge Barbara Rothstein of the U.S. District Court for the Western District of Washington sentenced Joseph Earl Meling, 31, last June 8 to two concurrent life terms plus 75 years in prison.

“The judge used sentencing guidelines for first-degree murder, stating that Meling’s planning and preparation for the crime was extraordinary, detailed and elaborate, and it was only through good fortune that more persons didn’t die,” said James A. Davis, director of the Investigations Branch in FDA’s Seattle district office.

In addition, Meling was ordered to pay $3.5 million in restitution to Burroughs-Wellcome, the manufacturer of Sudafed, and $4,794.29 to Blue Cross for his wife’s medical bills. Any money Meling earns through media contracts and book royalties will be used to make the restitution.

The district court jury found Meling guilty April 2, 1993, of six counts of product tampering that led to the deaths of two people and the near-fatal poisoning of his wife; two counts of perjury; and three counts of mail fraud.

During the investigation of the case, Meling’s wife, Jennifer, separated from her husband and filed for divorce. They later reconciled, and Jennifer testified in her husband’s defense at his trial.

According to court documents, Joseph Meling called 911 the evening of Feb. 2, 1991, to report that his wife had lapsed into unconsciousness moments after ingesting Sudafed, a decongestant, at their Tumwater apartment.

As emergency staff worked to keep her alive and to identify the underlying cause of her rapidly deteriorating state, Joseph Meling suggested to the doctors that they should check for cyanide poisoning.

On Feb. 4, the physicians caring for Jennifer Meling called police after she told them she had taken Sudafed. On Feb. 5, cyanide was identified in her blood.

“Meling attempted to kill his wife, Jennifer, on Feb. 2. The Tumwater Police executed their search warrant [of the Melings’ apartment] on Feb. 7, and then we were notified on Feb. 15 through Burroughs-Wellcome, the manufacturer of Sudafed,” that they had received a report of product tampering, says Thomas Piekarski, a Seattle district compliance officer.

“There was no information at that time to indicate that any other products on the market had been tampered with,” he says.

FDA received no new information until Friday, March 1, when the Seattle office learned that the Feb. 11 death of Kathleen Daneker, 40, of Tacoma, Wash., was due to poisoning. The Pierce County, Wash., coroner identified cyanide in her body fluids.

The next afternoon, March 2, Piekarski says, two Tacoma police officers arrived at the Seattle office with the blister pack of Daneker’s remaining Sudafed capsules to determine whether any other capsules had been tampered with.

“The police left with the evidence. However, we contacted Burroughs-Wellcome and others because now we knew there was something wrong,” Piekarski says. “We went public with the news late Saturday evening—it hit the 11 p.m. news.”

The Thurston County, Wash., coroner, meanwhile, was investigating the Feb. 18 death of 44-year-old Stanley McWhorter of Lacey, Wash. When he heard the news report, he recalled that McWhorter had died shortly after taking a Sudafed capsule, Piekarski says. That night the coroner provided FDA with tissue samples that showed cyanide poisoning.

The next day, March 3, at 7 a.m., nearly all of FDA’s Seattle district’s employees, as well as investigators from the agency’s Portland, Ore., and Spokane and Yakima, Wash., resident posts, started removing Sudafed capsules from store shelves.

For the next three weeks, district investigators worked around the clock collecting Sudafed from all stores along the 47-mile stretch of Interstate 5 from Olympia, Wash., north to South Seattle. Approximately 900 samples consisting of 248,000 capsules were collected and screened by analysts visually, microscopically, and by fluoroscopic x-ray.

“We found one [contaminated Sudafed capsule] at a Pay ‘n Save Drug Store in Tacoma,” says Victor Meo, a Seattle district investigator. “That’s where we saved one life.”
In addition, as a result of the publicity, two consumers returned packages each containing a cyanide-laced capsule they had purchased at the Drug Emporium Store No. 6 and a Kmart Discount Store, both in Tacoma, about 30 miles from Tumwater.

While most of the investigators were pulling Sudafed packages off store shelves, investigators Kim Rice, Spencer Morrison, Meo, and Piekarski, worked with the FBI. "At this point we didn't have a suspect," Piekarski explains. "We [FDA and FBI investigators] broke into three teams because, although we suspected Meling, he was only one of many suspects at the time. "We didn't assume that Joe Meling had done it. All we knew was that his wife was poisoned, there were two people dead, and there were some boxes of Sudafed found on the market which had tainted capsules in them.”

FDA’s team interviewed family members, friends, acquaintances, and co-workers of Jennifer Meling, and some store owners in the Tacoma area. Other agents were assigned to do the same with the Daneker and McWhorter family and friends.

