Best Sellers

This Week | NONFICTION
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1 | A LIGHT IN THE ATTIC, by Shel Silverstein. (Harper & Row, $10.95.) Humor in cartoons and verse.
2 | A FEW MINUTES WITH ANDY ROONEY, by Andrew A. Rooney. (Atheneum, $12.95.) Reflections on contemporary life by the television commentator.
3 | THE LORD GOD MADE THEM ALL, by James Herriot. (St. Martin's, $13.95.) The further adventures of the Yorkshire vet at home and behind the Iron Curtain.
4 | THE PHYSICIAN'S BELLY FULL OF KUMQUATS DIET, by Dr. U. Ben Hadd. (McGuffie Reader Press, $19.95.) How to eat all the kumquats you want and still remain svelte.
5 | COSMOS, by Carl Sagan. (Random House, $22.95.) Thirteen billion years of the universe's evolution explained by the NASA medal-winning space scientist.
6 | JANE FONDA'S WORKOUT BOOK, by Jane Fonda. (Simon & Schuster, $15.95.) An exercise book for women, seasoned with the film star's philosophy of physical well-being.
7 | THE WALK WEST: A Walk Across America 2, by Peter and Barbara Jenkins. (Morrow, $14.95.) A newlywed couple's adventures on a trek from Louisiana to Oregon.
8 | PATHFINDERS, by Gail Sheehy. (Morrow, $15.95.) How ordinary people cope with the normal crises of life.

Last Week | Weeks On List
---|---
1 | 13
2 | 6
3 | 30
4 | 52
5 | 64
6 | 2
7 | 6
8 | 13
New Routes for Drugs To Travel
Today drugs might be pasted on the skin in a form of adhesive bandage. No longer is the medical profession limited to prescribing medicines that are taken orally or injected.

Cookware as a Source of Additives
Food can be adulterated by the pot or pan it is cooked in. Here's a look at aluminum, copper and ceramic utensils.

Diet Books Sell Well But...
It seems there is always a place near the top of the best seller list for a diet book. But, as this article points out, few of the diets offered are sensible ones and some are even dangerous.

On Getting the Lead Out of Food
Lead is a poison and some of it gets into our systems from canned food. This article tells what FDA and the canning industry are doing to cut down on the amount of lead we ingest in that manner.

Some OTC Drugs That Work, Some That Don't
More reports to FDA from panels of outside experts on over-the-counter medicines. These cover smoking inhibitors, oral insect repellents, bellyache remedies, corn and callus treatments, hormone products and mercury compounds.

Pregnant Women Heed Advice
A recent nationwide survey showed that women are aware of possible health dangers that may arise from caffeine and alcohol consumed during pregnancy.

Updates
The Notebook
Investigators' Reports
Seizures and Postal Service Cases
Notices of Judgment

Some 20 billion cans a year, like those pictured at left, are used to pack food in this country. Most of them are sealed with lead solder. But lead is poisonous. And therein lies a problem, discussed in On Getting the Lead Out of Food on page 18.
Another Look at Fats

Fats in the diet are important sources of nutrients and are responsible for many of the characteristic flavors, aromas and textures found in food, according to a Scientific Status Summary released in December 1981 by the Institute of Food Technologists. Fats also are the most concentrated sources of food energy in the diet yielding nine calories per gram, over twice as many calories as are supplied by either carbohydrates or protein. However, the report also concluded that some people may need to limit their intake of fats.

Fat consumption in North America has increased significantly during this century, the report of the Chicago-based institute points out. This increased consumption includes both visible and invisible fats as well as fats and oils used in processed foods. Visible fats include those foods that are solely or almost all fat, such as table spreads and cooking and salad oils. Invisible fats are those found in whole milk, eggs, meat and cheese.

The proportion of calories derived from fat in the average U.S. diet also increased during the same period, according to the Scientific Summary, since consumption of animal products has increased while consumption of cereal grains and potatoes, both low in fats, has decreased.

The institute acknowledged the public concern over recently raised questions as to the role of dietary fat in atherosclerosis and various forms of cancer. The report cited studies by various organizations and individual researchers on health effects, and noted that the dietary recommendations from these studies as well as those from other countries and organizations are in basic agreement on several points: that the diet should be made up of a variety of foodstuffs, that fats should be consumed in moderation, and that appropriate body weight should be maintained.

"At the same time," the IFT report concluded, "the high density of energy (calories) supplied by fats and oils contributes to the risk of obesity, and certainly moderation of their intake by those individuals at risk would seem well advised."

The Institute of Food Technologists is a professional scientific society devoted to the discovery and application of new and existing knowledge to improving the world's food supply. The Chicago-based institute has 20,000 members who are active in academic, industrial and government organizations.

What constitutes too much or too little fat in the diet was explained in the article "On Being Too Rich, Too Thin, Too Cholesterol Laden" in the July-August 1981 issue of FDA Consumer.

More DMSO Seized

On three days last December, U.S. marshals in the state of Washington made seizures of dimethyl sulfoxide (DMSO) from two area distributors, Solvent Sales, a division of Nordic Laboratories, Seattle, and B. J.'s Enterprises (Smoke Shop) in Fife. The seizures were made under a court order after complaints were filed by the U.S. attorney for the western district of Washington at the request of the Food and Drug Administration.

