

FDA
CONSUMER

November 1984

"COMPUTERS
MAY BE GOOD
FOR YOUR HEALTH"

monitor





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Freshly harvested corn pours from an auger into a waiting wagon to become part of this country's \$20 billion annual corn crop. This mainstay of American agriculture is processed into thousands of products for the benefit of man and beast. To learn about the versatility of corn and its importance in our diet, see Basic To Our Food Chain Is Plain Old Field Corn, beginning on page 24.

—Photo courtesy of U.S. Department of Agriculture

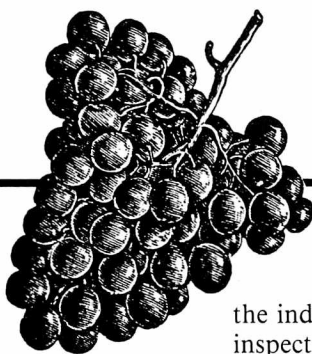
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Juice Makers Sound Off

Fruit juice manufacturers say they can live with FDA's labeling requirements and generally favor regulatory standards for their products. But they also believe that FDA, by its actions—or inactions—can stifle innovation in their industry and promote unfair competition.

These views were among those expressed by executives of 10 firms involved in the production of canned fruit juices, nectars and concentrates and reported by FDA in its second agency impact analysis. The first such study, conducted in the fall of 1982, dealt with manufacturers of pickles, sauces and salad dressings. (See "Straight Talk From The Pickle People" in the December 1983-January 1984 *FDA Consumer*.) In both studies, the opinions were gathered during informal discussions between FDA staffers and industry executives.

Many of the views expressed by the first group last fall were echoed by the fruit juice representatives. For example, the firms generally viewed themselves as trustworthy and responsible while seeing FDA as usually competent and reasonable but given to excesses and unpredictability.

But the fruit juice industry executives also said they felt susceptible to unreasonable cost burdens resulting from FDA actions. They said, for example, that cumbersome regulatory procedures and unpredictable agency behavior can stifle innovation and product development. They pointed to artificial sweeteners as an area where regulatory uncertainties have tended to make the industry "gun shy," fearing that even currently approved additives could go the way of cyclamates and be withdrawn from the market, without any consideration of the economic effects.

They also questioned the wisdom—and the adverse economic impact—of what they viewed as premature agency statements about public health problems. Agency advice for the public to reduce sodium consumption, for example, was seen by some of the executives as jumping the gun on what they believe has not yet been proven to be a problem.

Product labeling was a topic of great concern to

the industry representatives (second only to plant inspections by FDA investigators). The present scope of nutrition labeling requirements was generally deemed acceptable by the group, although two firms remarked on the high cost and technical difficulty of determining actual nutrition levels for their products. Two firms even felt that FDA should expand its labeling requirements to include "pull dates" (the dates at which the product should no longer be sold because of possible spoilage or loss of quality) to satisfy consumer demand.

FDA's role in helping to curb unfair competition also stirred considerable interest. The executives asked for more enforcement of regulations against adulteration of fruit juices by the "bad apples" in their industry, particularly importers of foreign-produced fruit juice concentrates, some of which may contain pesticide residues or other contaminants.

Product packaging was seen as an area ripe for cooperation between the juice industry and FDA. The group felt such cooperation can work not only in solving health problems, such as excessive amounts of lead in cans, but also in fostering technological innovation, such as aseptic packaging, which offers extended shelf life at less cost than bottles or cans.

What advice did the executives have for the agency? The suggestions voiced most often were that FDA be more circumspect and reasonable, especially by becoming more aware of the economic impact of its actions.

Suit Against Hair Analysis

A Maryland-based hair analysis service is deceptive and potentially harmful to consumers' health, the Federal Trade Commission charged in a complaint filed Aug. 7 in federal court. The commission asked a federal court to grant injunctions that would prohibit A & A Laboratories from making false claims about the service. The agency also asked the court to freeze the assets of the firm for possible consumer redress.

Included in the complaint were A & A Laboratories and its divisions—Trace Mineral Systems and New Age Nutritional Supplement

Co.—plus Arthur Furman, his wife Ethel, and their son Alan, who together control the companies.

According to the commission, the defendants sold hair analysis services as well as vitamins, minerals and other dietary supplements that they advertised in national health-oriented magazines and at “holistic” health fairs around the country.

The ads said the laboratory would perform a scientific analysis of hair samples and provide a detailed computer printout, based on the analysis, that identifies mineral deficiencies and excesses in the customer’s body. Then, according to the ads, specific vitamin, mineral and other dietary supplements would be recommended and offered for sale. Cost of the hair analysis was \$36.95.

The companies contend that mineral deficiencies and excesses are associated with physical and mental disorders, such as diabetes, arteriosclerosis, infertility and nervousness. However, the FTC said that the firms’ recommendation that hair analysis be done every four months may lead some individuals to forego proper medical attention during that time, exposing them to substantial health risk or injury.

The FTC charged that hair analysis does not provide a basis for determining mineral levels in consumers’ bodies not does it provide a reliable basis for recommending dietary supplements. (FDA agrees. See “Hair Analysis? May As Well Be Bald” in the April 1983 issue of *FDA Consumer*.)

The Furmans, A & A Laboratories, and New Age Nutritional Supplement are based in Fort Washington, Md. Trace Mineral Systems and two other A & A divisions, Holistic Hair Analysis and Micro Trace Minerals, are located in Alexandria, Va.

The FTC filed the complaint in the U.S. District Court for the Eastern District of Virginia, Alexandria Division.

Magazine Price Reduced

The price of *FDA Consumer* has been reduced to \$17 a year domestic. The subscription cost had been \$19 for the 10 yearly issues. The foreign price will now be \$21.25, down from \$23.75. Single

copies are reduced from \$2.50 to \$2. The changes, made by the Government Printing Office, are effective with this issue. They reflect, in part, economies made in publishing the magazine.

Steroid Substitute Questioned

Weider Health and Fitness Inc. and its president, Joseph Weider, falsely represented that their Anabolic Mega-Pak and Dynamic Life Essence nutrient supplements were effective substitutes for anabolic steroids, the Federal Trade Commission has charged.

Ads for Weider’s products claim the Anabolic Mega-Pak is “scientifically created,” produces “faster-than-ever-before muscle growth,” and is a “Natural Steroid Replacement Kit You Can Live With.” Ads for Dynamic Life Essence say it is superior to “conventional protein sources to muscle up,” is “unlike any other amino acid source in the world,” and that “Life Essence Builds Bigger Muscles—Faster!”

Weider’s appeal is primarily to bodybuilders and weight trainers who believe anabolic steroids increase muscularity and strength. The company advertises in two major bodybuilding magazines it publishes through subsidiaries, *Muscle and Fitness* and *Flex*.

The Anabolic Mega-Pak contains five pills or capsules with various amino acids, minerals, vitamins and herbs. A 30-day supply costs \$24.95. Dynamic Life Essence consists of capsules or powders of amino acids, which can cost up to \$60 for a 30-day supply.

Weider’s ads suggest that the two products be taken together and claim that after several months of use the results will be similar to those obtained from taking anabolic steroids, but without their dangerous side effects. (What those side effects can be was discussed in “Anabolic Steroids: Pumping Trouble” in the September 1984 issue of *FDA Consumer*.)

According to FTC, in an administrative complaint filed July 27, Weider lacked proof for these claims and for the allegations that the products would result in faster or greater muscular develop-

ment, that Dynamic Life Essence is unlike any other amino acid source in the world, and that the Anabolic Mega-Pak was developed by a team of the world's most renowned nutritional biochemists, exercise physiologists and trainers.

The FTC issues an administrative complaint when it has reason to believe that the law has been or is being violated and when it appears in the public interest to initiate a hearing before an administrative law judge.

If Weider is judged to have acted illegally, the commission could order him to stop making the claims and to notify all mail-order customers, distributors and retail outlets of the FTC order. The commission might also ask a court to order consumer redress or refunds.

Weider Health and Fitness is based in Woodland Hills, Calif.

11th Orphan Drug OK'd

A new "orphan" drug to treat severe cases of Tourette syndrome has been approved by FDA. The drug, pimozide, was shown in clinical trials to decrease the involuntary muscular movements and uncontrollable vocal sounds that characterize this rare neurological disorder.

The new drug, to be marketed by McNeil Pharmaceuticals under the name Orap, is for people who do not respond to or cannot tolerate Haldol (haloperidol), a drug that has been used for years to treat cases of Tourette syndrome.

Because Tourette syndrome is rare (there are an estimated 100,000 persons in the United States with the disorder), the number of patients participating in clinical studies of pimozide was relatively small. Thus, some safety issues remain unresolved, including the possibility of an increased rate of pituitary tumors. However, Tourette syndrome is so debilitating that the drug's benefits are considered to outweigh its potential risks.

Pimozide is the 11th orphan drug to be approved since 1982 when the Department of Health and Human Services set up its orphan products program. "Orphan drugs" are products that are of little commercial interest, usually because the diseases

they are intended to treat are relatively obscure. (For other *FDA Consumer* articles on orphan drugs, see "Rx For Orphan Drugs" in the September 1980 issue and "A Future For Orphan Drugs" in the April 1983 issue.)

Microwave Danger Discounted

Cooks who use microwave ovens are not in danger of getting cancer from the oven's radiation, FDA says. News reports of a recent study indicating possible carcinogenic effects in rats from exposure to microwave radiation have led to some consumer concern about the safety of microwave ovens.

In the study, conducted at the University of Washington and sponsored by the Air Force, 100 rats were exposed over their whole bodies to microwave radiation for 21 hours a day for their entire lives (up to 25 months), at a level equivalent to approximately 5 milliwatts per square centimeter in humans.

Even a person making extensive use of a microwave oven would be exposed to levels far below this, according to FDA. Most ovens tested by the agency leak no microwaves at all. The maximum leakage allowed by FDA's standards is 5 milliwatts per square centimeter at a distance of two inches from the oven. Even if an oven leaked to the maximum allowed, the portions of the user's body at a normal arm's length from the oven would receive no more than 2 percent of the level used in the study. Farther away from the oven the exposures would be dramatically lower.

In addition, the experimental animals were exposed over their entire lifetimes, whereas even frequent oven users are close to an operating oven only a small part of the time. To approximate the conditions of the study, a human's entire body would have to be exposed continuously at a distance of two inches from an oven leaking at the maximum permitted level.

Since FDA standards are being met or bettered by oven manufacturers, concern about microwave radiation from these products appears to be unwarranted, the agency says.



Diet and the Elderly

Oldsters Often Target Of 'Nutritional Cure' Hype

by Chris Lecos

This is the third in a series on dietary needs of the elderly.

How would you like to look better, feel younger, live longer, shed fat quickly, give your sex life a boost, or cure a chronic ailment—just by taking a vitamin or mineral supplement?

Sounds great, doesn't it? Too bad it isn't true.

The fact of the matter is, according to nutrition authorities, many people, particularly the elderly, are

often victimized by such advertised claims even though there is little or no scientific evidence to back them up.

Many older Americans are susceptible targets for a wide variety of false nutritional claims for products that, in fact, provide little or no health benefit. The products only serve to increase the financial burdens of many elderly who must live on small, fixed incomes, says S. Jaime Rozovski, Ph.D., an assistant professor of public health at the Institute of Human Nutrition at Columbia University.

In an article in *Aging* magazine (April-May 1984), Rozovski wrote: "Older persons are a major target for opportunists who pander to people's needs to feel better, cure disease, look younger and lose weight rapidly. They also play on people's fears by trying to convince them that they are being poisoned by food additives and pollutants and by claiming that the whole food supply is being downgraded by processing. They thus pave the way to sell their 'all natural' foods, which cost a great deal more and often have little overall effect on a person's health and longevity."

Some elderly men and women may need to take vitamin and/or mineral supplements but, Rozovski said, that determination should be based on sound medical advice. Unnecessary and ill-advised purchase of supplements not only deprives an older person of funds that could be spent for foods that are essential to good health, but it also may lead to excessive—and potentially toxic—intake of certain vitamins and minerals.

If "popular nutritional cures" are used as a replace-

“Older persons are a major target for opportunists who pander to people’s needs to feel better, cure disease, look younger and lose weight rapidly.”

ment for sound medical ones, the ailment could get worse through lack of proper treatment, especially where serious illness is involved, Rozovski warned. There is no evidence, he continued, to support claims that health foods or so-called “natural” or organic foods are necessarily better than conventional food fare.

“Natural foods have no higher nutritional value than conventional foods; they just cost more,” he declared. “Because people have to spend so much on these foods, they are forced to reduce the money spent on other foods that actually may be more nutritionally balanced.”

A similar concern was expressed in a 1981 report of a study conducted by the Department of Family Medicine at the Medical College of Ohio in Toledo. The study involved 309 persons 60 and older in Defiance County, Ohio. The median income of those taking supplements was \$440 a month.

The study revealed that 49 percent of the participants (53 percent of the women and 38 percent of the men) were taking vitamin or mineral supplements, or both. Of those taking supplements, 77 percent used multiple vitamins, 28 percent used vitamin C, 21 percent vitamin B complex, 19 percent vitamin E, and 13 percent calcium supplements.

Forty percent of the supplement users reported they were doing so on the advice of their physicians, and another 4 percent on the recommendations of other health professionals. The remaining 56 percent relied on family members, friends, the media and other sources—a situation that the study described as “potentially alarming” since the majority of those “making such recommendations [for supplement use] are presumably uneducated in the field of nutrition and are unaware of the health problems of the person for whom they are making recommendations.”

The National Institute on Aging (NIA), in its publica-

tion *Age Page*, stated that a well-balanced diet will provide most elderly men and women who are in good health—in fact, most people of all ages—with the nutrients they need for healthy living.

A proper diet, NIA advised, should include at least two servings a day of milk or dairy products (such as cheese, cottage cheese or yogurt); two servings of high-protein foods (such as lean meat, poultry, fish, eggs, beans, nuts or peanut butter); four servings of fruits and vegetables, including citrus fruits or juice and a dark green, leafy vegetable; and four servings of bread or cereal products made with whole-grain or enriched flour, rice or pasta.

Certain diseases and other health problems may require supplements. A doctor, for example, treating a patient with osteoporosis—a condition in which the bones are thin and brittle from progressive mineral loss—may advise calcium supplements, usually in combination with vitamin D. Some elderly people recuperating from surgery or suffering from any of a variety of illnesses common to older people also may need a dietary boost by taking nutrient supplements. But that’s a decision only a doctor should make.

“But too often,” says the NIA publication, “people take high-dose supplements of various vitamins and minerals without a doctor’s advice in the hope of preventing or curing a disease or condition. This can be a waste of money or, worse, a threat to health.”

“Scientists still have much to learn about the special nutritional needs of the elderly. At present, there is no reason to believe that large amounts of vitamins and minerals in supplement form will help prevent or treat health problems or slow the aging process.”

Guidelines for the nutrient requirements of the general population are spelled out in the recommended dietary allowances (RDAs) published by the National Academy of

“Large amounts of some supplements may upset the natural balance of nutrients that the body normally maintains.”

Sciences' Food and Nutrition Board. Many of the multi-vitamin and mineral pills that are used as supplements contain the full RDA levels; in some instances, they contain less. Many people take such pills as “insurance” that daily nutrient needs are being met. But the *Age Page* article warns that this insurance can backfire: “Large amounts of some supplements may upset the natural balance of nutrients that the body normally maintains. Too much of some of them can affect the way others act. Although extra amounts of some nutrients are not absorbed and pass out of the body, others can build up to dangerous levels.”

A recent survey by the Food and Drug Administration on vitamin and mineral supplement use in the United States disclosed that nearly 40 percent of the population—excluding pregnant and breast-feeding women—consumed one or more supplements. In many instances, the survey indicated, Americans of all ages were taking anywhere from “5 to 10 times” the recommended amount of individual nutrients. The FDA survey also found that—for all age groups—use of supplements was more prevalent among women than men.

The use of “megavitamins”—large amounts of individual vitamins or combinations—concerns many scientists because many such supplements, notes the NIA publication, “contain 10 to 100 times the RDA for some vitamins and minerals. People may take them because they think the RDAs are only minimum requirements and that, if a little is good, a lot will be better. The allowances, however, are set high enough to cover the needs of most healthy people.”

Large doses of some nutrients can have serious effects. Vitamins A and D are essential to good health but in large amounts can be harmful. An excess of vitamin A can cause headaches, nausea, diarrhea and, eventually, liver

and bone damage. High vitamin D doses can cause kidney damage in adults. Excessive amounts of iron also can build up to harmful levels in the liver and other body organs in some individuals.