"We interviewed people to find out if Joe had confessed to them that he had done it," Piekarski says. "We also asked what Joe’s and Jennifer’s marital situation was, if he lived beyond his means, what his behavior was around the time his wife was hospitalized, what he had talked to people about regarding her death. "We talked to a number of Jennifer’s co-workers at the school where she taught. They all knew there was some sort of marital strife—some were aware she had to place a call to the Tumwater police department one night when she thought he was going to put her head through the wall,” he says.

In addition, in trying to identify the source of the cyanide, Rice, Morrison, Meo, Piekarski, and FBI agents visited all the places that sold cyanide in the Puget Sound and Yakima areas, collecting copies of the toxic registry list of cyanide purchasers. (Washington has a Toxic Substance Registry that requires all those who purchase toxic chemicals to leave their name and address.)

Joseph Meling’s name was not on any of the lists. The investigators visited everyone whose name appeared on a list to question them about their purpose in purchasing the cyanide.

FBI agents later learned that on Jan. 11, 1991, Joseph Meling had purchased one pound of sodium cyanide for $11 from the Emerald City Chemical Co., in Kent, Wash., according to court documents. He presented a false Washington state driver’s license, in the name of “Richard Johnson,” to a sales clerk who required the identification for the purchase.

Joseph Meling then emptied his wife’s supplement capsules, which resembled Sudafeds, and replaced the contents with cyanide. He then placed the cyanide-laced capsules in blister packs, replaced the packs in Sudafed packages, and returned them to store shelves.

Sudafed capsules are made tamper-resistant by a blue band sealing the two shells, making it virtually impossible to pull them apart. The supplement capsules Joseph Meling used had no such seal and came apart easily.

According to court documents, Joseph Meling pressed police for a Sudafed recall because he knew that other cyanide-laced capsules would be recovered, enabling him to claim his wife’s poisoning was the result of tampering.

The court document states: “Joseph Meling summoned a police officer to the hospital. Believing he would be swiftly..."
exonerated upon the inevitable discovery of the other cyanide-laced Sudafed, he brazenly labeled himself the ‘primary suspect’.”

Jennifer Meling claimed her supplement capsules were green and white. FDA’s Morris later determined there are no green and white over-the-counter capsules for the supplement she was taking and that her supplements were instead nearly identical in color to Sudafed capsules.

FDA’s team showed a montage of six photographs, one of which was Joseph Meling, to store employees where the cyanide-laced capsules were purchased or found to see whether any employee could place him in the store about the time the Sudafed was purchased. FBI agents later found a KMart employee who identified him from a similar montage and recalled him being in the store about the time the Sudafed was purchased.

Most of the 18-month investigation was completed by the end of June, although investigators continued to follow leads and collect evidence up to the trial date.

Joseph Meling was initially indicted in the district court on 20 counts on April 21, 1992. Nine charges were later dropped by the prosecution.

FDA’s Meo assisted in trial preparation and served as a prosecution witness.

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

Caught in the Act

When a Hawaiian food importer returned to the scene, he got caught in a crime.

The scene was the Waimanalo dump, where Amador Remular, owner of Philippine Food Distributors, Waipahu, deposited condemned lumpia (pastry) wrappers, and then got caught sneaking back to try to salvage some of them. His illegal salvage operation cost him $2,130 in fines and forfeiture of the wrappers.

The case started last Feb. 25 when an FDA investigator at the island port sampled a shipment of lumpia wrappers consigned to Remular. Laboratory tests showed the wrappers were contaminated with cat and dog hairs and insect fragments. On March 10, the shipment was detained. FDA refused entry of the shipment on April 22 and gave Remular the option of reexporting or destroying it. He chose to destroy the goods.

U.S. Customs instructed Remular to bring the condemned lumpia wrappers to the pier on May 19, where federal agents would join him and accompany him to the Waimanalo dump. Lee Johnson, consumer safety inspector at FDA’s Honolulu resident post, went to U.S. Customs to check the shipment with the Customs agents.

Remular arrived at Customs with 59 of the 96 cases of condemned wrappers because the entire shipment did not fit in his van. He was to arrange to destroy the remaining 37 cases at a later date. Johnson says there were no discrepancies, so Remular left for the dump accompanied by another van with U.S. Customs and National Guard personnel.

After unloading 57 cases at the dump, Remular asked Customs to allow him to keep two cases for his personal use. He was told he could not, so the remaining two cases were dumped with the others.

Customs checked Remular’s van at the exit to the dump. Satisfied it was empty, they left. When the agents didn’t see Remular drive onto the main highway, however, they became suspicious and returned to the access road. Through binoculars, they watched Remular’s van returning up the hill to the area where the shipment had been dumped. When the van disappeared over the hill at the dump, the agents returned to the main highway and waited for Remular to reappear.