The marshals seized approximately $200,000 worth of DMSO in the possession of Solvent Sales in the form of 6,485 various size bottles and four 55-gallon drums. In addition, 29,366 empty bottles labeled for DMSO were seized. The complaint charged that the DMSO seized from Solvent Sales failed to bear adequate directions for its intended uses. Although the company claims that it is selling DMSO as a solvent only, FDA had obtained advertising and literature found distributed by the firm to promote the chemical for medical use. For example, a promotional piece distributed to prospective retailers stated:

"Despite the fact that DMSO sold without prescription must be sold for use as solvent and disclaim all medical applications, let's be frank: the bulk of bottled DMSO is being used by your customers as a pain relief medication."
At B. J.'s Enterprises, the marshals seized 38 eight-ounce bottles of DMSO. The complaint filed by the government charged that DMSO distributed by B. J.'s is a "new drug" that has not been approved by FDA for marketing for the uses for which it is promoted by B. J.'s and that the drug labeling fails to bear adequate directions for use. The firm promoted the sale of its DMSO through use of a pamphlet, "Wonder Drug or Industrial Solvent? DMSO," which claims that DMSO is effective in the treatment of 34 conditions including cancer, gout, aortic aneurisms, burns, arthritis, baldness and herpes simplex.

These were the fourth and fifth seizures of DMSO intended for medical use. Earlier seizures were made in Buffalo, N.Y., Menominee, Wis., and Tampa, Fla. The history of DMSO was the subject of a short article titled "DMSO: No Proof of 'Miracles'," in the September 1980 FDA Consumer.

**PPI Replacement**

A Committee on Patient Education has been established within FDA to help educate consumers about prescription drugs. The committee was formed by FDA Commissioner Arthur Hull Hayes Jr., M.D., at the direction of Health and Human Services Secretary Richard S. Schweiker after a proposal to test patient package inserts (PPIs) for 10 drugs was rescinded.

The patient education committee will not only have a public education function but will also serve as a catalyst for private sector initiatives in this area. The PPI program was to be tested over a 3-year period.

Commenting on the committee and the PPI proposal, Secretary Schweiker and Commissioner Hayes said in a joint statement:

"This department remains committed to the need for patients to have more information about prescription drugs. Patients must actively participate with their physicians and others involved in health care in deciding on the best therapeutic approach to treating illnesses.

"The question is what is the best system, or systems, for providing that information. Our review of the 10-drug pilot program developed last year showed it to have significant limitations and to impose unreasonable constraints on the health care system. Moreover, we learned during our review that many physicians, pharmacists and other health professionals believe there are more effective and cost-efficient ways to bring information to consumers.

"We recognize that the government has an important and necessary role to play in consumer education about prescription drugs and other health care products and that the private sector has begun to take innovative and effective steps toward more patient information. These efforts need to be encouraged and supported by the government."

The functions of the Committee on Patient Education, to be chaired by Commissioner Hayes, are as follows:

—to identify new ways to bring information about prescription drugs to consumers.

—to encourage additional private sector initiatives.

—to work closely with health professionals on systems that will facilitate the providing of more information to patients.

—to evaluate existing patient information systems as well as new ones.

—to encourage the formation and to serve as a liaison for outside organizations that are or want to become active in patient information systems.

—to provide guidelines and serve as a clearinghouse for firms that want to draft prescription drug information.

—to alert consumers and health professionals to the usefulness and availability of prescription drug information.

—to assess the adequacy and effectiveness of private sector patient information systems and to provide to the secretary of HHS on a regular basis reports and recommendations.

—to identify the need for patient information in the use of other products regulated by FDA, such as medical devices, X-rays and biological products.

In addition to Dr. Hayes, the members of the committee are:

Mark Novitch, M.D., deputy commissioner, vice chairman; Robert Brady, executive assistant to the commissioner; J. Richard Crout, M.D., director, Bureau of Drugs; Jerome Halperin, deputy director, Bureau of Drugs; James Benson, deputy director, Bureau of Radiological Health; Victor Zafra, acting director, Bureau of Medical Devices; Harry Meyer, M.D., director, Bureau of Biologies; Thomas Scarlett, chief counsel; Michael Peskoe, associate chief counsel for drugs; Kenneth Durham, acting associate commissioner for policy coordination, executive secretary of the committee.

Also Stuart Nightingale, M.D., acting associate commissioner for health affairs; Gerald Barkdoll, associate commissioner for planning and evaluation; Alexander Grant, associate commissioner for consumer affairs; Robert Wetherell, associate commissioner for legislative affairs; Wayne Pines, associate commissioner for public affairs; Peter Rheinstein, M.D., director, division of drug advertising and labeling, Bureau of Drugs; Lloyd Millstein, Ph.D., deputy director, division of drug advertising and labeling, Bureau of Drugs; and Louis Morris, Ph.D., head, patient labeling branch, Bureau of Drugs.

FDA now requires PPIs for isoproterenol inhalation preparations, oral contraceptives, estrogen drugs.
used by menopausal and post-menopausal women and for drugs containing progestins. PPIs are also required to be given to women before they decide to use an IUD—an intrauterine contraceptive device. These PPIs are not affected by the December actions. Several articles on PPIs have appeared in FDA Consumer, the most recent being “Rx With a Dose of Info” in the November 1980 issue.