Some supplements—like the misnamed “vitamin B₁₅,” or “pangamic acid”—are valueless despite claims made for them. For example, pangamic acid sometimes is promoted as a treatment for heart disease, diabetes, glaucoma, allergies and other ailments. It is not a vitamin and, as the *Age Page* piece noted, it “has no medical usefulness.” Still another unnecessary supplement sold in pill form is superoxide dismutase (SOD), sold as an “anti-aging” pill. It was given some credence—falsely—after scientists discovered that animals with long lifespans have more SOD in their bodies than those that live shorter lives.

There is no doubt that some elderly men and women do not get enough vitamins and minerals from the food they eat. Illness, economic difficulties, digestive problems, chewing and dental difficulties, certain drugs, and other factors can affect one's nutrient intake, sometimes so much that use of a dietary supplement becomes necessary. But, as the NIA publication notes: “If you are taking a supplement, or thinking about taking one, ask your doctor or a registered dietitian if it's really necessary. He or she can check your health status and your diet, and decide if any steps should be taken to improve your nutrition. . . . Consider checking with your doctor before taking any over-the-counter dietary supplement, particularly if you have illnesses such as diabetes, high blood pressure, or others.” ■

Chris Lecos is a member of FDA's publications staff.

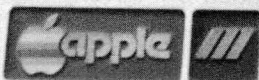
NEXT: The effect of alcohol and medications on nutrition.

WORK-OUTS

**"COMPUTERS
MAY BE GOOD
FOR YOUR HEALTH"**



monitor ///



When computers were first introduced into medicine, they were seen primarily as devices to store great amounts of information, producing cross-checks where needed and retrieving selected portions on demand.

Then came the growing use of computers in the laboratory, often connected to electrocardiogram (EKG) devices and equipment used to facilitate analysis of patient samples, such as blood and urine.

Still later came increasing use of the computer to magnify, extend and sometimes replace older medical technology, such as procedures used in non-surgical exploration of the body. The traditional X-ray method was improved upon in the early 1970s with computerized axial tomography (CAT), which made use of computer techniques to give a realistic and never-before-seen view of inner body structures.

While the CAT scan has made it possible to see what ordinary X-rays cannot detect, even newer computer-based non-surgical devices, such as nuclear magnetic resonance (NMR) machines, are making it possible to obtain three-dimensional views of the human body. NMR makes possible more detailed images of tissues than can be obtained with a CAT scan. (See "NMR Offers A Better Focus On What's Inside Us" in the September 1984 *FDA Consumer*.)

Capitalizing on CAT and NMR, a California physicist has invented a robot that he claims will perform one of the procedures in brain surgery better than a human can. By connecting this robot to a CAT scanner or NMR device, it is possible to compute and then pinpoint the area of the skull where the surgeon should drill to reach the desired section of the brain.

As computers increase in power and decrease in size and cost, entirely new technology becomes possible. Examples include body implants such as artificial inner ears and neural stimulators that relieve chronic pain.

Winner of the 1983 Inventor of the Year Award given by Intellect Property Owners Inc., a society of inventors, was physicist Robert Fischell, of the Johns Hopkins University Applied Physics Laboratory, who has developed a computerized pump that

can be implanted in the body where it will automatically dispense medicine, such as insulin, morphine, hormones and sleep-inducing drugs. The computer will record data about how the device is working, transmit the data, and receive instructions, such as changes in dose rates.

Dr. James D. Meindl, director of the Stanford University Electronics Laboratories, thinks that the widespread adoption of computers into medical research has "profoundly affected" the creative process—"the kinds of ideas that are conceived, what they deal with, and the terms in which they are considered. . . ." Dr. Meindl adds: "Computer simulation of disease processes, physiological mechanisms, and pharmacological interactions, as well as computer analysis of data, has made many important contributions to medical research."

One area where the computer has proven very useful is in the study and interpretation of diagnostic test results, such as those from an EKG. Since a significant proportion of most test results fall into the normal range, using a computer to review the results and signal any abnormality can free a physician from much burdensome and repetitious work; it can also increase the speed at which results are entered in a patient's record.

The computer is now essential to intensive care, where prompt and accurate information about a patient's condition is of the highest importance. "Computers offer tireless observation for such infrequent events as ventricular fibrillation [irregular heartbeats], whose detection is vital," says Dr. Meindl. "In addition, computers allow rapid and complete recall of data already collected. . . ."

At New York's Metropolitan Hospital Center and King County Hospital Center, computers have been used to evaluate the care given to children at outpatient clinics. By means of a set of diagnosis and treatment guides that cover 85 percent of childhood illnesses treated at a doctor's office or hospital clinic, it is possible to be sure that a child gets the same medical care from an intern that would be given by an experienced physician. This set of guides, known as the computer-assisted pediatric protocol system, has reduced

The computer is now essential to intensive care, where prompt and accurate information about a patient's condition is of the highest importance.

the use of unnecessary drugs and tests. It also has encouraged more appropriate treatment, such as the ordering of throat cultures for children with sore throats. One noteworthy accomplishment by this computer system was a reduction from 28.2 to 2.2 percent in antibiotic treatment for simple respiratory illnesses such as the common cold, where antibiotics are rarely needed.

Another advantage of computers is that they can compensate for human and organizational limitations. Dr. Lawrence J. Lutz, professor in the Department of Family and Community Medicine at the University of Utah, cites studies showing that physicians face information demands beyond the capability of the human memory. These studies show that memory failure is particularly evident in drug prescribing, where the physician must be familiar with indications, dosages, pharmacology, side effects and interactions associated with medication.

And Dr. Arthur Krieg, writing in the *Journal of the American Medical Association*, refers to a serious problem in the flow of information to and from the clinical laboratory. "In some settings," Dr. Krieg says, "more than 10 percent of the requests never reach the laboratory; more than 10 percent of reports never reach the patient chart; more than 10 percent of results do not reach the attending physician while still relevant; and . . . under some circumstances laboratory data may be misleading rather than helpful."

What is now being provided in some hospitals is a means of making sure that all relevant information is stored in one place, so it can be gathered easily by those who need it. For each patient, the computer stores results from various health-screening procedures—blood pressure, EKG, biochemistry, blood and urine analysis, X-rays, patient history, etc. Thus, at any time any medical staff member can get a complete and accurate picture of the patient.

Systems of this kind that are already operating include PROMIS (Problem-oriented Medical Information System) at the University of Vermont and HELP in Salt Lake City. The University of Utah's Dr. Lutz says that "having information from multiple sources with the ability to

cross-check will be incredibly useful. For instance, if a patient on digitalis [a heart drug] in the coronary unit had a potassium level drawn, and this level was low, a warning could be sent back to the unit from the laboratory immediately."

The computer's ability to reach into such patient data bases is already having a positive impact on medicine, as shown by use of the data-retrieval system at the National Library of Medicine in Bethesda, Md., which permits almost instantaneous electronic search of 5 million medical books and articles. A New Jersey hospital with a patient suffering from a rare disease recently asked the library for help. A computer quickly searched all relevant articles and discovered a report describing how a similar case had been treated many years before. The doctors followed this advice, and the patient recovered. Small, personal computers that can tap into such data bases through regular telephone lines will give the physician immediate command of far more useful information about patient, disease and treatment than was previously possible. This information can even include X-rays transmitted from remote-disk storage to the physician's office.

Increasing miniaturization of computer memory chips, Lutz believes, will inevitably permit patients to carry their entire medical history with them on a document the size of a credit card. This will enormously enhance the ability to keep track of patient information regardless of time or place, especially important in an aging population where there is a higher percentage of chronic illness.

Perhaps the most dramatic change to be produced by the computer will be to involve patients more directly in their health care. A system called MICKIE is already doing this in a British hospital. Here's how it works:

In the physician's office, the patient is shown the computer. The physician explains how the computer works, how it will help, and such matters as the confidentiality of the information. The patient is assured that the doctor will be available for consultation after the history is completed.

The patient then sits at the computer screen and keyboard and is greeted by the computer:

Increasing miniaturization of computer memory chips . . . will inevitably permit patients to carry their entire medical history with them on a document the size of a credit card.

"I am MICKIE and I am going to ask you some questions about your health. Are you satisfied that the information you give is confidential?" (The patient responds with a YES.)

"I also need some idea of how old you are [this helps to eliminate irrelevant questions]. Are you under 16?" (NO) "Are you over 65 then?" (NO)

"Now, how are you feeling? Do you feel well?" (NO)

"I'm sorry you're not feeling too good. Next I need to know a few details about your general health. Have you had German measles?" (NO) "Do you suffer from allergies or sensitivities of any kind?" (NO) . . .

This goes on for about a half hour, with the MICKIE continually making encouraging comments, as well as asking questions. When the patient is finished, all the doctor needs to do is type a code on his or her own computer to view a summary of the answers or obtain a full printout.

Other systems using the same technique provide more flexibility by permitting the patient to choose such responses as "Certainly yes," "Probably yes," "Possibly yes," and the equivalently qualified negatives.

The computer also is being tried for diagnosing illness. This will require transferring to the computer knowledge about a particular illness that is now available only from medical experts, medical journals and textbooks, and patient records.

The problem is to obtain the knowledge easily and in ways that can be interpreted properly by the computer. Despite the difficulties, computers have been used on an experimental basis to diagnose congenital heart disease, acute abdominal pain, jaundice and other illnesses. One such system, used in San Francisco's Pacific General Hospital to diagnose lung disorders, makes its diagnosis by comparing how a patient's lung is performing with profiles of lung disease victims. It is said to be accurate 80 percent of the time. Another far more sophisticated experimental system includes 3,550 disease symptoms and over 500 individual disease profiles (about three-quarters of all major diseases) based on a review of medical journals and consultation with experts. It analyzes a patient's medical history, suggests questions, and follows up the answers

with more questions before arriving at a diagnosis. In testing the system against cases reported in medical journals, it did about as well as half the hospital doctors did with the actual patients.

As pointed out in a *New England Journal of Medicine* article, a system such as this, at present, "is not sufficiently reliable . . . due to such deficiencies as inability to understand how a disease in one organ can affect others, or how diseases change over time, as well as . . . its occasional attribution of findings to improper causes, and its inability to explain its 'thinking.'"

Nonetheless, Carl Hammer, director of computer sciences for Sperry Univac Corp., says, "Computer-assisted diagnosis is definitely coming by the turn of the century. We are still in the research and development stage, but in 10 or 20 years, some simple diagnoses will be aided by computers [because] computer models can be refined, and we have shown that they can make better decisions than people can, on the average and over the long run."

The computer in medicine will undoubtedly create changes whose dimensions cannot now be fully measured. The rapid and complete reporting and tracking of adverse drug reactions (serious side effects) by means of computers will be of major assistance in making sure drugs are safe and properly labeled. Further, new drugs and medical devices themselves could be designed by computers. A computer-aided design will make it possible to model the impact of a molecule on body cells. It is also possible that FDA sampling and testing of drugs may eventually be totally automated and conducted in manufacturing plants under direct supervision by FDA chemists, thereby reducing the analytical work done in FDA's labs. Perhaps most significant, computers may offer a way to increase the productivity and effectiveness of all who provide health care, thus helping to alleviate a cost crisis as our national health-care bill moves past the \$200-billion-a-year mark. ■

Tim Larkin is a free-lance writer working out of Easton, Md.

What's That Alcohol Doing In My Medicine?

by Annabel Hecht

If you take your medicine in liquid form, with each spoonful you'll get the active ingredient—the chemical that's going to cure or relieve your symptoms—an assortment of inactive ingredients such as coloring and flavors, and, very likely, some alcohol.

Alcohol? In drugs?

Surprising as this may seem, alcohol appears in varying amounts in hundreds of liquid preparations, both prescription and over-the-counter (OTC) drugs. A lot of

these are cough and cold medications taken by all members of the family. While this is not a cause for alarm—the alcohol serves a useful purpose—it is something consumers should be aware of, for there are times when even a little alcohol in a drug could have serious consequences—especially for youngsters.

Parents may wonder if drug companies put alcohol in cough medicine to make tiny tots into toppers. Not in this day and age, although that might well have been the case before the enactment of federal food and drug laws. Patent medicines (as OTC drugs—often sold at traveling medicine shows—used to be called) were liberally laced with alcohol and narcotics. Even the indomitable Lydia Pinkham fortified her vegetable compound with 20 percent alcohol (since reduced to 13.5 percent).

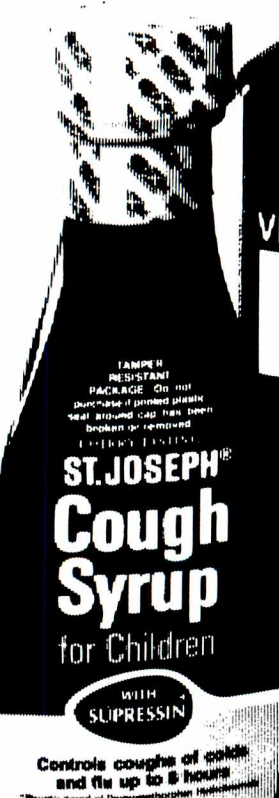
Despite the name, most “patent” medicines were not in fact patented. Manufacturers patented the distinctive shape of the bottle but not the contents, thus avoiding a revelation of their secret formulas. The alcohol in drugs can no longer be a secret, however. To combat the abuses of the patent medicine hucksters, the 1906 Food and Drugs Act required that the quantity, kind and proportion

**How Much Alcohol?
Read The Label**

25%

Here is a sampling of over-the-counter drug products that contain varying amounts of alcohol. Consumers can determine how much alcohol is in the products they use by reading the label.

0.38%



VICKS' NEW IMPROVED
NyQuil

NON-HALLUCINATING
COLD & FLU
PAIN RELIEVER
DECONGESTANT / DEPRESSANT

8.5%



25%



5%



of alcohol in a drug had to be disclosed on the label, or else the product would be considered misbranded.

Today, a person taking an OTC drug can find out if there is alcohol in it simply by reading the label. The alcohol content of prescription drugs is included in the professional labeling (information prepared for doctors, pharmacists and other health-care personnel), and in most cases this information also can be found in such reference books as the *Physicians' Desk Reference*.

Alcohol is most often used in drugs because it is an excellent solvent, in some ways better than water for keeping the other ingredients dissolved in the proper liquid form. Preparations made with alcohol will keep almost indefinitely while many made with water will not.

How much alcohol is used as a solvent in a drug product depends on the solubility of the active ingredients. Some dissolve better in water, while others are more soluble in alcohol. Thus, one liquid product may have less than 1 percent alcohol and another, such as the cough medicine elixir terpin hydrate, as much as 44 percent. Compound benzoin tincture, used to protect irritated tissues in the mouth, contains 64 to 80 percent alcohol,

the amount needed to dissolve the active ingredient. Concentrations of alcohol up to 35 percent are used in many mouthwashes.

Alcohol has other properties that make it medically useful. Alcohol may be included in a drug for its astringent effect in helping to stop bleeding or other secretions. Because it can kill bacteria, it is used to clean and disinfect minor wounds. Alcohol sponge baths have been used to reduce fever because of alcohol's cooling effect as it evaporates. Alcohol increases blood flow when it is rubbed on the surface of the skin, making it an effective ingredient in some liniments.

Two kinds of alcohol are most often used in drugs: ethyl alcohol (also called ethanol or simply alcohol) and isopropyl alcohol (isopropanol). Both have similar solvent properties, although isopropanol may be preferred in some manufacturing processes because it contains less water. However, isopropanol can't be taken internally, so it is used only in products such as lotions or liniments that are applied to the skin.

While any liquid preparation might contain alcohol, those that are called elixirs must, by definition, include



this ingredient. Many cough remedies are elixirs.

(Interestingly, it was misuse of the term "elixir" that gave FDA the legal authority to seize "Elixir Sulfanilamide," a drug that caused more than 100 deaths in 1937. At that time, federal drug laws contained no provisions against dangerous drugs; but the law did state that if the product was called an elixir, it had to contain alcohol. Elixir Sulfanilamide, however, contained not alcohol but diethylene glycol and thus was misbranded, as well as lethal. Had it been called a solution, FDA would not have been able to charge the company with violating the law.)

Although there are advantages in using alcohol in some drugs, there can be risks as well. Alcohol is a sedative and in sufficient quantity can cause drowsiness—a fact duly noted in the labeling of alcohol-containing medications.

People who take medicine, such as disulfiram (Antabuse), to control their consumption of alcoholic beverages have to be on guard against drugs that contain alcohol. Disulfiram discourages drinking by reacting with alcohol in a most unpleasant and potentially life-threatening way, producing flushing, throbbing in the

head and neck, nausea, vomiting, sweating, thirst, chest pain and a host of other reactions. According to the *Medical Letter* (Jan. 11, 1980), mildly unpleasant reactions can occur with as little as one tablespoon of some cough medicines.

Alcohol in drugs poses special problems for children as well. A report by the American Academy of Pediatrics, prepared for FDA and published in March 1984, warned that even small amounts of alcohol can affect a child's central nervous system, causing decreased reaction time, muscular incoordination, and behavioral changes. Alcohol-containing medications also may affect the way other drugs behave in the child's body.