When Remular reached the highway, he met big trouble. Customs agents stopped the van, searched it, and found seven cases of the condemned lumpia wrappers. They arrested Remular and seized his van and cellular telephone on the grounds that they were used in the commission of a crime. A National Guardsman drove the vehicle back to Honolulu.

After being questioned by Customs, Remular left to pick up the remaining 37 cases of the refused shipment for destruction. Customs released Remular when he finished the delivery, but retained the van and the cellular telephone.

Johnson went to the Customs office on May 20 to observe the destruction of the ...
seven cases of lumpia wrappers Remular had tried to salvage. The officials tore open the cases and individual packages and poured bleach on the product.

Customs released Remular’s van and phone to him on June 14 after Remular paid a $2,130 deposit. The deposit included the $1,200 appraisal value of the van, $300 for the phone, $307 for van storage, and a $325 fine for taking back the lumpia wrappers. On Aug. 13, Remular’s deposit was remanded as his fine.

—Judith E. Foulke

Illegal Stimulants Seized

The U.S. Marshals Service recently seized over-the-counter drugs valued at approximately $97,000 because they were being marketed as stimulants without approved new drug applications.

The Hammer Corporation, Atlanta, Ga., distributed the drugs under its own labels and trade names—“Kickers” (manufactured by Threshold Industries, Scotts Valley, Calif.) and “Efedrin” (manufactured by Alpine Health Industries, Orem, Utah). Label statements and promotional displays promoted the drugs for use as stimulants.

FDA regulations allow only one active ingredient, caffeine, to be used in over-the-counter stimulant drugs. Neither Kickers nor Efedrin contains caffeine. Kickers contains various ingredients derived from plants, and Efedrin contains ephedrine hydrochloride.

Although Kickers was labeled as a nutritional supplement, FDA considered that descriptors on the labels and display and promotional materials such as “instant energy,” “high performance,” “feel the power,” and “energy pills” promoted the product for use as a stimulant.

Efedrin contains 25 milligrams of ephedrine hydrochloride per tablet, which may be sold legally to relieve difficult breathing caused by bronchial asthma. However, the Efedrin was sold in retail displays with big signs saying “POWER-UPS” along with caffeine-containing stimulant tablets called “Caf-Tab.” FDA determined that this display promoted both products as stimulants.

On March 9, 1993, U.S. marshals seized the following products at Hammer Corporation’s Atlanta plant:

• about 100 one-tablet packets labeled “All Natural Kickers Nutritional Supplement”
• about 10 cases, each containing 1,000 one-tablet packets of Kickers, labeled “Kickers Instant Energy Hammer Corp., 1000 PCS”
• about 17 cases, each containing six cartons of 48 14-tablet bottles, labeled “All Natural Kickers Nutritional Supplement”
• about eight cases, each containing six cartons, of 48 100-tablet bottles labeled “Efedrin Maximum Strength Bronchodilator”
• about seven cases, each containing 7,000 six-tablet packets, labeled “Asthma Relief, Fast-Acting Efedrin”
• display material promoting Efedrin and Kickers.

FDA’s Atlanta district office first inspected Hammer in October 1990 after a consumer complained to the agency that Efedrin was being promoted as a recreational drug to high school students. In addition, the agency’s Detroit district office asked the Atlanta office to inspect Hammer after finding Ma Huang listed as an ingredient on Kickers packages sold in Michigan. Ma Huang is a Chinese herb that has been linked to serious adverse effects, including stroke and memory loss.

Investigator Emily L. Molony found that the labels on Hammer’s products and the display cartons Hammer distributed to retail stores included unsubstantiated medical claims such as “Heightens Awareness,” “Ultimate Energy Source,” and “Increases Physical Performance.” In addition, the address for Hammer listed on the labels was for an old building the firm no longer occupied, and the firm did not have a complaint file or an established recall procedure. These findings violated FDA regulations.

FDA sent Hammer a warning letter in June 1991. However, Hammer’s response on July 15 was unsatisfactory, according to FDA’s division of drug labeling compliance. Although the letter indicated the firm would revise the Efedrin labels, it made no commitment to bring the Kickers labels and display material into compliance with FDA regulations.

On Oct. 31, FDA investigators returned to Hammer and found labels for Efedrin no longer included the claim “Heightens Awareness.” Although there were no new labels for Kickers, the firm promised revised labeling was in production and would be ready by the end of November.

Investigators returned to Hammer on July 14, 1992, after FDA’s Minneapolis district office queried Atlanta about the accuracy of the “nutritional supplement” labeling found on Kickers products sold in Minnesota.