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Angina Drug Approved

A new drug, nifedipine, has been approved by FDA. It is a potentially important alternative treatment for patients with angina—the vise-like chest pains that result when narrowed or contracting arteries starve the heart muscle of oxygen-bearing blood.

Dr. Arthur Hull Hayes Jr., FDA commissioner, said the approval represents a “significant medical advance for patients who cannot tolerate or are not helped by other drugs.”

To be marketed by Pfizer Inc. of New York under the trade name Procardia, the drug is one of a new group of drugs called “calcium blockers.” Calcium molecules play a role in causing the blood vessels to contract and narrow. By blocking this action, the drugs keep open the vessels supplying blood to the heart. Nifedipine is the first in the calcium blocker group to be approved in an oral dosage form.

Other drugs for angina are nitroglycerin, which has been used for more than a century, and beta blockers, which have been available since 1967 but which generally cannot be used for angina patients with asthma or weak hearts.

Nifedipine is not necessarily more effective than beta blockers but has a different mechanism of action and range of side effects. It may sometimes be useful as added therapy, although great care must be taken when used with other angina drugs, Dr. Hayes said.

FDA has approved one other calcium blocker, verapamil (marketed by Knoll as Isoptin and by G. D. Searle & Co. as Calan) as an injectable for emergency room use to calm irregular or rapid heartbeats known as arrhythmias.

Both old and new drugs to treat the symptoms of heart disease were described in the article “Drugs Are Dear to Many Hearts” in the December 1981-January 1982 issue of FDA Consumer.

Prison Drug Testing

FDA has proposed a new policy on the use of prisoners for drug and medical device research. Under the new proposal, published Dec. 18, 1981, FDA would accept the results of research other than that intended to directly improve the health of prisoners if the sponsor shows a need to use prisoners and meets other conditions. One key condition is that the prison environment permit prisoners to freely consent—or decline—to participate in the research. Local institutional review boards would be charged with ensuring that this condition is met.

Under an earlier version of the regulations only research aimed directly and specifically at improving the health of the prison population would have been accepted. Prisoners at the State Prison of Southern Michigan at Jackson had objected to this policy, saying it would end existing drug testing programs. Four of the prisoners filed suit in 1980 to block the regulation. The Upjohn Co. of Kalamazoo, Mich., which operates research facilities at the prison, joined in the suit.

The prisoners contended that they were protected by Michigan Department of Corrections policies from coercion and other abuses. Upjohn said research at Jackson was under careful medical supervision and was open only to prisoners who were fully informed volunteers.

The U.S. District Court for the Eastern District of Michigan in Detroit then dismissed the prisoners’ suit after FDA agreed last June to take a new look at the
regulation.

FDA believes the new proposal is in keeping with the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. That commission was created by Congress under the National Research Act of 1974. The commission was concerned that crowding and promises of parole not be used to pressure prisoners, and sought to ensure that prisoners had grievance rights and contact with the public.

The final rule will become effective 90 days after publication in the Federal Register (FR Dec. 18, 1981).

Poison Plants Brochure

The indoor greening of America has created a poisoning problem of some magnitude: The problem is that plants used to adorn homes and businesses are also of interest to the younger set. Their interest often leads to tasting the growing stuff, and much of what grows was not meant to be eaten.

FDA's division of poison control noted that its tracking of poisoning case reports from 400 poison control centers finds ingesting of plant materials by children to be the leading cause for a visit or report to a center. Fortunately, in most cases, the child doesn't become ill or require hospitalization. Nevertheless, it's always best to be on guard. To help people identify troublesome plants, the division of poison control has available a full color brochure titled "Common Poisonous and Injurious Plants." Copies may be obtained by writing to:

Division of Poison Control, HFD-240
Food and Drug Administration
5600 Fishers Lane
Rockville, Md. 20857

Up to five copies will be provided per request. There is no charge for the publication.
New Routes For Drugs To Travel

by Annabel Hecht

Anyone suggesting that some day drugs might be directed to specific sites inside the body by magnets on the outside or that miniature pumps could course through the digestive system and release a steady stream of medication as they go might reasonably be accused of spending too much time curled up with Ripley's "Believe It Or Not."

Such unique ways of getting drugs to the right place inside the patient are not as far out as they may seem. In fact, a number of drugs in unusual packages already have been approved by FDA. They were developed because present-day drug dosage forms don't always deliver.

Drugs, as most people know them, come in many forms and shapes. There are tablets and capsules to be swallowed and there are tablets that are to be dissolved under the tongue. Liquids, both colorful and flavorful, help the medicine go down, especially when the patient is a tiny tot. Then there are aerosol sprays that send drugs up the nose or down into the lungs, creams and ointments to be rubbed on the skin, drops for the eyes, and solutions that are injected into a vein or muscle.

Despite this variety, drug taking has its problems. An oral dose usually provides a high level of the drug in the blood right away, but as the drug is eliminated from the body, the level of the medication in the blood drops. Another dose shoots the level up again. What results is roller coaster therapy. If the patient should skip a dose, the amount of drug in the system might drop dangerously low—a serious situation if the drug was being taken to prevent a condition such as irregularities of the heart beat.