Children exposed to alcohol may develop hypoglycemia (low blood sugar levels), according to the National Institute on Alcohol Abuse and Alcoholism. The blood sugar level is the concentration of glucose, or simple sugar, in the bloodstream. Produced in large part by the liver, glucose provides the energy the body's cells need to carry out their functions. Alcohol can lower blood sugar because, when it is metabolized, or broken down in the

14.5%

6%

26.9%



liver, the production of glucose is shut down.

A person who has fasted for at least 24 hours, or has been on a low-carbohydrate diet, will have used up most of the liver's supply of glucose. Drinking alcoholic beverages under these circumstances can lead to fasting hypoglycemia, usually within six to 12 hours. Keith Ryan, writing in the winter 1983 issue of *Alcohol Health and Research World*, says children are particularly susceptible to hypoglycemia after consuming alcohol because they use up glucose stores rapidly. Some children have died of hypoglycemia after drinking alcoholic beverages, Ryan says. He reminds parents that "a little early-morning experimentation by a child the day after the party could be dangerous, as the level of hypoglycemia does not seem related to the quantity of alcohol a child ingests."

Not only beverages but other alcohol-containing liquids, including medications, cologne and mouthwash, can bring about potentially lethal hypoglycemia in children.

Adults probably would not deliberately drink a mouthwash because denaturing—the adding of certain chemicals to the alcohol—makes it undesirable as a

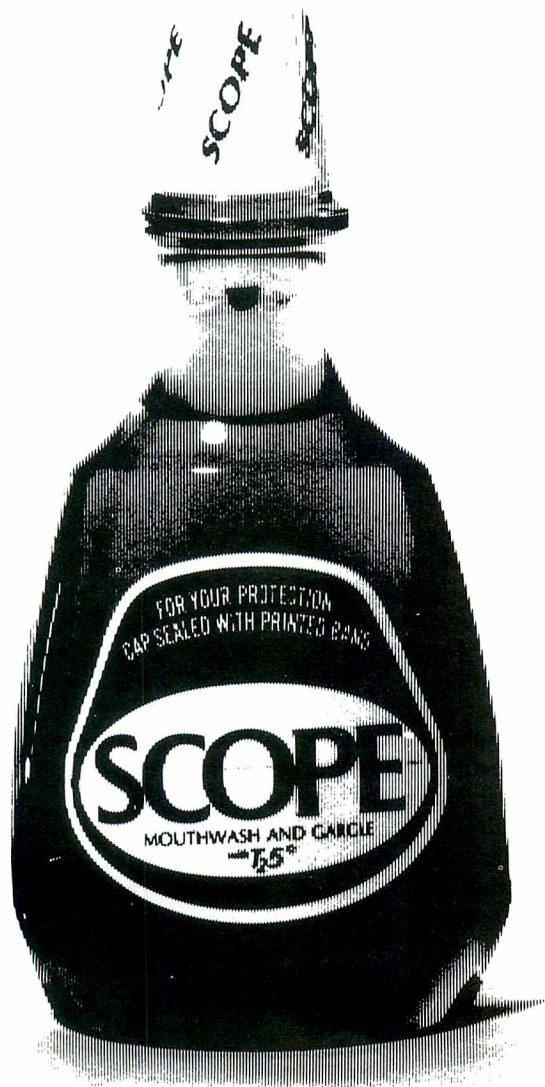
beverage. But children are not so discriminating. The bright colors and pleasing flavors of these products make them particularly tempting to youngsters. The bottles, usually without child-proof caps, are easily accessible in the family bathroom. Persuasive television advertising depicts people smiling happily after using that minty green liquid, but they are never shown spitting it out. A young viewer might think the product is supposed to be swallowed.

Whether it is this mistaken notion or some other reason that prompts them to take a swig of mouthwash, children have been accidentally poisoned by these pretty liquids, some of which contain more alcohol than beer or wine.

Because of growing concerns about the dangers of mouthwashes to youngsters, the Iowa Society of Pedodontists (pediatric dentists) early this year recommended that mouthwashes be packaged in child-resistant containers, in less than potentially lethal volumes, with special labeling to warn parents of the potential hazard, and with a reduced alcohol content.

FDA is concerned about the high alcohol content of

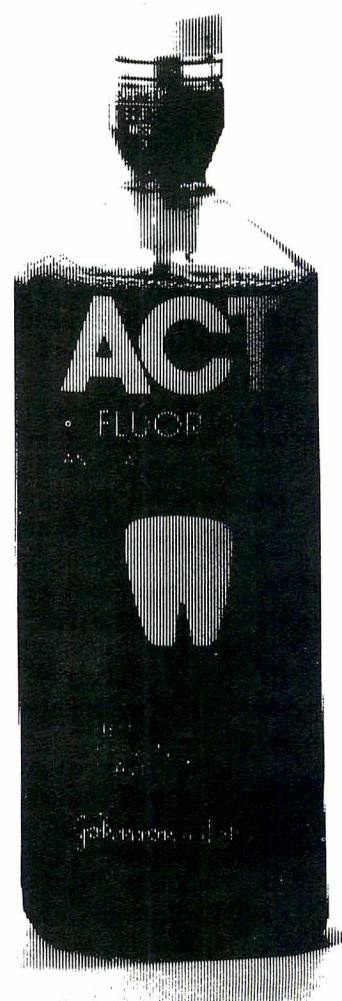
18.5%



14%



7%



It's Still Taxed

FDA is concerned with the safety and effectiveness of the ingredients in the medicines we take, but when one of those ingredients is alcohol the U.S. Treasury Department steps in as well. Whether it is used in manufacturing or consumed as a beverage, alcohol is taxed at the rate of \$21 a gallon.

The alcohol used in making drugs is not the same as the liquid that comes out of a whiskey bottle. What drug makers use is 190 to 200 proof—that is, 95 to 100 percent alcohol. In order to purchase it, the manufacturer must have a permit from the Treasury's Bureau of Alcohol, Tobacco and Firearms (BATF). The buyer pays the full tax but can get back a portion of it by applying to BATF for a "drawback."

To be eligible for a drawback, the manufacturer must pay a special tax and must submit the formula for the product containing alcohol to BATF,

unless the product is made according to a formula prescribed in the *U. S. Pharmacopeia* or the *National Formulary*. BATF chemists check the formula, and if it is found to be a medicine or medicinal preparation that is unfit for beverage purposes, it is approved.

On occasion, the bureau may ask for a sample of a drug for further analysis. The chemists usually taste any product containing more than 20 percent alcohol—the point at which the alcohol becomes apparent—to make sure it can't be passed off as beverage alcohol.

Products that fail the formula review and taste test are rejected. This means that the manufacturer cannot claim the tax drawback.

Specially or partially denatured alcohol—ethyl alcohol made unfit for drinking by the addition of other substances—is used in the processing of various types of drugs, including antibiotics and vaccines, and a number of other FDA-regulated products. There are 46 different formulas for specially denatured alcohol spelled

out in BATF regulations. Each formula is authorized for specific uses.

As in the case of pure alcohol, the drug manufacturer who uses denatured alcohol must have a permit to purchase it and must submit the formulas for his products for BATF review. There are some restrictions on the use of denatured alcohol, however. Drugs and flavoring extracts that are going to be swallowed are not to be made with denatured alcohol if any of the alcohol remains in the finished product. Some mouthwashes do contain high levels of denatured alcohol, but these products are not supposed to be swallowed.

Rubbing alcohol is another product that comes under BATF's watchful eye. It is to be made only with alcohol specially denatured by one particular formula. An alcohol rub made with any other material, such as isopropyl alcohol, can't be called "rubbing alcohol," and it must be labeled in such a way that the consumer will know the product is not rubbing alcohol. ■

OTC liquid preparations, and in 1982 asked the American Academy of Pediatrics to review those drugs that are likely to be consumed by children. The academy's report, recently published in its official journal, *Pediatrics*, made the following recommendations for drugs containing alcohol:

- The amount of alcohol in any medication should be no more than 5 percent.
- Children under 6 should not be given alcohol-containing drugs except under a physician's supervision.
- A single recommended dose of the drug should produce a blood-alcohol level of no more than 25 milligrams per 100 milliliters.
- Appropriate dose intervals should be prescribed to prevent the accumulation of alcohol in the bloodstream.
- The size of the container should be small enough to prevent lethal ingestion.
- Drugs containing more than 5 percent alcohol should have child-resistant caps. (Decisions regarding which products need child-proof safety caps are made by the Consumer Product Safety Commission.)

FDA is evaluating these recommendations as well as those of several expert advisory panels that have assisted in the agency's ongoing review of all nonprescription drugs.

The panel that reviewed cough, cold, allergy, bronchodilator and anti-asthmatic products recommended that pediatric preparations contain as little alcohol as possible, ideally eliminating it entirely. The panel also said that cough/cold products with more than 10 percent alcohol should not be given to children under 6 except under a

physician's supervision. Labeling for elixir terpin hydrate products should warn against giving them to children under 12 except under a physician's supervision, the panel said.

The panel of experts reviewing OTC drugs for relief of oral discomfort said that containers for compound benzoin tincture should hold no more than 30 milliliters (1 fluid ounce) and have child-proof caps.

The advisory panel that reviewed mouthwashes noted in its report that ethyl alcohol lacked evidence of effectiveness as an OTC antimicrobial agent for topical use on the mucous membranes of the mouth and throat in concentrations less than 70 percent. No percentage was recommended, however, since alcohol is used as a solvent for other germ-killing ingredients. In these cases, alcohol could be effective at concentrations below 70 percent. Even as a solvent, the alcohol content of mouthwashes is limited to 35 percent because of its potential for abuse, the panel noted. Mouthwash labels should warn the user to try to avoid swallowing, the panel said.

With alcohol so widely used in so many medications, consumers should be on the lookout for this ingredient, checking the labeling of OTC drugs and asking their physician or pharmacist about prescription products. Parents, especially, should find out whether the medicines their children are taking contain any alcohol, so that their use "for medicinal purposes only" will help, rather than hurt, their youngsters. ■

Annabel Hecht is a member of FDA's publications staff.

Osteoporosis, Calcium and Estrogens

by Roger W. Miller

Osteoporosis is a condition in which bones become weakened. Usually afflicting older people, it results in fractures of the hip, wrist, spine and other bones. Some 1.3 million fractures a year are attributed to the condition.

Women are more prone to osteoporosis than men. Among those who live to be 90, about one out of three women and one out of six men will suffer a hip fracture, most due to osteoporosis. So prevalent is the problem among women that a condition in which the spinal bones become so weak they literally collapse, leaving a hunched back, has become known as "dowager's hump." Such a condition can rob a woman of 2 to 8 inches in height.

In osteoporosis, the weakening of the bones is due to a loss of bone mass or density. A shortage of calcium is one reason for this loss. Another is a lack of the hormone estrogen. Body levels of estrogen decline during menopause, and the resultant bone mass loss continues three to seven years after.

But estrogen loss is not the only reason that four times as many women as men over 55 suffer bone fractures. Women start out with 30 percent less bone mass than men. This is particularly true of Caucasian women, making osteoporosis more of a problem for whites than blacks.

Osteoporosis was the subject of a consensus conference at the National Institutes of Health (NIH) in April 1984. Conference experts agreed on the need for more calcium in the diet as well as the possibility that some women require extra doses of estrogen.

Stepping up calcium intake may also mean a need for more vitamin D, which is required for optimal calcium absorption. The vitamin D link is particularly important because

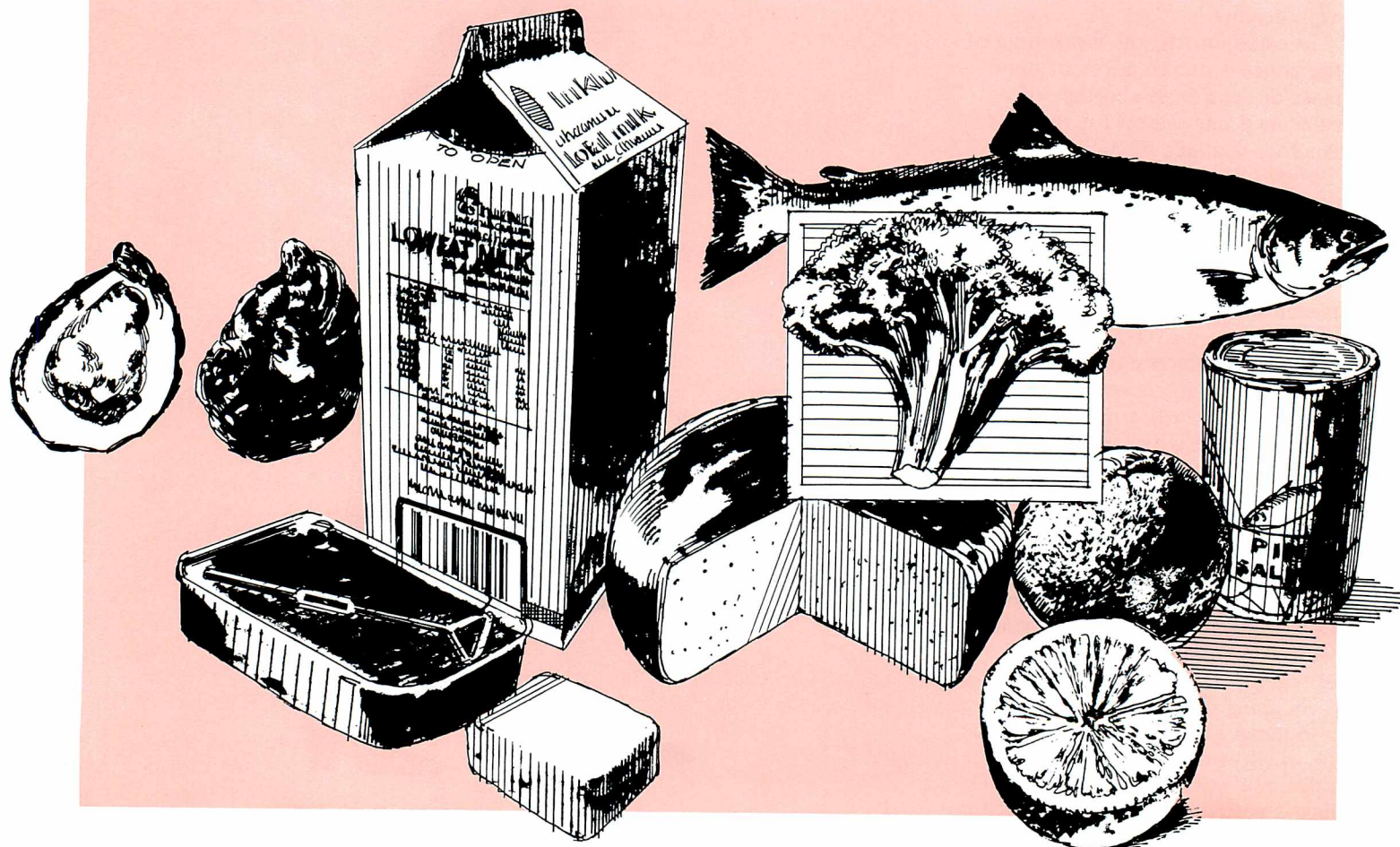


Adult Calcium Consumption

Estimated actual intake 450-550 mg daily

U.S. Recommended Daily Allowance (USRDA) 1,000 mg daily

Recommended by osteoporosis consensus conference experts for post-menopausal women 1,500 mg daily



as people get older their intestines may not absorb calcium as well.

The conferees said that smoking and alcohol contribute to osteoporosis. On the other hand, they agreed that exercise could help prevent bone loss, and they endorsed "modest weight-bearing exercise," such as walking.

The NIH conference findings were based on much research that has been conducted over the years. One of the researchers, Dr. Hunter Heath III of the Mayo Clinic, Rochester, Minn., summed up the situation in the June 1983 issue of *The Annals of Internal Medicine*: "Not entirely in jest, the person at grave risk of postmenopausal osteoporosis may be pictured as a slender 5 foot 2 inch, blue-eyed woman who works behind a desk, smokes a pack a day, enjoys her cocktail before steak, and abjures milk."

The size of Dr. Heath's candidate is a reference to women of smaller stature having less overall bone mass than their larger counterparts.

Bones contain 99 percent of the calcium in the body. The other 1 percent is found in the blood and other body fluids where, among other things, it helps in blood clotting and nerve transmission. (See "Calcium: More Than Just The Strong Stuff Of Bones" in the July-August 1981 *FDA Consumer*.) Calcium is stored in the bones and drawn upon when the daily intake isn't enough to meet the body's needs.

The U.S. Recommended Daily Allowance for calcium is 1,000 milligrams (mg) for adults. However, the consensus conference said that actual intake for adults is only 450 to 550 mg a day, and that women who have passed menopause may need as much as 1,500 mg daily.