They found that Hammer had deleted the claims “Ultimate Energy Source” and “All Natural Chinese Herbal Blend” from new labels for Kickers, but continued to use old labels. In addition, the firm had not changed its promotional materials.

FDA considered Hammer’s actions inadequate and, at the agency’s request, the U.S. Marshals Service seized all Kickers and Efedrin in the company’s possession on March 9, 1993. The firm never filed a claim for the seized drugs and on Aug. 4, FDA requested that the court enter an order for destruction.

—Dori Stehlin

FDA Consumer / November 1993 / 39
Medical Gloves Destroyed

More than 2,200 pairs of medical examination gloves with labeling, valued at about $51,000, were each pierced with a large screwdriver and destroyed last July, under the terms of a consent decree.

F&L Medical Products Company of Vandergrift, Pa., promoted its gloves as sterile and intended for reducing physicians’ exposure to scattered radiation during fluoroscopic procedures. The gloves, however, did not meet federal standards. FDA worked with the firm to try to bring the gloves into compliance, but F&L finally chose to destroy the gloves rather than recondition them.

On a routine inspection of F&L from Feb. 28 through March 19, 1991, investigators with FDA’s Philadelphia district found the firm had failed to:

- adequately test for compliance with required specifications for sterile examination gloves, such as leaks and pouch seal integrity
- establish and implement quality control measures, such as proper validation of sterilization procedures
- properly audit the quality assurance program.

In addition, product labeling indicated that after one use, the gloves could be re-sterilized and reused, but F&L had not included instructions for re-sterilization, nor had it tested the product or submitted evidence to FDA to support the claim.

On June 20, FDA sent the firm a warning letter detailing the firm’s violations and explaining that reuse of the gloves, even after re-sterilization, would constitute a significant change that could affect the product’s safety and effectiveness, and that reuse would require additional FDA approval.

Fred S. Foust, owner of F&L, replied that he would stop advertising that the gloves could be re-sterilized and reused and outlined some basic corrective actions. In a follow-up letter, FDA reemphasized the need for pre-market approval for the reuse claims in the labeling.

On Dec. 16, 1991, and Jan. 6 and 9, 1992, FDA reinspected F&L. Investigator Cynthia Rakestraw found that previous violations had not been corrected. When Rakestraw asked about the labeling, Foust showed her a product information sheet with the re-sterilization statement blacked out with a sheer marker, but the wording was still visible. He said he did not have any new product information sheets on hand because production had stopped for two months while the firm was moving from Leechburg to its new location in Vandergrift.

Rakestraw revisited F&L March 17. Foust showed her a product label from the latest shipment he had received from Ortho Tex, the San Antonio, Texas, distributor of the gloves. The re-sterilization statement was blacked out, and Foust said he would do the same for the rest of the labels. He said the statement was mistakenly printed because Ortho Tex had used the wrong printing plate.

Foust also showed Rakestraw new product information sheets with the re-sterilization statement changed to “For greater cost effectiveness, F&L Medical Attenuating Gloves can be re-sterilized without reducing their attenuating properties.” Stapled to the information sheet was a slip stating that FDA had not yet approved the firm’s autoclave re-sterilization procedure and that F&L recommends the gloves be reused only with sterile over-gloves. Foust said similar slips should be on all information sheets, but Rakestraw noted they were not.

On March 26, FDA detained F&L’s entire inventory of gloves, labels, and product information sheets pending seizure. (Detention prohibits shipment of products while seizure proceedings are being arranged.) F&L requested a hearing, but a U.S. marshal seized the goods April 10, the scheduled date of the hearing. The seizure in effect terminated the detention and canceled the hearing.

F&L claimed the seized goods for reconditioning and sent FDA a reconditioning plan Dec. 30. On April 8, 1993, F&L signed a consent decree of condemnation for the entire lot of gloves and labeling. The decree included a provision that allowed for reconditioning within 90 days, after which one more FDA inspection would determine whether the gloves were in compliance or would have to be destroyed.

To assist in the reconditioning, FDA wrote to F&L on April 16, noting additional steps the firm needed to take, including resubmitting an application for pre-market approval for reuse of the gloves. Foust chose instead to destroy the gloves. This was done July 29.

—Judith E. Foulke
Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against goods alleged to be in violation, and criminal and injunction proceedings are against firms or individuals charged to be responsible for violations. The cases generally involve foods, drugs, devices, or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce.