Some drugs are eliminated from the body so fast that the patient has to take them frequently to be sure there is enough medicine in the system and do its job. This may become such a burden that the patient sometimes just doesn't bother or may forget to open that bottle of pills.

Many drugs produce unpleasant side effects; some are poorly absorbed if there is food in the patient's stomach. Powerful drugs used to treat cancer often damage healthy as well as disease cells. Injecting drugs in a vein or muscle can cause pain and discomfort and possible infection where the needle enters the skin.

Some of these problems have been overcome by "controlled release" dosage forms that became prevalent in the late 1950s. Such forms have a number of aliases including delayed action, repeat action, slow release, prolonged release and timed release forms.

Perhaps the most familiar is the widely advertised over-the-counter drug capsule containing hundreds of "tiny time pills." Variations in the thickness of the coating on each pill determines when the active ingredient will be released. In another form, the drug is divided between an outer layer that gives the first burst of medication and inner core protected by a waxy coating designed to release the rest of the drug six hours after it has been taken. Still another form is a tiny wax basket through which the drug diffuses gradually over a period of time. The basket itself remains intact until excreted.

In addition to controlled release drugs taken orally, there are pellets containing hormones that are implanted under the skin. Used to treat hormone deficiency diseases and some types of cancer, these implants release their medication over periods of several months while being absorbed into the tissues. One unusual, if not bizarre, approach to drug implantation started in 1955 when a French researcher developed a technique for implanting tablets of disulfiram under the skin of patients being treated for alcoholism. Disulfiram (trade name Antabuse) reacts with alcohol and makes the person who mixes drug and drink ill. The ease with which alcoholics could circumvent their treatment, by not taking the drug orally, was what led the researchers literally to sew the pills into the patient. The technique has never caught on in the United States.

One of the oldest controlled-release dosage forms is the tablet that is coated to assure that absorption takes place in the intestines rather than in the stomach. Enteric coating, as it is called, dates back to 1884.

Nearly 80 years after that early effort to control drug release an entirely new approach to achieve this end began to evolve—the concept that drugs would diffuse at a steady rate from implantable polymer containers. A polymer is a plastic-like material, similar to the synthetic fabrics from which clothing is made. Drs. Judah Folkman and David M. Long, then with the National Naval Medical Center in Bethesda, Md., are usually credited with the idea of using containers to control drug release. The two observed that thyroid hormone placed in a very small silicone rubber capsule was released at a steady rate day after day in a laboratory dish. The same steady release also occurred when the capsule was implanted in the heart muscle of dogs. After publication of their findings in 1964 other researchers demonstrated that a variety of drugs would diffuse through similar capsules over long periods of time.

Unfortunately, the silicone rubber capsule has one drawback—fat-soluble drugs of small molecular structure can't pass through it. Therefore, researchers in the late 1960s and early 1970s sought a material that would let larger molecules through without causing inflammation of the tissues. The perfect material—a polymer called ethylene-vinyl acetate copolymer—was found by Dr. Robert Langer of the Massachusetts Institute of Technology and Folkman, now with Harvard Medical School. They made the discovery while studying a substance that stops the growth of capillaries into certain tumors.

Three basic types of implantable drug release systems have
resulted from research with polymers. They are:

- The swelling system in which the drug is completely surrounded by a polymer. The polymer swells allowing the drug to migrate into the tissues.

- The chemical system in which the drug is dispersed throughout the polymer. The drug is freed to do its job when the polymer dissolves or erodes.

- Diffusion systems from which the drug migrates from within a polymer to the outer surface. The drug can be stored in a reservoir or dispersed throughout a polymeric matrix.

One unusual drug system, called OROS, uses polymers in an oral dosage form. Although it looks like a conventional tablet, OROS is actually a miniature osmotic pump. It consists of a drug reservoir, a surrounding semipermeable polymer membrane with a minute opening through which the drug is released. As it goes through the intestines, water enters through the membrane, gradually dissolving the solid core of drug. The internal pressure generated by the water then forces the solution out of the tiny hole in the capsule. Not yet on the market, the OROS system, developed by Alza Corp., is being tested with major drugs by several companies.

Unusual containers for controlled release systems have not been limited to polymers. Researchers throughout the world have been encasing drugs in tiny packages through the process known as microencapsulation. Microcapsules used in pharmaceutical research are measured in microns, a micron being one millionth of a meter (a meter is 39.37 inches). These incredibly small containers have been made of materials such as nylon and ethylcellulose and natural substances including albumin and liposomes. The substances encapsulated in them have included enzymes, hormones, cancer drugs, antigens, pentobarbital sodium and phenothiazines. Even red blood cells are being tapped to serve as microcapsules to carry corticosteroids and anti-cancer drugs.

Because of their extremely small size microencapsulated drugs can be injected into the subject and even manipulated once inside. A Chicago research team mixed ultrafine magnetic particles with a drug in an albumin microsphere (a microsphere differs from a microcapsule in that the drug is mixed with the polymer or other material instead of being surrounded by it). When the microspheres were injected into a rat’s tail, the researchers were able to move them to the desired site by moving a magnet outside the animal’s body. Another investigator has found he can increase the amount of drug released by passing a magnet over an implanted polymer matrix in which tiny magnetic steel beads have been embedded along with an active drug.