Milk and other dairy products, fish

with bones (such as canned salmon and sardines), oranges, leafy green vegetables (such as collards and turnip greens) and broccoli are among the major sources of calcium. A cup of lowfat yogurt contains 350 to 450 mg of calcium, while a cup of skim milk has 300 to 350 mg. A half cup of ice cream and an ounce of mozzarella cheese offer 100 and 150 mg respectively. Those figures indicate that getting up to 1,500 milligrams a day may be no easy task, particularly for people who do not regularly consume such calcium-rich products.

As a result, some experts are recommending calcium supplements for older women. The consensus conference went a step further, recommending that the calcium intake be increased "well before the menopause."

However, a couple of words of caution have been voiced about calcium supplementation. Some people form urinary tract (kidney) stones. Anyone with a history of kidney stones should consult a physician before using calcium supplements.

The second caution concerns the source of calcium. Some people take bonemeal and dolomite (a rock mineral source) for additional calcium. But FDA warned in its April 1982 issue of the *Drug Bulletin* that the two products may contain lead in amounts that would constitute a risk for infants, children, women of childbearing age, and possibly the elderly.

Calcium supplements are readily available in supermarkets and drugstores, and the market is growing rapidly. In February 1984, nearly two months before the NIH conference, both *Advertising Age* and *The Wall Street Journal* ran articles on the growing calcium supplement market

and the producers' plans, now evident, to advertise their products to the public. Previously, their advertisements had been limited mostly to medical and other health professional publications.

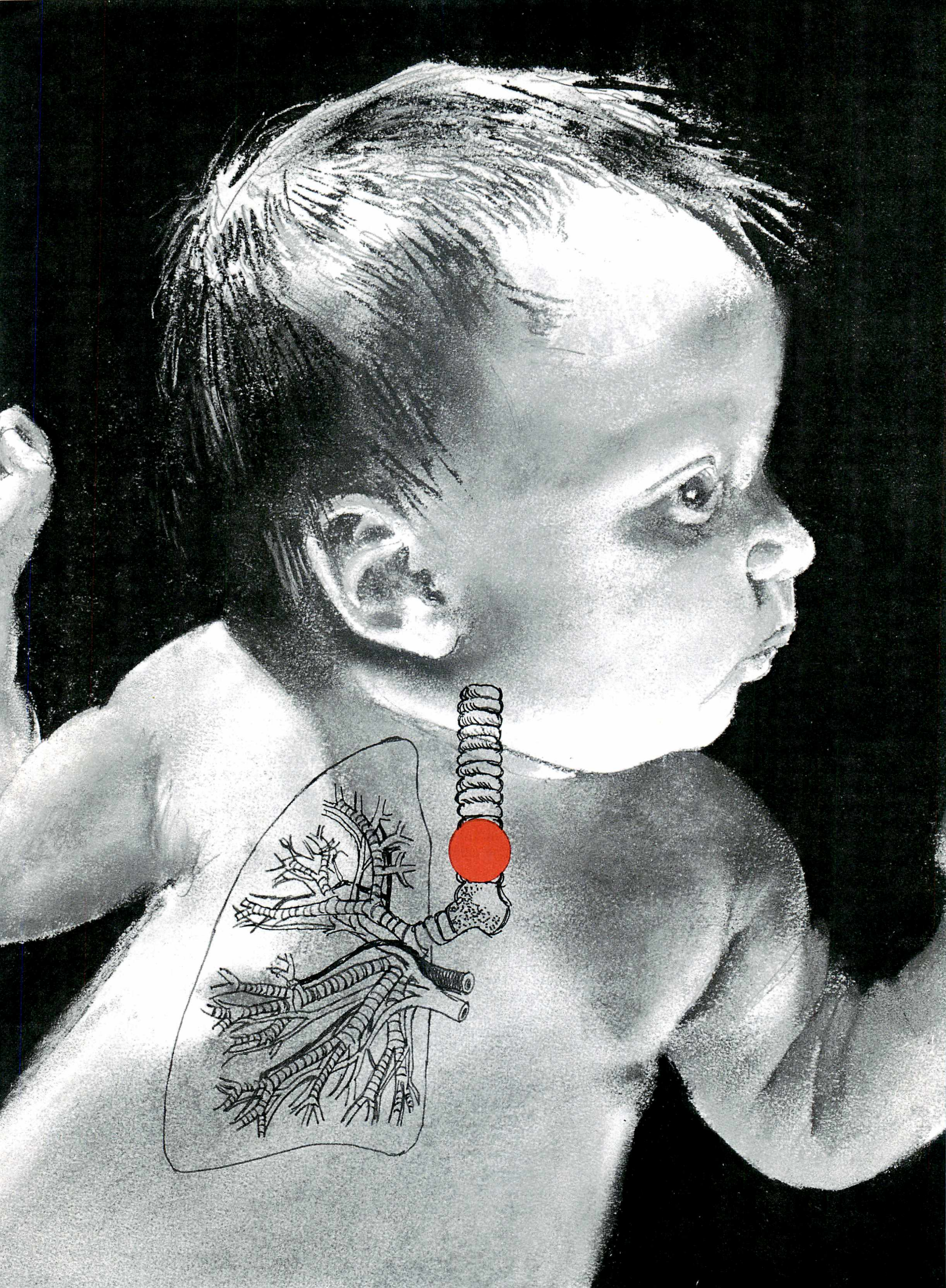
Vitamin D, which helps in calcium absorption, also is found in milk and other products to which vitamin D has been added. In addition, it's available free from the sun. If dietary supplements containing vitamin D are used, they should not exceed the Recommended Daily Allowance of 400 IU (international units) because continued use of high doses has toxic effects.

Growing along with calcium supplement sales is the market for oral estrogen drugs, although a prescription is required to obtain these. The dominant estrogen pill maker had a 6 percent sales gain in the first seven months of 1984.

FDA's Fertility and Maternal Health Drugs Advisory Committee has recommended a labeling change for estrogens that would include their use for prevention and treatment of osteoporosis. The committee also recommended retention of the boxed warning on estrogen labels about the reported increased risk of endometrial (lining of the uterus) cancer faced by women who receive estrogen therapy. The consensus conferees noted that estrogen-associated endometrial cancer "is usually manifested at an early stage and is rarely fatal when managed appropriately."

Estrogen therapy also has raised some concern about breast cancer, but both the NIH experts and the FDA advisory group said the bulk of evidence didn't back up such a link. ■

Roger W. Miller is editor of *FDA Consumer*.



Parents: Guard Against Food-Related Chokings

by Louise Fenner

Every year an estimated 66 to 77 children under the age of 10 die by choking on food. This translates into one death every five days. The vast majority of these victims are less than 5 years old.

Parents who consider safety when buying their children's toys—and who carefully keep small objects such as marbles out of reach—may forget to use the same caution in choosing and preparing their children's food. Some foods, such as peanuts or hard round candies, should never be given to children younger than 4 or 5. Foods that must be chewed should not be given to children until they have developed a complete set of teeth (around age 2).

Food asphyxiation accounts for as many childhood deaths annually as poisoning, but it has received much less public attention. In 1984, however, some concerned parents, along with researchers from Johns Hopkins University in Baltimore, completed a nationwide study of children's food-related choking fatalities. The study examined death reports from 41 states over a three-year period (1979-1981) and analyzed the characteristics of the foods most often involved. The estimate of 66 to 77 childhood deaths per year is based on this study.

Looking only at children under 10, the study found that more than 90 percent of the victims were under 5. The risk was highest in 1- and 2-year-olds and dropped substantially at age 3.

Hot dogs were the item that kids choked on most often, the researchers found. Other foods high on the list were candy, peanuts and other nuts, grapes, cookies, meat, carrots, ap-

ples, popcorn and peanut butter.

Most of these foods are popular with children and are likely to be part of an American youngster's diet. The foods that children choke on are likely to be round, hard or of the type that easily slips down the throat. Round or cylindrical foods cause trouble because they fit so well into a child's airway. Candy and carrots are examples of hard or tough foods that may be difficult to chew, so that large pieces are swallowed. Foods that are small, smooth or slick when wet may easily slip down the throat. Foods that are pliable or compressible, such as pieces of meat, hot dogs or grapes, may form a particularly tight plug in the throat. Peanut butter can block the airway because it is so thick and sticky. Adding to the danger is the fact that most foods are adult size, but a child's airway is small and more susceptible to blockage.

Besides causing choking, another danger is that the food can get deep into the bronchial tubes, which take air to the lungs, or even into the lungs themselves. This can occur when a food particle—for instance, a seed or peanut shell—is too small to completely plug the airway. Such inhaled foreign objects can trigger pneumonia and other complications. It's not always easy to recognize that a child has inhaled food. The initial coughing fit may suddenly cease and the victim will appear to have recovered. However, more serious symptoms may show up days or even weeks later (for example, pneumonia). If food inhalation is suspected and the food particle is not coughed up, a physician should be contacted.

Among those who conducted the Johns Hopkins study were the parents of a 14-month-old Virginia child who nearly choked to death in 1982 on a sausage-shaped meat product for children. That incident led to a review of the product by FDA's Health Hazard Evaluation Board, which recommended that the product label be changed to discourage parents from giving it to children who cannot chew solid food properly. (See "Determining When A Food Poses A Hazard" in the June 1983 *FDA Consumer*.)

Following the board's recommendation, the manufacturer changed the label on the product to read:

"This product is intended for children with teeth. To reduce the possibility of choking, serve these sticks only to toddlers who have learned to chew solid foods properly. It is important that mealtime and snack time of small children be supervised. They should be fed in an upright position and never during vigorous activities."

The Johns Hopkins study was done in response to the health hazard board's call for an up-to-date study to identify the foods most likely to cause children to choke.

The American Academy of Pediatrics (AAP) also looked into the choking problem in a 1983 conference on the subject. The conferees called for better labeling of foods intended for young children and proposed a nationwide education campaign.

Conference members noted that environment also plays a part in choking. Because children around the age of 1 explore the world by putting things into their mouths, foods and other objects (such as toys) that—because of their size, shape or makeup—could be unsafe should be kept out of the reach of toddlers. Many choking incidents, including those involving older children, occur when the victim is eating or drinking while lying down, crying, laughing, talking, running or playing. The importance of adult supervision during meals and snack time was strongly emphasized.

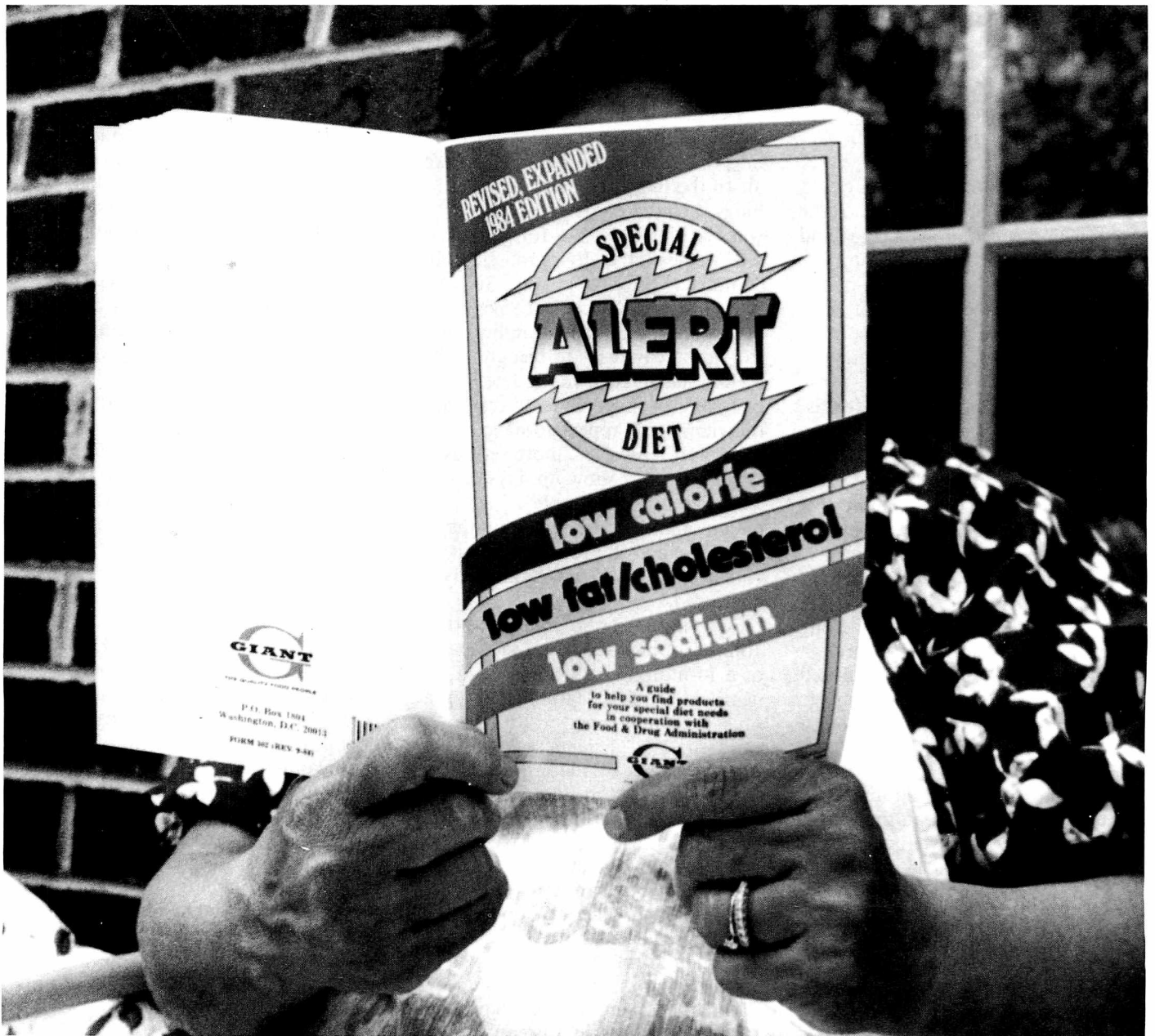
Concerning product labeling, the AAP conferees specifically recommended that the "food industry should label presently marketed food products intended for children to provide appropriate information for caretakers to reduce the risk of choking."

In response to the Johns Hopkins study and the AAP conference, the Food and Drug Administration and the U.S. Department of Agriculture's Food Safety and Inspection Service are planning a public education campaign to alert adults to the child choking problem, and how to avoid it. By being alert to the potential choking hazard that many common foods pose to young children, parents can make mealtime and snack time safer for their youngsters. ■

Louise Fenner is a member of FDA's publications staff.

Consumers Opt For Special Diet Foods

by Gloria Logan



. . . 50 percent of shoppers looking for special diet products said they used the Special Diet Alert program to find them.

A major U. S. supermarket chain has raised the flag over special diet products on its shelves, and shoppers have saluted, buying significantly greater amounts of foods that are lower in sodium, calories, cholesterol and fat.

In fact, the Special Diet Alert shelf-labeling program has been so successful that the chain, Giant Food Inc., is expanding the effort from the original 400 products to 1,200. Giant, the largest supermarket chain in the Washington, D.C., vicinity, also will expand the program from its 90 stores there to its 43 other stores in and around Baltimore.

Giant began the experimental program in March 1981, in close cooperation with FDA, to provide more nutrition information about specific food products to its customers. (See "Using The Store Shelf As A Food Label" in the July-August 1982 *FDA Consumer*.) Special labels are used to flag products that are low or reduced in sodium, fat, cholesterol or calories. The chain also makes available copies of a booklet that explains what is meant by "low" or "reduced" on the shelf labels and lists brands of products that meet the definitions, giving the amounts of nutrients in the products along with diet hints.

Many supermarkets around the country are experimenting with similar programs, but few have measured the results and even fewer have been able to show that the programs actually caused changes in shopping habits.

An analysis of sales of the specially

flagged items in Giant's program, however, found a significant increase in sales over a two-year period in eight of 16 food categories. These were: cottage cheese, low-sodium tomato sauce, tuna fish, low-sodium frozen vegetables, low-sodium soft drinks (such as spring and seltzer water), mayonnaise, and low-fat or low-sodium butter and margarine. In Giant's Washington-area stores, where the Special Diet Alert program was in effect, sales in those eight categories increased 4 to 8 percent faster than in the chain's Baltimore stores, where the program has not yet been introduced. Such sales increases are considered significant in the highly competitive, low-markup retail food business.

Giant also surveyed its shoppers to find out how many read the shelf labels. Thirty-one percent of all shoppers surveyed said they used the labels and 50 percent of shoppers looking for special diet products said they used the Special Diet Alert program to find them. Use of shelf labels was lower for men than women.