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

SEIZURE ACTIONS

Food/Contamination, Spoilage, Insanitary Handling

PRODUCT: Cod fillets, frozen, four lots, at Portland, Dist. Ore.; Civil No. 92-1554 BE.
CHARGED 12-8-92: While held for sale, each lot of the article contained either wood splinters or was decomposed; and, in addition, one lot contained insect filth and one lot was unfit for food due to rancid fish—402(a)(3).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66636; S. No. 92-591-732 et al.; S.J. No. 1)

PRODUCT: Egg whites, cooked and peeled, frozen, at St. Louis, E. Dist. Mo.; Civil No. 4:93CV 0021 SELF.
CHARGED 2-1-93; When shipped by AlMark Foods, Inc., Gainesville, Ga., the articles contained a decomposed substance—402(a)(3).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66666; S. No. 93-527-177; S.J. No. 2)

PRODUCT: Herring steaks, canned, and other labeled and unlabeled canned fish products, at Stonington and Prospect Harbor, Maine; Civil No. 92-0072-B.
CHARGED 4-21-92: While held by Stinson Seafood Co., L.P., Stonington, Maine, the articles (some of which were labeled "Beach Cliff . . . Bite Size Herring Steaks in Soy Bean Oil . . . Stinson Seafood Co., Prospect Harbor, Me.") had been prepared and packed under insanitary conditions—402(a)(4).

DISPOSITION: The articles were claimed by the dealer, who denied the charge, and petitioned to obtain samples for testing purposes. The government did not object to the claimant conducting sampling, but did object to that part of the claimant’s petition which requested permission on behalf of the State of Maine to test 130 cans of the articles, when the claimant had no standing to petition on behalf of the state and the state was not a party to the action. Pursuant to stipulation of the parties, no action was taken concerning state sampling, but the claimant was authorized to take post-seizure samples. The claimant served written interrogatories on the government, and the government served written interrogatories and a request for the production of documents upon the claimant. Subsequently, the parties entered into a consent decree of condemnation authorizing the claimant to attempt to bring the articles into compliance by relabeling for use as non-human animal food. After three amendments to the decree to facilitate procurement of the required bond, the articles were reconditioned and the good portion, consisting of 545,195 cans was released. (F.D.C. No. 66405; S. No. 92-660-683/684; S.J. No. 3)

PRODUCT: Rice, glutenous, and sweet rice, at Portland, Dist. Ore.; Civil No. 93-173-BE.
CHARGED 2-11-93: While held for sale, the articles had been held under insanitary conditions—402(a)(4).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66658; S. No. 93-667-726; S.J. No. 4)

PRODUCT: Shrimp, frozen, at Whistler, S. Dist. Ala.; Civil No. 92-1038-RV-M.
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66638; S. No. 92-609-381; S.J. No. 5)

Animal Feed

PRODUCT: Tuna fish chunks, canned, at Brooklyn, E. Dist. N.Y.; Civil No. 92-1121.
CHARGED 3-10-92: While held for sale, the article contained decomposed tuna fish—402(a)(3); the article was pet food which had been relabeled as human food, thereby concealing its inferiority—402(b)(3); and the article was offered for sale under the name of another food—403(b).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66354; S. No. 92-647-582; S.J. No. 6)

PRODUCT: Tuna fish chunks, canned, at McKeensport, W. Dist. Pa.; Civil No. 91-1161.
CHARGED 4-30-92: While held for sale, the article contained decomposed tuna fish—402(a)(3); the article was pet food which had been relabeled for human use, thus concealing its inferiority—402(b)(2); and the article was offered for sale under the name of another food—403(b).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66406; S. No. 92-607-533 et al.; S.J. No. 7)

PRODUCT: Tuna fish chunks, canned, at Norwich and North Syracuse, N. Dist. N.Y.; Civil No. 92-CV-441.
CHARGED 4-6-92: While held for sale, the article was pet food relabeled as human food, thus concealing its inferiority—402(b)(3); and the article was offered for sale under the name of another food—403(b).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66396 and 66400; S. No. 92-543-695; S.J. No. 8)