Although much remains to be learned about these unusual drug delivery systems, some of the principles behind them have been applied to products now on the market. The first of this new breed to get FDA approval was the Ocusert system for the treatment of glaucoma. The usual treatment for this eye disease calls for drops containing pilocarpine to be put in the eyes three or four times a day. Not only is this inconvenient, but there always is the chance that too little or too much of the drug will reach its target. The Ocusert system, consisting of two transparent membranes of ethylene-vinyl acetate copolymer with a reservoir of pilocarpine in between, is placed under the lower eyelid where it releases a steady dose of drug for about a week. The advantages of the Ocusert are obvious: It simplifies the glaucoma patient’s drug-taking schedule, reduces the temporary blurring associated with the eyedrops and exposes the patient to less of the drug with the same effect. Ocusert was developed by Alza Corp. and is marketed by Ciba.

Another implantable slow release drug product is the Progestasert Intrauterine Progesterone Contraceptive System, also developed by Alza. In this system precisely controlled amounts of progesterone are released from a polymer reservoir in the long bar of a T-shaped device inserted within the uterus. The amount of progesterone delivered in the device’s one-year life span is said to be equivalent to that contained in only three oral contraceptive pills.

Drugs don’t always have to be taken internally to do their work; some can reach their target transdermally or through the skin. One such skin-delivery system is the Transderm-V, again developed by Alza, which is an easy way to take scopolamine for motion sickness. Oral scopolamine is effective but has many side effects. Transderm-V is a tiny, thumbnail size disc made up of an outer layer of polyester film, a reservoir to hold the drug, a polypropylene membrane that controls the release of the drug, and an adhesive layer to hold the disc in place behind the ear.

The system provides enough scopolamine for three days and is claimed to reduce some of the side effects usually associated with this drug. Some reports, however, indicate that side effects such as dryness of the mouth, drowsiness and blurred vision do occur with the transdermally delivered scopolamine.

FDA has given provisional approval to three similar drug systems that deliver nitroglycerin through the skin. Nitro-
the pain occurs. Since the effect lasts only about 15 minutes, the patient dissolves a nitroglycerin tablet under the tongue when that comes when the heart is deprived of oxygen. Usually the glycerin is the primary treatment for angina, the chest pain for angina (chest pain) attacks. The medication is fed un-formly through the skin over a 24-hour period.

Nitroglycerin is the primary treatment for angina, the chest pain that comes when the heart is deprived of oxygen. Usually the patient dissolves a nitroglycerin tablet under the tongue when the pain occurs. Since the effect lasts only about 15 minutes, many pills may have to be taken during the course of a day. With all three new drug systems, a whole day's supply of nitroglycerin is contained in a single adhesive bandage that is applied to the chest or upper arm.

In one of these systems, the Nitrodisc, developed by G. D. Searle Co., the drug is dispersed throughout a polymer in tiny microcompartments. These compartments serve as tiny reservoirs from which the nitroglycerin is diffused into the skin at a steady rate. The Nitro-Dur system of Key Pharmaceuticals Inc. contains a number of chemical binding sites distributed throughout a three-dimensional polymeric matrix. Nitroglycerin molecules bound to these sites gradually dissolve into a fluid phase, which then permeates the skin. The third system, Alza's Transderm-Nitro, is a four-layer disc consisting of an outside layer impermeable to nitroglycerin, a drug reservoir containing the nitroglycerin, a membrane through which the drug will diffuse, plus a layer of silicone adhesive to hold the disc in place.

While drugs in these transdermal systems reach their site of action through the bloodstream, direct delivery to the spot where the drug is needed is the concept behind the INFUSAID, an implantable pump soon to be approved by FDA. In contrast to the microcapsules and microspheres of some controlled-release drugs, INFUSAID is about the size of a hockey puck and is implanted in the patient's abdomen. The pump is a disc made of titanium, divided inside into two chambers by a bellows. The bottom compartment contains a fluorocarbon propellant that exerts a constant pressure against the bellows. The drug, in the upper chamber, is pushed by the propellant into a catheter that is inserted into a vein or an artery. The upper chamber can be refilled as needed by means of a hypodermic syringe without discomfort to the patient.

Developed at the University of Michigan Medical Center, INFUSAID was originally designed to infuse heparin, a blood thinning drug, into patients with severe blood clotting problems. It has now been adapted to deliver powerful cancer drugs directly into the hepatic artery to treat liver tumors. The infusion pump not only is prolonging the lives of victims of liver cancer, but is making those years better in a number of ways. For instance, toxic drugs are confined to the malignant cells rather than being dispersed throughout the body, thus keeping side effects to a minimum. In addition, the patient does not need to be hospitalized and can pretty well carry on a normal life.

Infusion pumps, transdermal systems and polymer capsules might be just the tip of the iceberg. Interest in controlled release delivery systems is high not only in the pharmaceutical industry, but also in university laboratories. What new and unique systems will result is anybody's guess.

Microencapsulation of drugs to release them at target sites is viewed as one of the emerging technologies that will need FDA's attention in the next five or so years, according to a survey of a group of 190 scientists within and outside the agency.

Scientists studying polymers see their potential for the sustained release of insulin, heparin, growth hormone, interferon and other potent macromolecules produced by the body.