Other recent efforts to place nutrition information at the point of purchase in supermarkets have met with limited success. In-store nutrition education programs, usually involving poster displays or handouts, have sometimes been able to raise awareness of certain health issues, increase nutrition knowledge, and even produce better consumer attitudes about nutrition. But, as a rule, they have not succeeded in changing shoppers' buying habits. Because the results of these information programs

have seldom been analyzed to the extent of the Giant campaign, it is not certain whether lack of success was due to the design, the implementation, or a lack of precision in measuring effect on sales.

The success of Giant's effort is probably due to a number of factors, according to FDA officials who worked with the firm in the analysis of the program. First, the campaign highlights foods that have low or reduced levels of sodium, calories, fat or cholesterol, which are of great interest to many of today's health-conscious consumers. Also, the program was long-lasting; most other efforts have been relatively short-term. Finally, the greatly simplified and brand-specific nutrition information is provided on the shelf, next to price information. (Giant lists prices only on shelves for most products, not on the product itself.) In effect, the special shelf labels point out desirable products to shoppers.

Ultimately, the success of shelf-labeling programs of this type depends on well-educated and well-motivated shoppers. In-store and community nutrition information programs can be useful by providing the basic knowledge consumers need to understand and use a shelf-labeling program such as Giant's. The question remains as to how both types of programs should be designed to best complement each other. ■

Gloria Logan is a consumer affairs specialist in FDA's Center for Food Safety and Applied Nutrition.

Basic To Our Food Chain Is Plain Old Field Corn

by Evelyn Zamula

A legend about corn is that it makes a faint, crackling noise as it grows. To test this belief, firmly held by some old-time corn farmers, a group of plant scientists several years ago went deep into a midwestern cornfield on a hot, quiet night to catch the sounds. Equipped with recording instruments and wind gauges, the scientists listened. They

came out of the cornfield convinced that they did indeed hear the sound of corn reaching up toward the sky.

If they were right, the sound must have swelled into a roar in 1982, when the United States produced a record 8.4 billion bushels of corn. Not sweet or roasting corn, but field corn, our most important agricultural product. In that year, corn production completely overshadowed the next two most important crops, wheat

and soybeans, which had a combined total of 5 billion bushels. The corn crop was worth \$22.4 billion, just about equal to the value of wheat and soybeans combined.

Corn's popularity is well-deserved. As Dr. Paul Mangelsdorf says in his book *Corn, Its Origin, Evolution and Improvement*: "It is the most efficient plant that we have for capturing the energy of the sun and converting it into food. True, we consume directly only small amounts of corn: roasting ears, breakfast cereals, Indian pudding, and, for a somewhat different purpose, a beverage invented by a Kentucky minister of the Gospel, Bourbon whiskey. But transformed, as three-fourths of it is, into meat, milk, eggs, and other animal products, it is our basic food plant, as it was of the people who preceded us into this hemisphere."

The figures back him up. Of the 8.4 billion bushels produced in 1982, 4.6 billion bushels were fed to animals, in one form or another. (About four bushels out of 10 never leave the farm.) The United States exported 1.87 billion bushels in 1982, much of which also was destined for animal feed.

Besides getting into the human food chain as animal feed, corn is manufactured by corn processors into other food products, including prepared cereals, cornmeals and flours, starches, corn sweeteners and oils. The corn-processing industry uses 6 to 7 percent of the total corn crop grown in the United States, or one out of every six bushels sold. Corn provides raw material for many industrial uses, too, ranging from the alcohol used in gasohol to insecticides.

Wrapped tightly in its husk, corn long ago lost the capability of releasing its kernels from the ear or spike spontaneously, and it no longer occurs as a wild plant. It must be cultivated by man, who removes the kernels from the cob to plant them. He develops new corn varieties for greater resistance to disease, greater yields, color uniformity and other



specific desirable qualities.

Of the trio of grasses that feed the world—wheat, corn and rice—only corn is native to America. It was the basic food of three great pre-Columbian civilizations—the Incas of Peru, the Aztecs of Mexico, and the Mayas in Yucatan and Guatemala. The Indians of North and South America have cultivated corn about five or six thousand years. Two of Columbus' crew discovered "maiz" in Cuba in 1492. Later explorers found it growing as far south as Chile and as far north as what is now the U.S.-Canadian border, as low as sea level in Florida and as high as 10,000 feet above sea level in the Andes.

Corn played an important role in the early days of our nation. Although they had brought wheat and rye seeds from England, the Pilgrims arrived too late in the year 1620 to plant crops. Corn saved them from starvation. They had found a large supply cached by an Indian tribe that had wandered off elsewhere, and it tided them over their first winter.

When spring came, the Pilgrims had difficulty growing corn in fields bristling with tree stumps. Friendly Indians showed them how to plant the kernels without having to fell trees or plow, and fertilize them with the fish that were then so plentiful along the Atlantic coast. For 40 days after planting, all the dogs in the community had one forepaw tied to the neck to keep them from digging up the fish.

The Indians showed them how to prepare corn porridge, simple corn breads, and other dishes. Until milk animals were imported from Europe, the Pilgrims fed babies with a kind of milk made from corn, mixed with juices from boiled hickory nuts and chestnuts.

Corn's versatility has continued to increase. Not only has modern technology discovered new products that can be extracted from the kernel, but it has devised some kind of use for every bit of the corn plant, including stalks, husks, leaves and cobs.

The kernel, though, is the economic powerhouse. It consists of three main parts: the seed coat (or pericarp), the starchy endosperm, and the embryo (or germ). The pericarp is the outer skin, or hull. The endosperm, which accounts for about 80 percent of the weight of the kernel, contains about 90 percent starch and 7 percent gluten, or protein. The germ, the oval shape seen in the inner tip, contains 40 to 50 percent oil.

The starch is probably the most useful part of the corn kernel. Because the United States grows so much corn, there is plenty of it to manufacture into cornstarch and products derived from cornstarch.

In early times, starches were made from such grains as wheat and rice. An essay by Cato from 184 B.C. described a way to make starch and mentioned its uses in medicines, cosmetics, foods and fabrics. In one old method of making starch, the

Of the 8.4 billion bushels produced in 1982, 4.6 billion bushels were fed to animals.










"It is our basic food plant, as it was of the people who preceded us into this hemisphere."

grain was soaked and crushed, put into a linen bag, and kneaded in a tub of water until some of the starch separated out. The starch settled to the bottom and was scooped out and dried on porous bricks in the sun.

It wasn't until the middle of the 19th century that an efficient process for large-scale extraction of starch from corn was developed. The first cornstarch factories in the United States were built in 1844 by Colgate and Co. Today about 4 billion pounds of cornstarch are manufactured in this country each year. Cornstarch is used in the manufacture of aspirin and antibiotics, in pancake mixes, salad dressings, baby foods, cosmetics and thousands of other products.

Approximately half of the corn-

(Continued on next page)

<div> Distribution Of Corn Production (1982) </div>		
	8.4 billion bushels production	
	4.6 billion bushels animal feed	
	1.87 billion bushels exported	
	1.1 billion bushels surplus	
	774 million bushels food products	
	109 million bushels alcoholic beverages	
	14.5 million bushels seed	

starch produced is converted into syrups and sugars. Starch is changed into corn sweeteners, such as dextrose, and into syrups by different chemical processes.

Dextrose, the chief source of energy for living organisms, is an important product. Since it is identical to the sugar found in human blood, dextrose (also known as glucose) is used for intravenous feeding after surgery and at other times when it is not feasible for a patient to take food by mouth. The pharmaceutical industry is the largest single user of dextrose; for example, it is the starting point for manufacturing vitamin C and is used in fermentation to produce penicillin and other antibiotics.

Corn sweeteners are used in many segments of the food industry. Besides providing sweetness and body and improving the texture of various processed foods and beverages, corn

syrups are used to retard sugar crystallization in confectionery products; to control the freezing point and prevent crystal formation in frozen desserts; to prevent baked goods from drying out and help them form a nice, brown crust; and as a preservative in canned fruits.

One special type of corn sweetener is high-fructose corn syrup. Though it was not developed until the late 1960s and not widely marketed until the early 1970s, production of high-fructose corn syrup now exceeds over 9 billion pounds annually.

Despite the relative newness of the industry, the technology of turning starch into sugar has been around a long time. An early 19th century chemist found that if starch were heated with a weak acid, a thin syrup containing glucose resulted. The problem with acid-converted starch was that syrups produced by this

process were less sweet than sugar syrups manufactured from cane or sugar beets. In 1935, enzymes were used with the acids in a dual conversion process to make certain types of syrups, but differences in sweetness remained a major challenge to the corn-refining industry.

In the 1960s, the Japanese opened the way to an entirely new all-enzyme process that produced a sweeter syrup. Two researchers isolated a soil organism that could produce an enzyme (xylose isomerase) capable of converting part of the glucose from starch into fructose, a much sweeter sugar that occurs naturally in honey, ripe fruits and most vegetables. A number of American starch manufacturers saw the commercial possibilities and scrambled to get the rights to the enzyme process. The Japanese li-

(Continued on next page)

The Whence Of The Cornflake

It was a lucky accident for sure. During one of their kitchen experiments, the brothers Kellogg of Battle Creek, Mich., chanced upon a way of manufacturing cereals that was to revolutionize the industry and lay the foundation for an immense fortune.

Dr. John Kellogg, a physician and "health food" pioneer, managed the Battle Creek Sanitarium for the Adventist Church. The sanitarium's diet was exclusively vegetarian and somewhat boring to the many patients there, so Dr. Kellogg and brother Will Keith Kellogg, the business manager known as "W.K.," had set up a little laboratory in the kitchen to develop new foods that would liven up the menus.

The Kelloggs believed grains had an important place in the diet. In one series of experiments they ran boiled wheat dough through rollers to produce thin sheets of wheat. They then toasted the wheat and ground the sheets into a meal.

The brothers were working with boiled wheat one day in 1894 when Dr. John was called away for

emergency surgery and Will departed to make funeral arrangements for a patient who had died. When they returned over 24 hours later, the Kelloggs decided that instead of throwing out the panful of boiled wheat grains, as they normally would have done, they would run it through the rollers. To their surprise, instead of a sheet of wheat, the rollers discharged large, thin flakes, each individual grain forming one flake. What made the difference was the overnight wait, which had caused the moisture to be distributed almost evenly through each wheat grain, allowing individual flaking. They had stumbled on the principle of the "tempering" of grains. Thus, with only slightly additional refinement, was born the cereal flake.

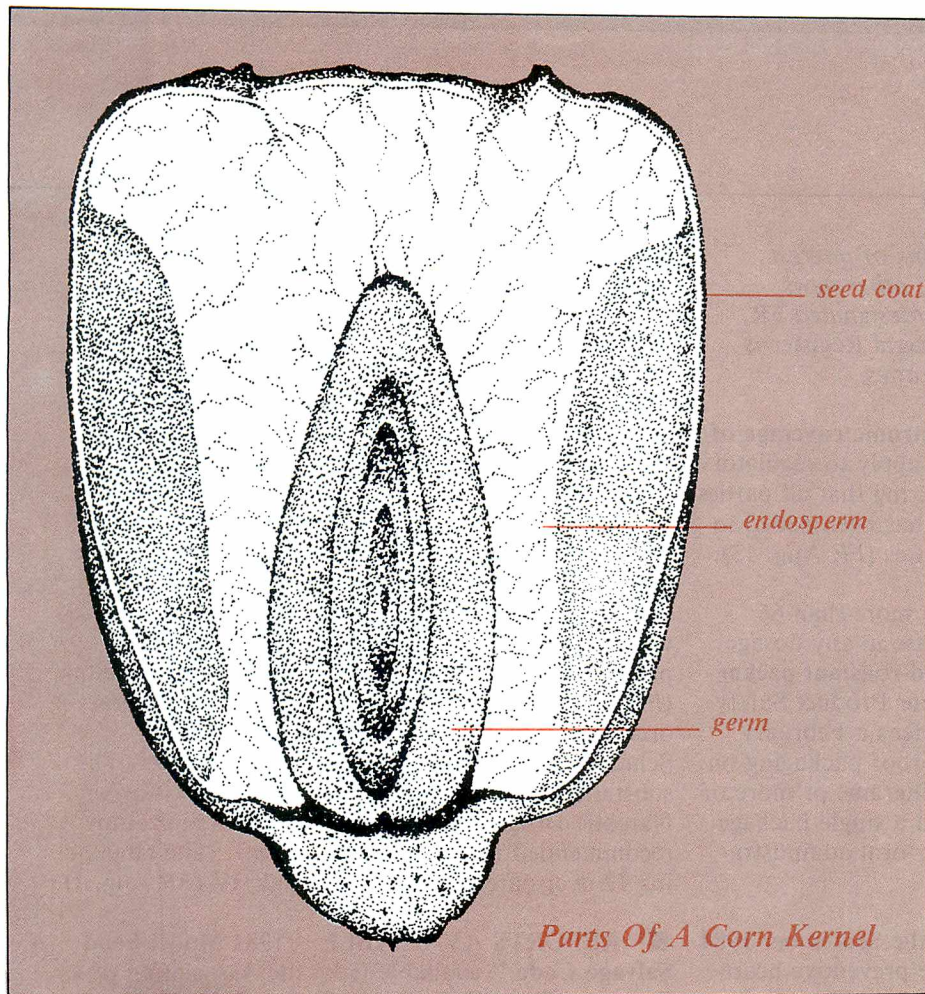
When former patients wrote back for supplies of some of the health foods they had been served in the sanitarium, Dr. Kellogg set up a small factory called the Sanitas Nut Food Co. and began manufacturing a few of the more popular items, including the wheat flakes.

In 1898 the Kelloggs tried processing whole corn kernels the same way they had done with wheat, but the cornflake wasn't as popular as the wheat flake. It wasn't until a year

later, when Will Keith decided to make the cereal from the heart of the corn (the starchy part, or grit) and add malt flavoring, that a cornflake similar to the one we know today was produced.

W.K. formed his own company in 1906. (Dr. John had never liked his brother's advertising methods, among other things, so he sold his rights to his brother and concentrated on his medical career.) By this time, other cereal companies had picked up the technology and were manufacturing both wheat flakes and cornflakes. Among them was C.W. Post, who had been a patient at the sanitarium at one time and was to become an arch-rival in the cereal business (Post's factory was located just across the street from Kellogg's in Battle Creek).

In cereal manufacturing, the corn grits are cooked in steam under pressure with malt flavoring, salt, sugar and some vitamins. The cooked grits mixture is then dried and passed between two large rollers for flaking. After being toasted and sprayed with more vitamins, the flakes are inspected, packaged and sent on their way to market. The whole process, from grits to package, takes about eight hours. ■



censed the rights to an American firm in 1965.

High-fructose corn syrup has proved to be a boon to food processors. It is used extensively by the canning, pickling and baking industries as a substitute for sugar, as well as in wines, jams and jellies, confectionery products and frozen desserts. Manufacturers of "reduced-calorie" foods have found high-fructose corn syrup useful because a slightly smaller amount of it can provide the same sweetness as sugar. It also is cheaper than sugar.

The soft drink industry is the biggest user of high-fructose corn syrup. Today every major non-diet soft drink is sweetened completely or partially with high-fructose corn syrup. It's added both to fountain syrups and to canned and bottled soft drinks. High-fructose corn syrup is generally recognized as safe (GRAS) by the Food and Drug Administration.

Per capita consumption of high-fructose corn syrup has been rising at the expense of sugar. The U.S.

Department of Agriculture reports that the use of sugar in soft drinks declined about 335,000 tons in 1983. The Iowa Corn Promotion Board expects the consumption of sucrose (from cane or beet sugars) to remain relatively unchanged in the years to come, while consumption of high-fructose corn syrup is expected to rise to 31 pounds per person in 1985 (it was five pounds per capita in 1975). Since each bushel of corn yields approximately 33 pounds of high-fructose corn syrup, every American will consume the amount of syrup derived from one bushel of corn each year.

A bushel of shelled corn, which weighs 56 pounds, provides nearly two pounds of corn oil, another important corn product.

Modern processors use presses or chemicals to extract oil from corn. The kernel contains about 4.5 percent oil, but 85 percent of that is in the germ. In extracting the oil, the germ is separated from the starch, gluten and hull materials at the mill, then dried and subjected to intense pres-

sure in the expeller, or continuous screw press. This machine was developed about the turn of the century and is best described by comparing it to the old household grinder in which a rotating screw forces materials under pressure against cutting or grinding edges.

Pressing reduces the oil content of the germ from 50 percent to about 15 percent. The residue, called corn-germ cake, is heated, flaked by rollers, and the bulk of the remaining oil is extracted by a solvent (hexane). The remaining solids are ground into corn-germ meal and become an ingredient in animal feed.

Oil also may be extracted from corn entirely by solvents. Whatever process or combination of processes is used, the composition of the corn oil remains fairly constant and is similar to that of other crude vegetable oils.