Drugs/Human Use

PRODUCTS: Various drugs, at Washington, Dist. Columbia; Civil No. 92-1039.
CHARGED 5-1-92: When shipped from outside the District of Columbia, the labels of various medicated antiseptic and germicidal soaps (e.g., “Asepso soap . . . Prickly Heat and Infections ... Edward Cook & Co. Ltd. . . London EC4, England,” “1G Skingard soap . . . International Generics Ltd. . . London England,” “Top Gel MCA Germicidal Soap . . . SR.Liscate (Milan) Italy” and “Topsyne . . . Germicidal Soap . . . Supplied By: Well Use Co., Ltd. . . New York, N.Y.” . . Nigeria Agent: Zeco Enterprises”) lacked the established name and quantity of each active ingredient—502(e)(1)(A)(ii); the labels of two prescription drugs (“Top-Gel MCA . . . tube of 30 g. Fluconzoline . . . M.C.A. . . (Milan), Italy” and “Topsyyn . . . Gel tubo da 30g . . . Recordati . . . Syntex”) lacked the prescription legend—503(b)(4); one of the prescription drugs (i.e., Topsyyn Gel in tubes) lacked a label containing all the required statements in English—502(c); the label of one lot of soap (“Dermovate . . . Germicidal Soap”) lacked the name and address of the manufacturer, packer or distributor—502(b)(1); and most of the various drugs (e.g., “Tura . . . Medicated Skin Lightening Cream with Special Sun Screening Agent . . . Tura International Limited . . . Made In England,” “Woodward’s Celebrated Gripe . . . Water . . . Made in Nigeria by Novapharm,” and “Topsyyn . . . Cream . . . Laboratoires Cassene . . . Paris”) were new drugs without effective approved New Drug Applications—505(a).
DISPOSITION: A claim to the articles was filed by International Wholesalers Corp., Washington, D.C. Subsequently, pursuant to an unopposed motion by the claimant, the court granted the claimant additional time to file an answer to the complaint. Ultimately, pursuant to stipulation, the parties consented to the entry of a consent decree disposing of the action, authorizing the claimant to withdraw its claim, and providing for the destruction of the articles. (F.D.C. No. 66372; S. No. 91-645-201 et al.; S.J. 9)

CHARGED 1-15-93: When shipped by Nutritional Enterprises, Inc., Deer Park, N.Y., or Sundown Products, Oakland Park, Fla., the articles labeled “ARX2000 . . . tablets . . . Yucca Extract . . . [or “POTION ONE . . . tablets . . . Yohimbe” or “Essential . . . softgels . . . Pumpkin seed oil” or “Salubrin . . . tablets . . . shitake extract”]” Distributed by Research Health Care . . . New Troy, MI,” and accompanied by a “Doctors’ Guide to Mechanical Herbs Written By: Pamela Love . . . Published By: Research HealthCare . . . Yucca . . . Pumpkin Seed . . . Yohimbe . . . Shitake” were new drugs without effective approved New Drug Applications—505(a); the articles’ labeling was false and misleading due to representations and suggestions that the articles were safe and effective for their intended purposes and uses—502(a); and the articles’ labeling lacked adequate directions for their intended uses—502(f)(1).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66613; S. No. 92-550-769; S.J. No. 10)

Medical Devices

PRODUCT: Laser medical devices, two seizure actions, at Dallas and Arlington, N. Dist. Texas; Civil Nos. 3-92-CV-584-H and 4-92-CA-234-Y.
CHARGED 3-26-92 and 3-27-92: The articles, which were labeled “AZ5000 . . . Laser Photonics . . . Orlando, Florida . . . Model YCM- OOA-AZTH . . Manufactured July [or “February”] 1990,” were class III devices, and the articles did not have approved pre-market approval applications in effect—501(f)(1)(B).
DISPOSITION: Default decrees ordered destruction. (F.D.C. Nos. 66394 and 66397; S. Nos. 92-617-034 and 92-604-480; S.J. No. 11)

PRODUCT: Lasers for medical uses, three seizure actions, at Dallas and DeSoto, N. Dist. Texas; Civil Nos. 3-92-0047-G, 3-92-0048-T, and 3-92-0049-G.
CHARGED 1-8-92: The articles, which bore labels such as “AZ 5000 Laser Photonics . . . Orlando, Florida Model YCM- OOA-AZTH . . Manufactured August 1990,” were classified as class III devices, and the articles lacked effective approved pre-market approval applications—501(f)(1)(B).
DISPOSITION: The articles were claimed by A.Z. Health Care Group, Inc., Dallas, Texas, who denied the charges. The actions were consolidated for trial. A partial default judgment defaulting all persons except the claimant was entered. Subsequently, the court struck the claims for lack of service. Ultimately, after withdrawal of
certain retained council, a default decree ordering destruction was entered and the articles were destroyed. (F.D.C. Nos. 66270, 66301 and 66302; S. Nos. 91-583-793 et al.; S.J. No. 12)

PRODUCT: Pin hole eyeglasses, and components, at Brooklyn, E. Dist. N.Y.; Civil No. CV-92-1877.
CHARGED 4-21-92: The articles (which were assembled by Professional Product Research, Inc., t/a Professional Foot Care Products, Brooklyn, N.Y., and which were accompanied by the package insert reading “The Vision Clear Story . . . Professional Product Research, Inc.”) were class III devices, and the articles did not have an approved pre-market approval application—501(f)(1)(B); the articles' labeling contained false and misleading claims for improving vision and preventing additional eyesight loss—502(a); the articles' labeling lacked adequate directions for their intended purposes since such could not be written—502(f)(1); and the articles were not included in a required list, and required information respecting the device had not been provided—502(o).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66410; S. No. 92-600-115; S.J. No. 13)