The next major breakthrough in infusion pump design may be a closed-loop infusion system, according to a recent report to FDA. In such a system the patient's need for a drug will automatically trigger the release of an appropriate amount.

Whatever is developed, be it drug or device, any new delivery system is subject to FDA scrutiny. However, most controlled release preparations are simply old drugs in a new dress. Since the safety and effectiveness of the original dosage form of these products has been established, manufacturers usually are not required to carry out large controlled clinical tests. They do have to provide bioavailability data to show that the product meets the controlled release claims made for it; that it is designed to prevent dose dumping—that is, the active ingredient is not released all at one time; that its effect is the same as approved conventional dose forms or controlled release forms containing the same active ingredients; and that each individual dose behaves in the same way.

Drugs marketed for the first time in controlled release form do need to be tested for safety and effectiveness.

Devices that are implanted in the patient must be approved before they go on the market and, of course, must be shown to be safe and effective. In some cases the manufacturer may be required to monitor patients for certain periods of time after the device is put inside to make certain no problems develop.

Annabel Hecht is a member of FDA's public affairs staff.
COOKWARE
As A Source Of
ADDITIONS

by Doug Henderson

The truly discriminating gourmet cook with a healthy supply of cash can purchase a 10-inch silver frying pan from Tiffany and Co. of New York City for $1,675. One would be hard-pressed to label that a bargain. But consider that silver is the number one metal for conducting heat, and consider how much class a silver skillet would add to the pegboard on almost any kitchen wall.

Fortunately, there are affordable alternatives: copper, aluminum, iron, stainless steel, glass and pottery, to name a few. In general, FDA considers food prepared in these cookware alternatives to be safe, although questions have been raised by consumers about the safety of cooking utensils made of some metals, particularly cookware made of aluminum and copper, and pottery coated with lead glaze.

Some of the questions: Does metal from aluminum cookware ever get into our food in dangerous amounts? Are there precautions that should be taken when cooking with copper? Is there a problem with cooking or holding foods in pottery coated with glazes that contain lead?

FDA’s responsibility for the safety of our food supply extends to the safety of metals in cookware because of the possibility that some metals may leach into food in amounts large enough to be potentially harmful. To leach means to dissolve and wash into. Under the law, any food is considered adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health.” Products that are found hazardous by FDA are subject to immediate removal from the market.

Increased public concern has focused on aluminum since July 17, 1980, when, in a letter to the highly regarded New England Journal of Medicine, Dr. Stephen Levick of the Yale University School of Medicine hypothesized a connection between the use of cheap aluminum cookware and Alzheimer’s disease, a progressive brain disorder characterized by memory loss and learning deficiencies.

Levick wrote that as a “financially strapped medical student,” he had purchased inexpensive aluminum pots and pans. After two years of use, he noticed “corrosive pitting and whitish powdery deposits around the pots.” Afterward he learned that in Alzheimer’s disease, higher than normal levels of aluminum had been found in the brain tissue of deceased victims. Levick then suggested a possible connection between Alzheimer’s disease and the ingestion of aluminum, but expressed the belief that his hypothesis required more systematic study. In the meantime, he said, he would no longer use his cheap aluminum pots.

Levick made no reference to a 1980 study which showed that autopsies of Alzheimer patients revealed slightly lower levels of aluminum in their brains than were found in autopsies of normal adults. There were also greater levels of mercury in the brain tissues of these victims as compared to normal adults. Nor did Levick mention that scientists remain puzzled over a major question concerning the concentrations of aluminum in brain tissue from Alzheimer patients: Does aluminum ac-
cumulation in the brain cause the dis-
ease or does the disease itself alter body
chemistry to allow accumulation of
aluminum? According to FDA officials,
no direct causative effect between
aluminum and Alzheimer's disease has
been shown to date.

Does the ingestion of aluminum in
the diet, either that naturally present in
food or added from aluminum
cookware, pose any other human health
hazard? While a portion of any ingested
aluminum is absorbed into the body
through the gastrointestinal tract, the
total amount is far less than that which
could be expected to result in any ad-
verse health effects. A large percentage
of the aluminum ingested is excreted
along with other waste material.

When one cooks with aluminum,
does it migrate into the food? Under
normal conditions the total amount of
aluminum added to food from
cookware is relatively small. However,
prolonged retention in aluminum
cookware (from five or six hours to
several days) of certain highly acidic
foods such as tomato sauce, sauerkraut
or beverages including citrus juices and
carbonated drinks may cause more
aluminum than usual to enter the food.
Similarly, higher levels of aluminum
will migrate into acidic or salty foods
stored in aluminum foil. Because
metallic aluminum is subject to some
disintegration from salt or acid foods,
white powdery deposits may ac-
cumulate on the aluminum foil or it
even develop pinholes after exten-
ded contact with such foods. However,
there is no conclusive evidence showing
toxic symptoms from consuming acidic
or salty foods, either cooked in
aluminum pans or stored in aluminum
foil.

Many aluminum compounds are
sanctioned by FDA for use as buffering
agents (acid neutralizers) in antacids,
bleaching agents in cheeses, leavening
agents in bread and flour and mordants
(color fixers) in some coloring agents.
Such approval has been based on a
number of studies that have
demonstrated the relative safety of
these aluminum compounds at the pre-
sent levels of use.