The crude oil goes through several refining steps. The final product is an almost tasteless, odorless product, light golden in color, reminiscent of the corn from which it came, and with a high resistance to smoking (460 degrees Fahrenheit) when used in frying. Preserved in the refining process are some of the tocopherols, constituents of vitamin E, a natural antioxidant. Corn oil is rich in unsaturated fatty acids, mostly linoleic acid, an essential nutrient. A tablespoon of corn oil, like other food fats, contains about 120 calories. Corn oil is also generally recognized as safe by FDA.

About 40 to 50 percent of the corn oil manufactured in the United States is used for frying and in salads, about 30 to 35 percent in margarine, 10 percent in soaps, and the remainder in shortening and for other minor uses. As more and more corn is milled in this country to meet the increasing demands for high-fructose corn syrup, more corn germ has become available for oil extraction. According to the Bureau of the Census, 817.3 million pounds of refined corn oil were produced in the United States in the 12-month period ending Sept. 30, 1983. ■

Evelyn Zamula is a member of FDA's publications staff.

The Notebook

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

■ FDA's new **guidelines on electronic coverage** of public administrative proceedings apply to regulatory hearings as well. A provision ensuring that all parties to a proceeding are aware of this has been added to FDA's regulatory hearing procedures (FR Aug. 13).

■ Drug preparations containing more than 66 milligrams of diphenhydramine base in any dosage form will be required to have **child-resistant packaging** by Feb. 11, 1985, the Consumer Product Safety Commission has ruled. This broadens a February 1984 regulation calling for child-proof packaging on any preparation containing 75 milligrams or more of diphenhydramine hydrochloride in a single package and in a dosage form intended for oral administration (FR Aug. 15).

■ **CORRECTION:** An item in the September 1984 Notebook erred in stating that the preventive heartworm drug Nemacide was unapproved. The product is a prescription animal drug that has been sold without a prescription in some southern states. FDA has not approved the drug for nonprescription sale. Nemacide can be harmful if not used under the direction of a veterinarian.

■ The BSD-1000 Hyperthermia System, manufactured by BSD Medical Corp., Salt Lake City, Utah, initially approved for treatment of certain solid surface and **subsurface malignant tumors**, has received FDA approval for use as an adjunct to radiation therapy (FR Aug. 27).

■ Shaklee Corp., the Council for Responsible Nutrition, the National Nutritional Foods Association, the National Association of Pharmaceutical Manufacturers, the Save the United States Movement, and the American Dry Milk Institute were invited to make oral presentations at a Federal Trade Commission hearing regarding a proposed FTC rule on advertising and labeling of **protein supplements** (FR Aug. 17).

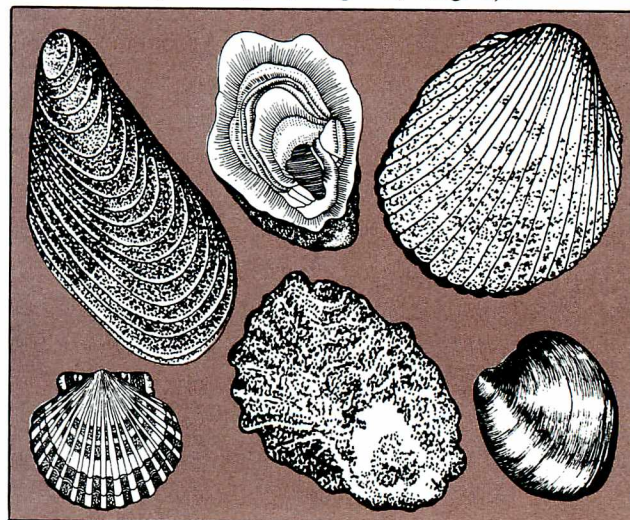
■ FDA's Office of Orphan Products Development has announced the availability of approximately \$250,000 for a grant or grants to support a randomized, double-blind, placebo-controlled study of **lithium and phenytoin** in adult patients who have episodes of extreme violence and aggressiveness. The office also is seeking a New Drug Application for an

antipyrene test to monitor the drug-metabolizing capacity of the liver (FR Aug. 10, Aug. 28).

■ An Allergenic Products Advisory Committee has been established in FDA's Center for Drugs and Biologics to review and evaluate data on materials used for the diagnosis, prevention or treatment of **allergies and allergic diseases** (FR Aug. 1).

■ The Drug Enforcement Administration (DEA) has issued a final rule putting the depressant **methaqualone** in Schedule I of the Controlled Substances Act. This action was required by Public Law 98-329, which also called for the withdrawal of FDA approval of the new drug application for methaqualone (FR Aug. 27). DEA has also proposed a temporary order placing 21 **benzodiazepine** substances in Schedule IV of the Controlled Substances Act. The substances were among 33 that the Commission on Narcotic Drugs of the World Health Organization recommended for Schedule IV control. The remaining 12 drugs are already in Schedule IV (FR Aug. 1).

■ **REPORTS AVAILABLE:** "1984 Model **Food Salvage Code**," available from the Association of Food and Drug Officials, P.O. Box 3425, York, Pa. 17402. . . . "Report on **In Vitro Screening Devices**" (factors FDA considers when assessing the safety and effectiveness of *in vitro* screening devices), available from Tracy Summers (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857. . . . A working draft of the "National Shellfish Sanitation Program Manual of Operations, Part I, Sanitation of **Shellfish Growing Areas**," available from the Center for Food Safety and Applied Nutrition, Shellfish Sanitation Branch (HFF-344), FDA, 200 C St. S.W., Washington, D.C. 20204 (FR Aug. 9, Aug. 13, Aug. 8).





Not In The Pink

The clue was an Easter ham that was the wrong color. It should have been rosy pink instead of grayish. The first detective was an alert meat cutter, but by the time the story ended the cast of characters included three government agencies and 26,000 pounds of ham gone wrong.

The incident started one Saturday a couple of weeks before Easter at the Wesley Kling Meat Co. in Wyoming, Del. It was there that a meat cutter sliced into a ham and noticed an unusual color. He had intended to put the ham on display in the retail store attached to the plant, but instead he contacted a Delaware Department of Agriculture inspector who lived nearby. The inspector visited the plant that afternoon and

oxygen-carrying capacity of the red blood cells. A high enough concentration in the bloodstream can cause death by suffocation.

What had caused such a serious error? The problem turned out to be the cure mix, a combination of spices custom-formulated for Kling Meat Co. by the Baltimore Spice Co. of Maryland. The cure mix should have contained a package of sodium nitrite weighing $7\frac{1}{2}$ ounces. Instead, the mix contained 7 pounds and a half ounce of the additive.

The U.S. Department of Agriculture embargoed 25,000 pounds of hams made with the questionable cure mix at the Kling firm. Late that same day FDA's Baltimore district office was brought into the case. FDA regulates spices and food additives such as sodium nitrite. Fur-

There they were embargoed by USDA.

The chase was not over yet. Further investigation by USDA showed there was a good possibility that shipments of suspect hams may also have gone to retail outlets in Maryland, Delaware, Virginia and Pennsylvania. FDA investigators visited each of these outlets to notify the dealers of the problem. USDA also issued a press release warning customers in the affected areas to return any Kling hams they may have purchased from the identified outlets.

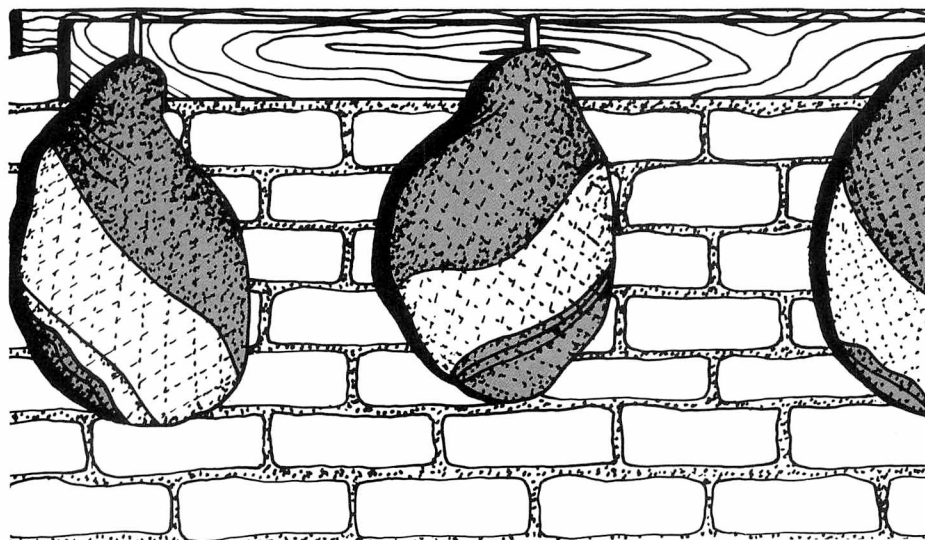
Meanwhile, a USDA laboratory in Georgia had analyzed three hams taken as samples from Kling Meat Co. The maximum amount of sodium nitrite allowed as a preservative in ham is 200 ppm (parts per million). These hams contained 1,186 ppm, 1,368 ppm and 4,112 ppm.

FDA's Center for Food Safety and Applied Nutrition did some calculations concerning the potential toxicity of the hams. FDA concluded that two slices of ham containing 3,500 ppm of sodium nitrite could be lethal to humans. A subsequent evaluation by the Health Hazard Evaluation Board, an ad hoc FDA committee of medical and scientific experts, affirmed the life-threatening potential of the hams.

Fortunately, the USDA-FDA cooperation paid off. All faulty cure mix and all suspect hams were accounted for. USDA monitored the return and arranged destruction of over 26,000 pounds of ham. FDA inspectors visited some 30 meat plants nationwide that used Baltimore Spice Co. products to be sure that no more faulty cure mix was at large. FDA also notified the Baltimore Spice Co. of quality control problems that contributed to the mix-up and will continue to monitor the firm.

Dangerous Pets

A case of salmonellosis, a bacterial disease, in a 4-month-old girl recently led to a crackdown on the sale of pet turtles in Puerto Rico. Despite a federal ban on sales and distribution, hundreds of the reptiles had been im-



realized that something was wrong.

An analysis showed that the ham contained several times the amount of sodium nitrite allowed by FDA regulations. Sodium nitrite is used as a preservative to prevent the growth of poisonous botulinum toxin, and it also fixes the red color in processed meats (although excess nitrite causes "nitrite burn," which may result in a grayish or greenish color). Excessive amounts of sodium nitrite in the human body can interfere with the

thermore, FDA had personnel who could help track down any additional suspect hams before they got to consumers.

FDA inspectors were sent to the Baltimore Spice Co. and to Monroe Foods Inc., also in Baltimore. The latter firm had received 30 cases of the suspect hams before the processing error was caught. The hams had been shipped to a retail outlet in York, Pa., but after FDA's visit they were shipped back to Monroe Foods.

ported to Puerto Rico and were suspected of causing numerous cases of illness in small children.

Turtles frequently carry *Salmonella* bacteria, which may cause severe diarrhea in children and adults. Baby turtles were sold in the United States as pets until 1975, when several studies by the U.S. Centers for Disease Control determined that bacterial contamination could not be prevented by any known treatment method. Since children are particularly sensitive to salmonellosis, the CDC studies resulted in a ban on the sales and distribution of turtles less than four inches long, the size most often sold as pets.

Early in 1984 the Puerto Rico Health Department learned of the salmonellosis in the 4-month-old girl and that it was associated with a pet turtle in her home. The department's epidemiology division evaluated other cases of salmonellosis reported in San Juan and surrounding towns during 1983 and discovered that 19 percent of cases involving children under 1 year were possibly linked to contact with a pet turtle at home.

Investigators from FDA's San Juan

district office then visited pet shops throughout Puerto Rico and discovered that there had been several recent shipments of small turtles to the island from Louisiana. United States producers are allowed to export turtles to countries where they are not banned; however, Puerto Rico, a self-governing commonwealth in union with the United States, falls within the 1975 ban.

In a cooperative effort, FDA and the Puerto Rico Health Department implemented several measures to eliminate the risk of salmonellosis posed by pet turtles. FDA notified all U.S. producers and shippers of pet turtles that Puerto Rico was included under the federal ban. Health department inspectors visited over 40 pet shops throughout the island and collected all turtles on hand. Also, island residents were warned in the media about the health risk and urged to bring their turtles either to the health department or the FDA district office.

In the three months following the initial salmonellosis report (the little girl eventually recovered), more than 2,300 pet turtles were collected by FDA and local health authorities.

They were disposed of by FDA in a humane manner to preclude spreading the contaminating organism.

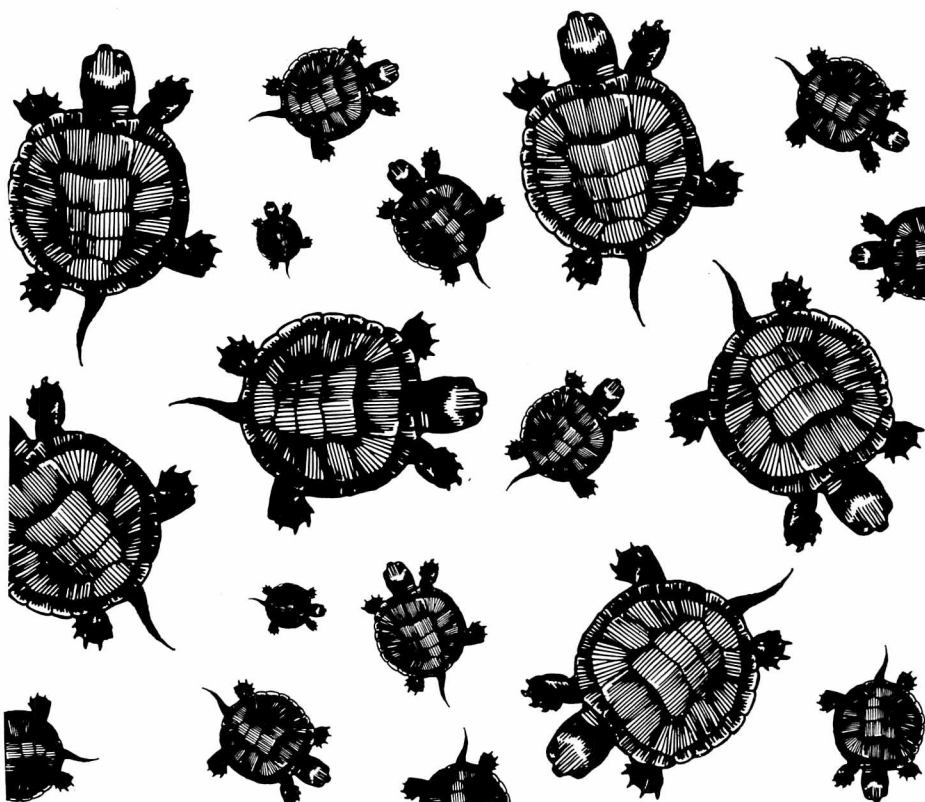
Was It Salt Or Sugar?

The bottle's cap identified the product as containing 0.45 percent sodium chloride, but the bottle's label said it contained 5 percent dextrose I.V., 1,000 milliliters. The Maryland hospital that noticed the conflicting information on July 12, 1984, immediately contacted the manufacturer, American McGaw of Milledgeville, Ga., to alert the firm to the contradictory labeling.

Both I.V. sodium and dextrose products belong to a class of drugs known as large-volume parenterals (LVPs). LVPs are drugs that are injected into patients to supplement body fluids. Dextrose (sugar) solutions are used primarily as a source of fluid and carbohydrates for nutrition. Sodium chloride (salt) solutions are used primarily as a source of fluid and electrolytes. The drugs are contained in bottles or plastic bags, which are placed by the beds of patients in hospitals or nursing homes, with a tube carrying the drug to the site of the injection. LVPs also are used to administer drugs that cannot be taken orally.

When alerted to the labeling problem by the firm, investigators from FDA's Atlanta district office visited the plant. They determined that the error occurred because an employee failed to follow standard operating procedures in handling filled bottles before labeling. The firm has since modified its operating procedures to reduce the chance of human error.

The firm immediately recalled the product, which was designated by FDA as a "Class I" recall (meaning that a life-threatening situation could result from administration of the incorrect solution to a patient). For instance, if the sodium chloride solution was administered to a diabetic suffering from hypoglycemic coma, the sodium chloride would not relieve the hypoglycemia (low blood sugar). Giving a cardiac patient a sodium chloride solution could result in salt-overloading syndrome, with possible damage to the heart or kidneys. Finally, not all medications that



might be administered with the solutions are compatible with both dextrose and sodium chloride solutions.

By afternoon of the day the firm learned of the problem, it had notified all its consignees about the recall. Approximately 11,300 units had been distributed to 72 accounts, mostly hospitals, in 16 states.

There have been no reports of injury due to the labeling mix-up.