PRODUCT: Stay-wet wetting solutions for contact lenses, other devices labeled “sterile,” and in-process and component materials, at Abita Springs, E. Dist. La.; Civil No. 92-0786.
CHARGED 3-4-92: The articles, which were manufactured by Sherman Pharmaceuticals, Inc., Abita Springs, La., had been manufactured, packed and stored under circumstances that failed to conform with current good manufacturing practice—501(h); and the manufacturer failed to submit required information—501(i)(2).
DISPOSITION: A consent decree of condemnation authorized the manufacturer to bring into compliance, although the charges were denied and the decree was entered for the purpose of compromise. The decree required that before the commencement of any attempt to bring the articles into compliance, the claimant would submit details of the proposed reconditioning and receive written authorization to commence reconditioning. The proposed reconditioning plan would include a number of specified provisions. Subsequently, the consent decree was amended to provide for an FDA inspection, an affidavit of compliance, and (4) the drugs used and the dosages used. Additional provisions provided for an FDA inspection, an affidavit of compliance by the defendant concerning notice of the decree, and various reimbursement to FDA of its costs. (Inj. No. 1128; S. No. 89-540-005 et al.; S.J. No. 16)

CHARGED 5-11-92: The article (which was labeled [insert] “The Sea-Band . . . For Your Traveling Pleasure . . . Manufactured by Sea-Band UK Ltd., England”) was a class III device, and it did not have an approved pre-market approval application in effect—501(f)(1)(B); the article’s labeling lacked adequate directions for the article’s intended purposes because such directions could not be written—502(f)(1); and the required pre-market notification covering the device had not been filed—502(o).
DISPOSITION: Default—ordered destroyed. (F.D.C. No. 66422; S. No. 92-609-774 et al.; S.J. No. 15)

INJUNCTION ACTIONS

CHARGED 6-27-90 in a complaint for injunction: That the defendants run a dairy operation and also sell and consign calves and cows for slaughter for human food by firms that ship the edible tissue of such animals—beef and veal—in interstate commerce. The defendants used antibiotic drugs (new animal drugs) to treat their calves and cattle; and reports by the government (FDA and the U.S. Department of Agriculture) show that during the approximately three preceding years at least 23 such calves and dairy cows contained, in their edible tissue, new animal drug residues above the amount permitted by law—402(a)(2)(D). FDA inspections of the defendants' operations documented a number of specified conditions concerning the defendants' animal husbandry practices that resulted in the edible tissue of the defendants' animals containing excessive new animal drug residues and such calves and cows being held under insanitary conditions whereby they might have been rendered injurious to health—402(a)(4).
DISPOSITION: A consent decree of permanent injunction enjoined the complained-of acts. In addition, the defendants were enjoined from interstate deliveries of cattle, including calves, for human consumption unless and until a number of specified conditions had been met. Such conditions included (1) the establishment of a record-keeping and guarantee system, (2) positively identifying each animal medicated by the defendants, (3) the dates of medication, and (4) the drugs used and the dosages used. Additional provisions provided for an FDA inspection, an affidavit of compliance by the defendant concerning notice of the decree, and various reimbursement to FDA of its costs. (Inj. No. 1128; S. No. 89-540-005 et al.; S.J. No. 16)

CHARGED 6-15-92 in a complaint for injunction: That the defendants were engaged in preparing and holding for sale foods for use on trains traveling throughout the United States; that foods had been prepared, packed or held under insanitary conditions—402(a)(4); that FDA inspections of AMTRAK rail service cars found evidence of rodent infestation and other insanitory conditions; that the defendants were well aware of continuing insanitory conditions on rail service cars; and that, unless enjoined, there was a substantial likelihood of continued violations.
DISPOSITION: A consent decree of permanent injunction was entered, without any admissions as to the allegations in the com-
plaint, but after the establishment and implementation of an interim sanitation program. The decree enjoined the complained-of violations and enjoined operations involving interstate food. The decree also enjoined doing any act that might cause, or failing to take any measure that might prevent, the transmission or spread of communicable diseases unless a number of specified conditions were met. Such conditions included the immediate and complete implementation of the interim program and the establishment and submission to FDA of a comprehensive written sanitation and food service program that should provide for a number of specified things (e.g., the regular inspection of all rail service cars; the removal of cars from service as necessary for cleaning, fumigation, repair, and replacement; and the training and, as necessary, retraining of all employees responsible for sanitation and food handling). (Inj. No. 1299; S.J. No. 17)