Copper is called a “noble” metal by
cooks and chemists, but for different
reasons. Noble to a chemist means that
the metal does not corrode easily. To a
cook or an ordinary layman, it means
magnificent in appearance. To both,
copper fills the bill.

Copper is also an excellent conductor
of heat (second only to silver); hence its
wide use in the kitchen. Cooks often
prefer copper cookware, particularly
for delicate sauces and foods that must
be cooked at precisely controlled tem-
peratures.

Most copper cookware is lined with
tin and presents no problem of copper
migration into food, although the pan
must be relined when the tin starts
wearing thin. Using unlined copper
utensils for cooking or storing food may
be harmful. Copper migrates to any
food with which it comes in contact, es-
pecially those high in acid. An essential
nutrient in the body, copper aids in the
absorption and metabolism of iron. But
copper can be toxic at much lower levels
than aluminum. Those persons who in-
gest food containing harmful levels of
copper may experience nausea,
vomiting or diarrhea. Thus FDA
recommends that consumers use only
tin lined copper cooking utensils for
cooking or storing food.

There are many types of enameled,
ceramic and glass cookware. Generally,
they present no safety problems. For ex-
ample, in the United States the enamels
applied to the food contact surfaces of
iron or steel cookware do not contain
lead or cadmium. When enamels con-
taining lead or cadmium or both are ap-
plied to aluminum vessels, they are not
applied to the food contact surfaces.
Therefore porcelain-enameled
cookware so manufactured does not
represent a potential problem.

But some foreign manufacturers at
one time decorated the interior of metal
cookware (including the lids) with
brightly colored cadmium-containing
enamels. As a result of this practice, a
number of shipments were denied entry
into the United States. However, this
practice was discontinued in the early
1970s.

Glass and glass ceramic ware should
be perfectly safe to use. The manufac-
turing process for these products is such
that they are of no concern.

China, crockery and earthenware are
also forms of ceramic cookware. If
glazes used on them are improperly for-
mulated, applied and fired, a health
hazard might ensue because of the con-
ditions of use. Acids from foods can
react with such products and cause
potentially hazardous levels of lead and
cadmium to leach into food.

Fortunately, quality control stand-
ards for the ceramics industry have been
made stringent as a result of concen-
trated efforts by FDA to educate in-
dustry about lead and cadmium migra-
tion problems. As a result, industry has
implemented its own surveillance
programs. Reputable domestic and
foreign manufacturers now use correct
firing and mixing methods to prevent
lead and cadmium leaching problems.
FDA continues to survey and obtain
samples to assure continued safety of
these products.

While efforts have been under way to
educate the art potter and hobbyist con-
cerning these potential problems, some
amateur potters may be unaware of
correct mixing and firing procedures.
Therefore, it may be prudent to use
such products for decorative purposes
instead of for cooking and storing
foods.

Doug Henderson is a technical writer in
FDA's Bureau of Foods.
H ope springs eternal not only in the human breast, but also, it seems, in the human stomach.

The person with a tummy that likes yummies yearns to feel full yet look flat. The human appetite hunger for some magic formula that allows eating abundantly at the same time that excess weight is being shed.

Increasingly in the last few decades, Americans have become more aware of the health consequences of being overweight and have come to consider an ideal body weight that sometimes seems on the emaciated side. The new diet—almost any new diet—turns up again and again as the focus of magazine articles and best selling books.

Scanning the popular literature for help in losing weight, the would-be dieter receives a confusing array of advice:

- Eat mostly protein foods and few, if any, carbohydrates.
- Consume an abundance of carbohydrates and little protein.
- Eat only rice—only ice cream—or only fruit.

One diet expert may advise eating only twice a day. Another proposes six meals a day, a third says eat as often as you like.

How are 50 million overweight Americans to sort it all out? How can they (and other millions who are not clinically overweight but who desire to be thinner) select a diet that will help them lose weight but not jeopardize their health?

Many dieters have asked FDA's advice about the various diets. FDA is responsible for the safety of foods and their appropriate labeling. But claims made in new articles and books for foods or dietary regimens are generally out of FDA's domain. In fact, such claims are protected under the First Amendment to the Constitution. This means that anyone, regardless of nutritional or medical expertise, can make any claims he wishes in articles or books. However, if a book or article is used to misbrand a particular food, its use may be regulated by FDA.

Consumers, then, need to protect themselves from diets that could be harmful. One way to do this is to consult a physician before embarking on any diet, and if possible, consult a dietitian or nutritionist as well. Consumers can also inform themselves about the basics of nutrition to understand the risks associated with specific diets and to discount the extravagant claims and unscientific reasoning put forward for some of them.

A concept essential to dieting is that of the calorie. Most promoters of diets consider reducing one's intake of calories essential to loss of weight. But there are some "experts" who claim that "calories don't count" or that some calories, for example calories from protein, are different from calories from carbohydrates.

Who is right?

A calorie is a measure of heat energy. One calorie (known technically as a kilocalorie) is the amount of heat it takes to raise the temperature of a kilogram (about a quart) of water by 1 degree Celsius. Therefore, it doesn't matter whether this energy is generated by protein, carbohydrate or fat, so long as it raises the temperature of a kilogram of water that 1 degree. The misconception about different types of calories may arise because different food nutrients provide different numbers of calories on a per gram basis: Carbohydrate and protein each supply four calories per gram, fat provides nine and alcohol eight. (There are 28.4 grams in an ounce.)