No Prizes For The Relishes

A woman who canned vegetables for a storekeeper in Chesapeake,

Joint investigation by the two agencies found that the relishes originated at the Old Country Store in Chesapeake, a five-mile, over-the-Ohio-River trip from Huntington. The store's proprietor had bought the raw materials and paid a local woman to can them. He then sold them to Conrad Produce, which distributed the goods to the roadside market.

Analysis by FDA's Cincinnati laboratory found that the products had been inadequately processed and showed signs of decomposition as well as bacterial growth. The lids on some of the jars had begun to swell.



Ohio, wouldn't have won any prizes for her corn and bean relishes. And they definitely shouldn't have been sold commercially.

For one thing, Ohio cannery laws make it illegal to sell home-canned food products commercially. For another, the products contained mold and bacterial growth.

The relishes—pickled corn, corn relish, and pickled beans—were on display in a roadside market, where they caught the eye of an inspector from the Ohio Department of Agriculture during a routine inspection. He noted that the products had been distributed by Conrad Produce, Huntington, W.Va. So he called on FDA's Charleston, W.Va., resident post for assistance.

All remaining jars of the relishes were destroyed by the Old Country Store.

Zapping Overexposure

X-rays are a valuable diagnostic tool. However, X-rays are a double-edged sword, having the potential to cause harm as well as good. This potential for harm can be reduced if X-ray equipment is properly manufactured and installed and used correctly.

FDA enforces the Radiation Control for Health and Safety Act, enacted by Congress in 1968 to protect the public from unnecessary exposure to X-rays and other radiation. Under provisions of this law, FDA

established performance standards for diagnostic X-ray equipment and other electronic products.

These standards apply not only to manufacturing but also to assembling. Assemblers of diagnostic X-ray equipment are required to submit reports to FDA covering their installations. Both FDA and state agencies acting under contract to the FDA routinely inspect places where X-ray equipment is assembled (such as hospitals and doctors' and dentists' offices) to make certain it's properly installed.

Three X-ray equipment manufacturers recently received fines and other civil penalties for failing to follow the rules. In one case, General Electric Co., Westwood, Mass., issued false certifications for eight diagnostic X-ray units. In another, CGR Medical Corp. of Baltimore, Md., failed to report accidental leakages of excessive radiation. And, in the third case, CGR Medical Corp. of Elmsford, N.Y., failed to correct poor diagnostic quality of its X-ray machines.

FDA's regulations require assemblers of diagnostic X-ray machines to certify that machines were assembled, installed, adjusted and tested. However, inspections by FDA's Boston district office of eight medical facilities in the New England area served by General Electric showed that machines had been falsely certified.

Most of the problems with the GE machines occurred because of incorrect installations resulting in misaligned X-ray beams and inoperable safety shut-off features.

In June, GE entered into a consent decree in the U.S. District Court for the District of Massachusetts in which the firm agreed to pay fines totaling \$16,000, retest approximately 100 similar systems already installed at other locations, and revise their quality control program to prevent future errors. The firm corrected the eight defective machines before the June settlement.

As a result of regulatory actions taken by FDA, CGR Medical Corp., Baltimore, Md., agreed in the U.S. District Court for the Northern District of Maryland to pay a civil penalty of \$50,000, the largest to date

under the 1968 law. The firm also agreed to submit to FDA for approval its plans for repairing 101 faulty diagnostic X-ray machines and to notify other users about the problems.

The actions stemmed from a 1982 incident at a hospital in Philadelphia, where two pregnant technicians and some patients were exposed to unnecessary X-rays from faulty machines. Despite the firm's knowledge of the accident, it did not immediately notify FDA. The hospital reported the accidental radiation occurrence to the regional radiological health representative who requested further FDA investigation.

Investigation also revealed that CGR Medical Corp. had failed to notify 101 other hospitals and users about the problems with the defective machines and had falsely certified the machines as meeting government safety performance standards.

In the third incident, FDA's Brooklyn district inspected hospitals in the New York City area serviced by CGR Medical Corp. of Elmsford. The investigators found several machines that were not in compliance.

Some of the firm's violations included: failing to submit reports of installation to FDA, certifying falsely that a non-complying machine was in compliance, and failing to correct poor diagnostic quality of X-ray machines, necessitating that patients be X-rayed twice.

The district sent letters to CGR informing the company of the problems and asking what it intended to do to correct the violations. In some cases, the firm failed to respond to the letters. In others, reinspection by FDA showed that machines were still out of compliance.

In light of this, and based on the district's recommendation, the U.S. District Court for the Southern District of New York imposed a \$33,000 civil penalty on CGR for continued violations.

Unhealing Oxygen

Victims of incurable diseases sometimes are tempted to try unproven therapies. For two Ohio residents with multiple sclerosis,

however, an unproven treatment method simply added to their woes.

The two were members of the W.L. Lakin Foundation in Dayton, Ohio, a group composed of multiple sclerosis victims. Multiple sclerosis is an incurable degenerative disease of the central nervous system, characterized by muscular weakness and lack of coordination, visual disturbances (such as partial blindness and pain), difficulties with bladder control, speech defects, and violent mood swings.

The foundation's members were treating themselves with a hyperbaric (pressurized) oxygen (HBO) chamber that had been donated to the group by a local boiler manufacturer. After treatment with the device, one member experienced temporary blindness; another had a fainting seizure and was admitted to a local hospital.

These reactions were reported to the Ohio State Medical Board, which in turn called FDA's Cincinnati district office. An investigation by the two agencies found that the foundation's members were operating the HBO chamber without medical supervision of any kind, and they did not have an Investigational Device Exemption required by FDA for an experimental device.

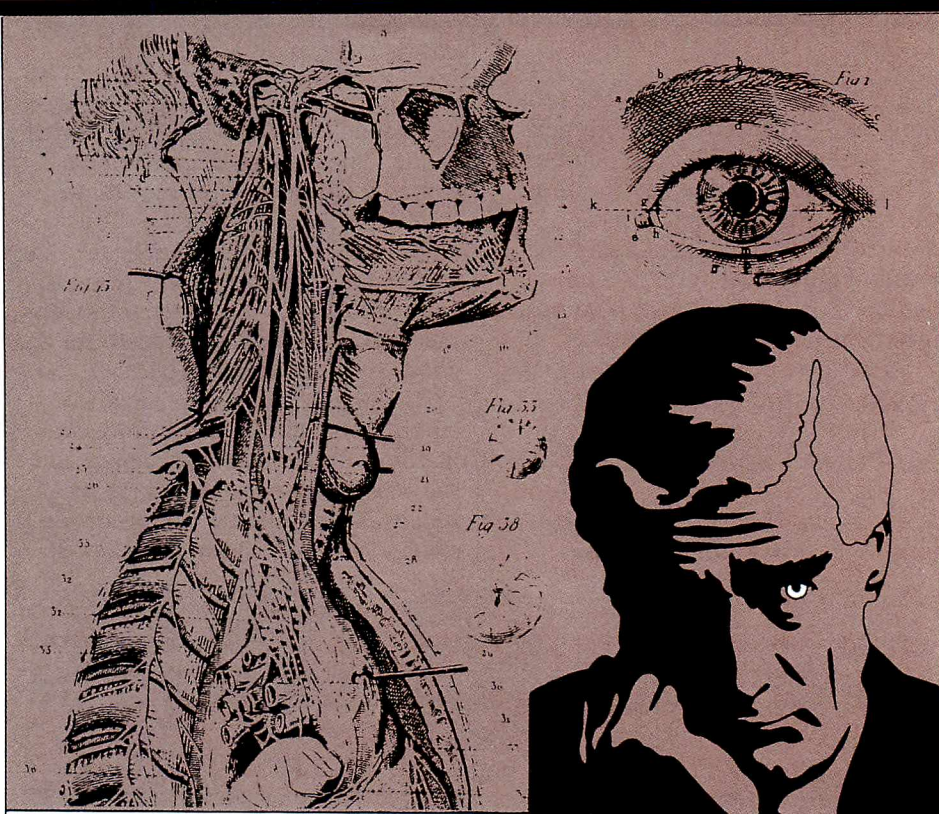
Each member relied on a relative to

operate the equipment. The members also signed a consent form releasing the foundation from liability in the case of injury. The consent form warned of possible side effects, such as ear damage, collapsed lung, vision problems (including blindness), numbness, convulsions and death.

Oxygen treatments have not been proven safe and effective in the treatment of multiple sclerosis, although they have been used experimentally. A study cited by the *Harvard Medical School Letter* in May 1983 found that MS patients treated with pure oxygen did seem to improve but not dramatically so. The publication concluded that "this work opens an important avenue for research, but it does not justify putting MS patients through a cumbersome and expensive routine for the relatively modest benefits that it seems to offer."

The Ohio State Medical Board cited the W.L. Lakin Foundation for practicing medicine without a license. The members discontinued their oxygen treatments and dissolved the corporation.

—This small sample of reports from the field was compiled and edited by Annabel Hecht, Carol Ballentine, Louise Fenner, Michael Herndon and Carolyn Hommel.



Summaries of Court Actions



Summaries of Court Actions are given pursuant to section 705 of the Federal Food, Drug, and Cosmetic Act. Summaries of Court Actions report cases involving seizure proceedings, criminal proceedings, and injunction proceedings. Seizure proceedings are civil actions taken against *goods* alleged to be in violation, and criminal and injunction proceedings are against *firms* or *individuals* charged to be responsible for violations. The cases generally involve foods, drugs, devices, or cosmetics which were alleged to be adulterated or misbranded or otherwise violative of the law when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. Full court opinions for these cases are published by either the West Publishing Company or the Commerce Clearing House Inc. Texts can be obtained from Commerce Clearing House at 1301 Pennsylvania Ave., N.W., Washington, D.C. 20004.

Summaries of Court Actions are prepared by the Food and Drug Division, Office of the General Counsel, HHS.

Published by direction of the Secretary of Health and Human Services.

SEIZURE ACTIONS

Foods/Poisonous and Deleterious Substances

PRODUCT: **Swordfish**, at Washington, Dist. Columbia; Civil No. 77-1477.

CHARGED 8-29-77: When shipped by Emerald Bay, Inc., Needham Heights, Mass., the article contained the added poisonous and deleterious substance, mercury—402(a)(1). **DISPOSITION:** Default—ordered destroyed. (F.D.C. No. 61374; S. No. 77-59-663; S.J. No. 1)

Foods/Contamination, Spoilage, Insanitary Handling

PRODUCT: **Chanadal beans, sloe berries, and ginger**, at Brooklyn, E. Dist. N.Y.; Civil No. 81-0891.

CHARGED 10-5-83: While held by Purity Millers, Inc., Brooklyn, N.Y., the articles contained insects and had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 63413; S. No. 81-270-507 et al.; S.J. No. 2)

PRODUCT: **Clams, canned**, at Tukwila, W. Dist. Wash.; Civil No. C-83-1242.

CHARGED 9-1-83: When imported, the article, labeled "S & W Seattle Boiled Baby Clams . . . Product of Korea," contained decomposed clams—402(a)(3).

DISPOSITION: Consent—authorized release to Mulsen Trading Co., Ltd., Seattle, Wash., for bringing into com-

pliance (destroyed). (F.D.C. No. 64079; S. Nos. 83-335-719/20; S.J. No. 3)

PRODUCT: **Cones for ice cream, salt, flour, and other food stocks**, at Chicago, N. Dist. Ill.; Civil No. 83-C-8659. **CHARGED** 11-29-83: While held by D & D Sales, Inc., Chicago, Ill., some of the articles contained rodent filth, and all of the articles had been held under insanitary conditions—402(a)(3), 402(a)(4).

DISPOSITION: Consent—authorized release to the dealer for salvaging. (F.D.C. No. 64150; S. No. 83-380-812 et al.; S.J. No. 4)

PRODUCT: **Fennel seed**, at Joplin, W. Dist. Mo.; Civil No. 83-5189-CV-SW-O.

CHARGED 11-17-83: When shipped by Sokol & Co., Countryside, Ill., the article, labeled "Sokol & Company . . . Countryside, Illinois . . . Whole Fennel Seed," contained rodent and insect filth—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64142; S. No. 84-250-544; S.J. No. 5)

PRODUCT: **Fruit cocktail, canned**, at Albuquerque, Dist. N.M.; Civil No. 83-1608-BB.

CHARGED 10-18-83: While held for sale, the article was in swollen and/or deteriorating cans—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64091; S. No. 83-331-585 et al.; S.J. No. 6)

PRODUCT: **Fruit mix, canned, and crushed pineapple, canned**, at Albuquerque, Dist. N.M.; Civil No. 83-1609-BB.

CHARGED 10-18-83: While held for sale, the article was contained in swollen and/or deteriorating cans—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64090; S. Nos. 83-331-590/2; S.J. No. 7)

PRODUCT: **Peas, canned**, at Norfolk, E. Dist. Va.; Civil No. 83-667-N.

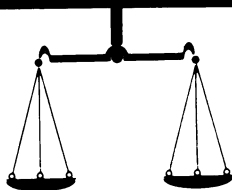
CHARGED 10-11-83: When shipped by Oconomowoc Canning Co., Newport, Tenn., the article (labeled in part "Stokely Van Camp's . . . Sweet Peas Mixed Sizes . . . Distributed by Stokely Van Camp, Inc., Indianapolis, Ind.") was unfit for food because it was held in swollen and leaking containers—402(a)(3).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64098; S. No. 83-395-366; S.J. No. 8)

PRODUCT: **Soy sauce**, at Williamson, W. Dist. N.Y.; Civil No. 83-387T.

CHARGED 7-13-83: While held by Williamson Storage & Ice Co., Williamson, N.Y., the article had been held under insanitary conditions—402(a)(4).

DISPOSITION: Default—ordered destruction. (F.D.C.



No. 63997; S. No. 83-351-442; S.J. No. 9)

PRODUCT: **Wheat**, at Lynchburg, W. Dist. Va.; Civil No. 83-0157-L.

CHARGED 11-4-83: While held for sale, the article contained insect filth—402(a)(3).

DISPOSITION: Consent—authorized release to Bartlett Milling Co., Lynchburg, Va., for salvaging. (F.D.C. No. 64114; S. Nos. 83-395-432/3; S.J. No. 10)

Foods/Economic and Labeling Violations

PRODUCT: **“Honey” (13 cases of unlabeled 1-pint jars, 31 unlabeled 5-gallon tubs, seven cases of 3-lb. jars, and three cases of 1-quart bottles and “sorghum” (two cases of 20-oz. jars and six cases of 4-lb. bottles),** at Las Vegas, Dist. Nev.; Civil No. CV-LV-82-133HEC.

CHARGED 3-5-82: When shipped by J. H. Pilgrim, Dekalb, Miss., all lots of the articles (except the six-case lot of 4-lb. bottles of “sorghum”) had had cane and/or corn syrup substituted for honey or sorghum—402(b)(2); the labeling of some of the articles (three cases) was false and misleading in representing that the articles consisted wholly of sorghum or honey when the articles contained cane/or corn syrup—403(a)(1); the two-case lot of 20-oz. jars (labeled “sorghum”) failed to conform to the definition and standard of identity for sorghum because the article contained a syrup from other than sorghum cane—401(g)(1); most of the “honey” lacked labels stating the common or usual name of the food, lacked labels bearing the name and place of business of its manufacturer, packer or distributor, and lacked labels stating the quantity of contents—403(i)(1), 403(e)(1), 403(e)(2); the six-case lot of 4-lb. bottles (labeled “sorghum molasses”) failed to bear on its label the name specified by the definition and standard of identity—403(g)(2); and the three-case and seven-case lots of “honey” were in violation of the Fair Packaging and Labeling Act since the quantity of contents statements were not expressed in fluid ounces followed in parentheses by a quantity declaration in accordance with regulations—15 U.S.C. §1453.

DISPOSITION: Default—ordered constructively destroyed by delivery to a suitable charity. (F.D.C. No. 63578; S. No. 81-219-988 et al.; S.J. No. 11)

Vitamins/Food Supplements

PRODUCT: **Mitchela compound herb tablets (in retail bottles and in bulk),** at Buffalo, W. Dist. N.Y.; Civil No. CIV-83-1024C.

CHARGED 9-16-83: While held by Zidrep Laboratories, Buffalo, N.Y., who manufactured the article using interstate squaw vine herb, the article (labeled “Dr. Dye’s Mitchela Compound Tablets . . . Zidrep Laboratories Successors to: Dr. J.J. Dye Medical Co. . . . Buffalo, N.Y.”)

contained the nonconforming color additive FD&C Violet No. 1—402(c); and the labeling of the article failed to declare the presence of such artificial color—403(k).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64085; S. No. 83-329-943; S.J. No. 12)

Drugs/Human Use

PRODUCT: **Calorex protein concentrate (starch blocker) tablets, and Carbo-Lite protein concentrate (starch blocker) tablets, two seizure actions,** at Memphis, W. Dist. Tenn.; Civil Nos. 82-2824-W, 82-2826-W.