CHARGED 12-11-91 in a complaint for injunction: That, at the defendant’s facility at Morattico, Va., the defendants processed, prepared, packed, held, and distributed in interstate commerce crab meat that contained the poisonous and deleterious substance Listeria monocytogenes (a pathogenic bacterium) and that had been prepared, packed or held under insanitary conditions—402(a)(1), 402(a)(4). FDA inspections and inspections by the Virginia Department of Health, Bureau of Shellfish Sanitation (VBSS), revealed both L. monocytogenes contamination in crab meat as well as insanitary food processing conditions in the RCV facility. FDA laboratory analysis revealed that samples collected by FDA of finished crab meat product contained L. monocytogenes. FDA and VBSS had provided the defendants with prior notice and warning concerning their violative conduct; and the government believed that, unless restrained by the court, the defendants would continue to violate the law.

DISPOSITION: An interim consent decree enjoining the processing and distribution of crab meat unless the crab meat had been first processed under specified conditions (e.g., crab meat for freezing would be processed with detailed thermal processing procedures and other crab meat would be processed with detailed pasteurization procedures). Meanwhile, the parties litigated the action and the defendants served written interrogatories on the government. In the defendant’s answer to the complaint, they denied the charges (except to admit that Listeria monocytogenes could be found in crab meat). The defendants also asserted, as affirmative defenses that there was no substantial likelihood of irreparable harm or injury sufficient to form the basis of injunctive relief and that they had taken prompt and direct steps to cure each and every alleged deficiency noted by FDA and VBSS; and there was no reason or necessity for granting injunctive relief. The parties served various requests for the production of documents on each other.

Ultimately, a consent decree of permanent injunction was filed. The corporation’s treasurer was dismissed as a defendant from the action. The remaining defendants were permanently enjoined from the complained-of violations; and were enjoined from preparing or shipping any crab meat from their Morattico facility unless and until specified conditions were met, including the thorough cleaning of their facility and its equipment, the implementation of all procedures of the corporation’s quality assurance manual, the certification of compliance by an expert selected by the defendants, and the appropriate pasteurization or moderate thermal processing of all crab meat on hand. (Inj. No. 1249; S. No. 90-585-278 et al.; S.J. No. 18)

MISCELLANEOUS ACTIONS


CHARGED 2-13-92 by McGhan Medical Corp., Santa Barbara, Calif., against HHS Secretary Louis Sullivan, M.D., FDA Commissioner David A. Kessler, M.D., and the Food and Drug Administration, in a complaint for declaratory and injunctive relief: That, by law, certain medical devices must be made subject to a Pre-Market Approval Application (PMA) approved by the HHS Secretary (who delegated his authority over PMAs to the FDA Commissioner; that the Commissioner was attempting to force breast implants containing silicone gel off the markets; that FDA had classified breast implants as class III devices in 1988, had issued a final regulation calling for PMAs for such implants in April of 1991, and required that PMAs be submitted by July 9, 1991 (on which date McGhan filed a PMA for its implants). At a November 1991 meeting of the General and Plastic Surgery Devices Advisory Panel, the panel recommended not to approve McGhan’s PMA, but unanimously recommended that such implants remain available.

However, on Jan. 6, 1992, the FDA Commissioner announced a voluntary moratorium on the manufacture, distribution, sale, and use of such implants, announced his intention to recall the panel to reconsider its recommendation of continued implant availability, and subsequently scheduled the panel meeting for Feb. 18–20, 1992. McGhan requested a postponement of the panel meeting, pointing out that it could not find credible experts to evaluate the data and appear at the panel meeting on such short notice. In McGhan’s suit, McGhan made various allegations of unfair and improper acts, including allegations concerning the members of the panel, concerning prejudgment by the Commissioner, and concerning FDA requests for information.

DISPOSITION: McGhan filed a motion for a temporary restraining order and a motion for leave to take depositions. The court reviewed and considered McGhan’s complaint and motions and heard argument from both parties. In accordance with an oral ruling made in open court, the court denied McGhan’s motions and found that there had been no violation of McGhan’s right to due process. Subsequently, McGhan voluntarily dismissed without prejudice its claims. (Misc. No. 969; S.J. No. 19)
Now is the time to teach your kids good habits. Like eating low-fat, low-cholesterol foods. And getting plenty of exercise. You might save wear and tear on their hearts. And on your chair. You can help prevent heart disease and stroke. We can tell you how. Call 1-800-AHA-USA1.