CHARGED 11-29-82 and 11-29-82: When shipped by Vita-Lite Laboratories, Inc., and Bio-Tech Laboratories, Inc., Batesville, Ark., the articles were new drugs without effective approved New Drug Applications—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. Nos. 63823/4; S. Nos. 82-276-764/5; S.J. No. 13)

PRODUCT: **Calo-Lite phaseolamin (starch blocker) capsules,** at Miami, S. Dist. Fla.; Civil No. 83-2096-Civ-WMH.

CHARGED 8-19-83: When shipped in bulk from outside the state of Florida and repacked locally by Athena Products Ltd., Margate, Fla., the article was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Consent—ordered destroyed. (F.D.C. No. 64063; S. No. 83-269-109; S.J. No. 14)

PRODUCT: **Carbo-Lite protein concentrate (starch blocker) tablets,** at Nashville, M. Dist. Tenn.; Civil No. 82-3911.

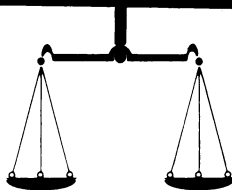
CHARGED 10-22-82: When shipped by Bio-Tech Laboratories, Inc., Batesville, Ark., the article was a new drug without an effective approved New Drug Application—505(a).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 63837; S. No. 82-275-494; S.J. No. 15)

PRODUCT: **Counterfeit drug tablets, peach-colored, and equipment (tableting machine, mixer, packaging machine, scale and punches) for making counterfeit drugs,** at Hauppauge, E. Dist. N.Y.; Civil No. CV82-2537.

CHARGED 8-26-82: While held by Pharmaceutical Dynamics, Inc., Hauppauge, N.Y., the article of drug (which bore the identifying mark, imprint or likeness of another manufacturer, packer or distributor) was a counterfeit drug and was a new drug without an effective approved New Drug Application—201(g)(2), 505(a); the articles of equipment were things used or designed for use in making a counterfeit drug—304(a); and the article of drug lacked adequate directions for use and was not exempted due to its new drug status—502(f)(1).

DISPOSITION: A consent decree condemned the article of drug and the equipment, ordered the article of drug destroyed, authorized release of the equipment to the



manufacturer upon specified conditions, and permanently enjoined the manufacturer from producing and distributing counterfeit or imitation drugs and enjoined other specified conditions upon the manufacturer. (F.D.C. No. 63796; S. No. 82-270-310; S.J. No. 16)

PRODUCT: Counterfeit drugs (black capsules, yellow capsules and white tablets), capsule-filling machines, capsule-imprinting machines, a packaging machine, a tableting machine, and imprinting punches, dies and rollers, at Pearl River, S. Dist. N.Y.; Civil No. 81-CIV-6038.

CHARGED 9-30-81: While held by V.I.P. Pharmaceutical, Inc., Pearl River, N.Y., who had manufactured the drugs, the drugs were counterfeit drugs in that, without authorization, they bore the identifying mark, imprinting or likeness of another drug manufacturer, packager or distributor; and the machines and equipment were things used or designed for use in making a counterfeit drug or drugs—201(g)(2).

DISPOSITION: The articles were claimed by the manufacturer, who denied the charges and asserted various affirmative defenses. The claimant served written interrogatories on the government. The government served written interrogatories and requests for admissions on the claimant. The government objected to parts of the claimant's interrogatories, which asked after all documents referring to the same or similar drug products that had been received by the government and all internal memoranda or other FDA communications referring to the products under seizure or any similar marketed products. The claimant filed a number of objections to the government's interrogatories.

Meanwhile, Elanco Products Co. (Div. Eli Lilly & Co.), Indianapolis, Ind., filed a claim for one of the seized capsule-filling machines. A partial consent decree of condemnation and a Rule 54(b) certification was entered into by the parties. Pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, it was certified that there was no just reason to delay entry of a judgment as to the drugs. The partial decree condemned as counterfeit all of the drugs and ordered their destruction.

The seized imprint rollers, punches and dies were also condemned and ordered destroyed. All of the equipment was judged to have been used in making the counterfeit drugs. The capsule-filling machine was claimed by Elanco Products Co. (which asserted that it had no knowledge that the seized equipment was used in violation of the law). Such machine was ordered released to Elanco Products Co., which was to remove the machine from the premises of V.I.P., Inc., and which was not to enter into any further agreement with V.I.P., Inc., respecting the continued use of the machine by V.I.P., Inc. The remaining equipment (a capsule-imprinting machine, a packaging machine, and a tableting machine) was to be the subject of a subsequent motion.

Ultimately, a consent decree of condemnation and permanent injunction was entered which authorized release of the

remaining equipment to V.I.P. Pharmaceuticals, Inc., upon payment of court costs and fees and conditioned upon performance in accordance with the terms and conditions of the decree. V.I.P. Pharmaceuticals, Inc., was permanently enjoined as follows: from manufacturing, packing, distributing, labeling or promoting for sale: 1) any counterfeit drug and 2) any over-the-counter drug that, by virtue of its size, color, shape and other marking, imitated a controlled-substances drug; that the manufacture and distribution of any drug by V.I.P., Inc., would immediately cease upon FDA notice that such drug is a counterfeit drug or an imitation of a controlled substance; that V.I.P. Pharmaceutical, Inc., would maintain for three years all drug production and distribution records, and would identify all drug products manufactured or processed in each piece of returned equipment; and that each drug distributor of V.I.P. Pharmaceutical, Inc., would be advised of this decree. (F.D.C. No. 63538; S. No. 81-138-234; S.J. No. 17)

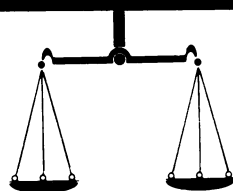
PRODUCT: Counterfeit drugs (yellow and black capsules), empty yellow capsules, empty black capsules, capsule-filling machines, packaging machines, labeling machines, 19 offset rollers, and two capsule-printing machines, at Milroy, M. Dist. Pa.; Civil No. 81-1127.

CHARGED 9-30-81: While held by Valley Run Pharmaceutical Corp., Milroy, Pa., who was manufacturing the OTC capsules that mimicked prescription drugs, the drugs were counterfeit drugs bearing, without authorization, the identifying imprint of another drug manufacturer, processor, packer or distributor—201(g)(1); and the equipment consisted of things used or designed for use in making counterfeit drugs—201(g)(1).

DISPOSITION: The articles were claimed by the dealer who denied the charges and asserted a number of affirmative defenses. Upon motion of the government, the court authorized post-seizure sampling of each of the seized drugs. The claimant moved for release of the two seized capsule-filling machines, two seized packaging machines, two labeling machines, and 19 imprint rollers. Subsequently, the claimant corporation, Valley Run Pharmaceutical Corp., together with its distributor Clifton, Inc., Milroy, Pa., and the president of both corporations, Clifford S. Kerstetter Jr., entered into a consent decree of permanent injunction and condemnation.

Under the terms of the consent decree, all of the seized articles were condemned, the seized drugs and the 19 imprint rollers were ordered destroyed, and the seized machines were authorized to be released to the claimant, upon the posting of a bond to cover payment of court costs and cost of destruction of the drugs and imprint rollers.

The consent decree also permanently enjoined the defendant parties from manufacturing, processing, packing, distributing, labeling or promoting for sale certain specified marked black capsules, yellow capsules, marked white or orange tablets, specified colored oblong tablets with blue



and/or green specks, specially marked round white tablets, and green, gold or pink triangular or shield-shaped tablets; enjoined the immediate cessation of the manufacture and distribution of any drug that FDA advised was a counterfeit or imitation drug; enjoined that Valley Run Pharmaceutical Corp. file specified reports with FDA; enjoined that Valley Run Pharmaceutical Corp. maintain records as specified by the current good manufacturing practice regulations, including, *inter alia*, the identification of the major pieces of equipment used for each lot of each drug product manufactured, processed, packed, held or labeled; and enjoined that FDA be supplied with copies of certain decree notification letters which were required to be mailed to past Valley Run drug distributors and consignees. (F.D.C. No. 63543; S. No. 81-224-648 et al.; S.J. No. 18)

PRODUCT: Stimulant drug capsules and tablets, including a counterfeit drug and an imitation drug, at Memphis, W. Dist. Tenn.; Civil No. 83-2356-HA.

CHARGED 5-2-83: When shipped by the Vitamin Shop, Pennsville, N.J., or by other interstate shippers, one lot of black capsules (imprinted "RJ8") was a counterfeit drug bearing the imprint of a drug producer other than the actual producer—201(g)(2); the articles were new drugs without effective approved New Drug Applications—505(a); the labeling of a number of articles was false and misleading as to the active ingredients because only caffeine and ephedrine sulfate were declared, although the articles also contained phenylpropanolamine HCl—502(a); a number of other articles (unlabeled) lacked the name and place of business of the manufacturer, packer or distributor, lacked a quantity of contents statement, lacked the established name of each active ingredient, and lacked adequate directions for use—502(b)(1), 502(b)(2), 502(e)(1)(A)(ii), 502(f)(1); one lot of brown and clear capsules was an imitation of Benzedrine Spansule capsules—502(i)(2); and one lot of white-scored tablets lacked labeling declaring the established name of the drug—502(e)(1)(A)(i).

DISPOSITION: Default—ordered destroyed. (F.D.C. No. 64001; S. No. 83-277-381 et al.; S.J. No. 19)

Drugs/Veterinary

PRODUCT: Nitrofurantoin suspension, at Elmont, E. Dist. N.Y.; Civil No. 78 C-702.

CHARGED 4-12-78: When shipped by Performance Products, Inc., St. Louis, Mo., the article (labeled "Equitoin Brand of Nitrofurantoin Suspension . . . Mfg For: Vitaplex Inc., . . . Elmont, New York") was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to its use and intended use—501(a)(5).

DISPOSITION: The article was claimed by the shipper, who denied the charge. The parties served written interrogatories on each other. A second set of interrogatories was served by the government upon the claimant. Ultimately,

after *certiorari* had been denied in a similar seizure action (*Performance Products, Inc. v. U.S.*, 103 S.Ct. 1497 (1983)), a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 61680; S. No. 78-140-060; S.J. No. 20)

PRODUCT: Procaine penicillin G (for veterinary use) in aqueous suspension, procaine penicillin G & dihydrostreptomycin in aqueous suspension, and other antibiotic veterinary drugs, at Concord, E. Dist. Mich.; Civil No. 83-CV-6179-AA.

CHARGED 5-13-83: While held by Kes-Ra Distributors, Inc., Concord, Mich., who had held the articles at room temperature for extended periods, the circumstances used for the holding of the articles failed to conform with current good manufacturing practices—501(a)(2)(B).

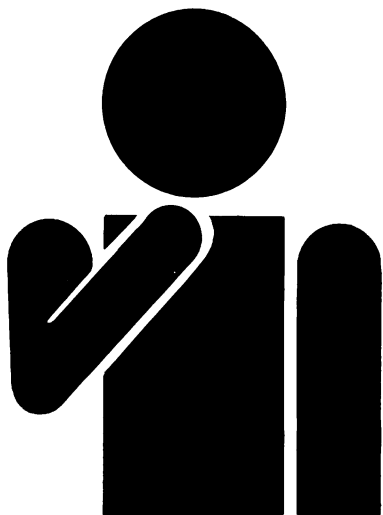
DISPOSITION: When no one claimed the articles, the government moved for a default decree. At the default hearing, the president of the dealer firm appeared *pro se* to claim the articles and submitted a response in which she said that she felt that the articles were not contaminated and that the inspection of the firm and subsequent seizure action were discriminatory. Treating the response as a claim and answer, the government moved for summary judgment. Ultimately, pursuant to stipulation between the government and the president of Kes-Ra Distributors, Inc., who did not oppose the government's motion for summary judgment, the court ordered the articles destroyed. (F.D.C. No. 64023; S. No. 83-309-615; S.J. No. 21)

Medical Devices

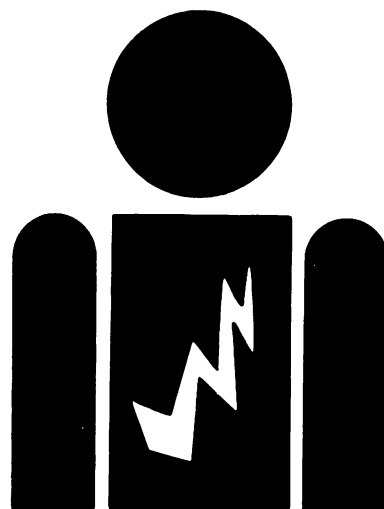
PRODUCT: Muscle stimulators, electrical, Figure-Tron II, at Norwalk, Dist. Conn.; Civil No. B-83-271.

CHARGED 4-22-83: The articles, which had been shipped from outside the state of Connecticut and were being repacked by Marilyn, Inc., Norwalk, Conn., were accompanied by labeling (*i.e.*, an instruction sheet) containing false and misleading claims for toning any area of the body—502(a); the articles' labeling lacked adequate directions for their intended uses (*i.e.*, as Europe's Miracle Body Shaper for vital figure-toning wonders of 3,000 sit-ups without moving an inch, 10 miles of jogging lying flat on your back, hours of exercise in 15 minutes, dialing a firmer, more youthful-looking, more beautiful body, shaping support muscles at the waist, tummy, bust, thighs, etc., and giving the tone-up result of doing sit-ups, leg raises, bendovers and miles of jogging—502(f)(1); the devices were being processed in an unregistered establishment and were not listed with FDA as required, and the required notice to FDA had not been provided—502(o)(1), (2) & (3); and the articles' label lacked the name and place of business of the manufacturer, packer or distributor—502(b)(1).

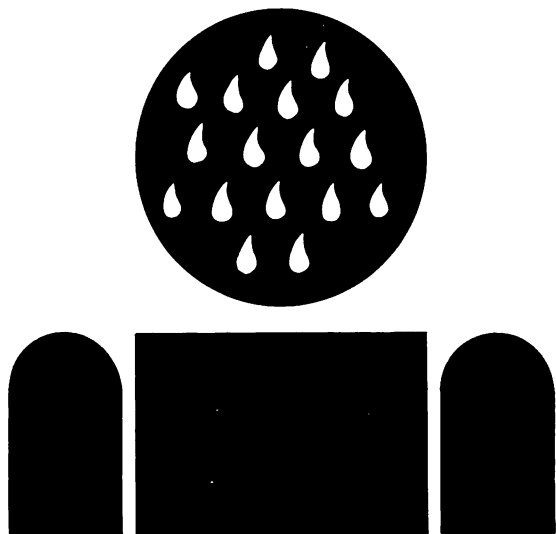
DISPOSITION: Default—ordered destruction. (F.D.C. No. 64012; S. Nos. 83-200-899 and 83-254-014; S.J. No. 22)



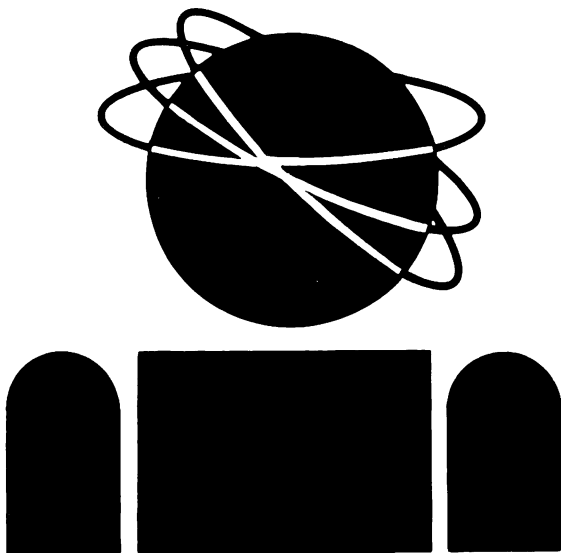
PAIN IN THE NECK



PAIN IN THE CHEST



SEVERE SWEATING



DIZZINESS

DON'T GIVE THESE SIGNALS A SECOND THOUGHT.

ACT IMMEDIATELY.

These signals may be the warnings your body gives you of a heart attack. And by ignoring them, you could be risking serious problems. Remember each year 350,000 Americans die from heart attacks before reaching the hospital. Often after much delay ignoring these warning signs.

So learn to recognize the symptoms of a heart attack. And when you see one or feel one, act quickly. As soon as you recognize a signal seek help immediately from a paramedic. Or get to an emergency room the fastest way possible.

You may not have a second to spare.

WARNING SIGNALS OF A HEART ATTACK

1. An uncomfortable pressure, fullness, squeezing or pain in the center of your chest behind the breastbone.
2. The sensation may spread to your shoulders, neck or arms. If it lasts for two minutes or more, you could be having a heart attack.
3. Severe pain, dizziness, fainting, sweating, nausea or shortness of breath may also occur, but are not always present.