The human body requires a certain number of calories each day to maintain its weight. The number varies with age, body size and activity. For each pound a dieter wishes to lose, he or she must cut out the necessary number of calories from the diet, or increase physical activity to burn these excess calories.

It takes 3,500 calories to burn a pound of body fat stored in the tissue. To lose one pound of fat a week, a person must either reduce food consumption by 500 calories a day, or expend enough energy to burn 500 calories a day more, or an appropriate combination of the two.

Advocates of some diets claim their plans will make it possible to lose weight at a faster rate, or at a higher caloric intake than other diets permit. This claim is often made for high protein, low carbohydrate diets. In The Doctor's Quick Weight Loss Diet, Irwin Maxwell Stillman claims that his high protein (virtually no carbohydrates) diet will cause the "system to burn more calories daily than with a diet of the same total caloric intake that includes other foods." He explains that fat is burned at a quicker rate on an "unbalanced" high protein diet than on a balanced diet.

The rationale for this claim is based on the concept of ketosis. Energy is obtained primarily from the breakdown of fat. Ketosis is a process that occurs when a person's diet is so low in carbohydrates that the fat deposits are broken down for energy faster than the body can use them. Ketone bodies are formed from the incomplete breakdown of fatty acids. In ketosis, the ketone bodies accumulate. This can lead to an acid and alkaline imbalance in the body. Because the excess ketones must be excreted into the urine, the dieter on a low carbohydrate, high protein, low carbohydrate diet gets rid of large amounts of water. This shows up as a quick and substantial weight loss. Ketogenic diets, therefore, require a large intake of water and other fluids to make sure that the body has enough fluid to rid itself of the ketones and to keep the dieter from becoming dangerously dehydrated. Because most of the loss is water, not body fat, many dieters find that much of the weight loss from this type of diet is regained soon after nor-
mal eating is resumed.

Another physiological fact to consider before embarking on a ketogenic diet is that in ketosis the body's mode of burning calories may be similar to that of fasting. The body's fuel comes from glucose, which is most easily obtained from carbohydrates and less easily from protein. When the body lacks carbohydrates, as when a person is fasting or is on a low calorie and very low carbohydrate diet, protein is degraded to supply the minimum level of glucose. This protein is taken from lean body mass muscles and major organs such as the liver, heart and kidneys.

This is primarily the reason for the rather dramatic initial weight loss in low calorie, high protein diets. While 3,500 calories are needed to burn a pound of body fat, it takes only 480 calories to get rid of a pound of "lean body mass."

Another ketogenic regimen is a very low calorie (fewer than 400 calories) protein diet, particularly the liquid protein diet. These diets have been associated with deaths resulting from ventricular arrhythmia (irregular heart rhythms) in 17 relatively young healthy persons, according to a team of investigators from FDA and the Centers for Disease Control. As a result of their study, published in the April 1981 issue of The American Journal of Clinical Nutrition, this team recommended that the use of these weight reduction programs be curtailed until scientists can find out how, or even if, they can be made safe.

The 17 deaths were among a number of deaths of dieters following very low calorie protein regimens. Some of the victims had underlying diseases that could have caused their deaths; however, these 17 dieters were free of serious underlying disease and their deaths had no apparent cause. The 16 women and one man all took vitamin or vitamin-mineral supplements while on the protein diets. Of these, 12 were dieting under medical supervision. All 17 patients died suddenly, some in the hospital. Cardiac arrest occurred in five patients before they were hospitalized. None of the five ever regained consciousness. Extremely rapid heartbeats and erratic heart functioning were documented in 11 people who died under observation.

Because of these deaths, FDA has pending a regulation to require warning labels on products for weight reduction (especially those intended for use as the sole source of nourishment) if more than 50 percent of the calories they contain comes from protein. The agency also is currently investigating several acute illnesses requiring hospitalizations associated with the Cambridge Diet, a 330-calorie-a-day plan in which a powder is mixed with liquid. In this product, less than 50 percent of its calories comes from protein.

Ketogenic diets not only include liquid protein diets (e.g., Robert Linn's Last Chance Diet) but also diets that consist
almost entirely of protein in the form of solid foods such as meat, fish, poultry and eggs (e.g., Irwin Maxwell Stillman’s Doctor’s Quick Weight Loss Diet, Robert Atkin’s Diet Revolution), and high protein diets in which carbohydrates are allowed at a low level (e.g., Baker and Tarnower’s Scarsdale Medical Diet).

Almost the exact opposite of the high protein diet is a food plan published recently by Nathan Pritikin. Pritikin says his diet plan is primarily aimed at the prevention or treatment of high blood pressure, diabetes, gout, atherosclerosis, gallstones and other diseases. However, it also includes a weight loss plan that is a 1,000 calorie diet with protein intake limited to 10 percent to 15 percent and meat limited to less than a quarter pound daily. It is high in complex carbohydrates (whole grains, fruits and vegetables) and low in fats (5 percent to 10 percent), cholesterol and highly refined carbohydrates such as sugars. Salt is restricted, and coffee, tea and alcohol are not allowed.

The scientific community appears to be divided in its assessment of the Pritikin plan. Some see it as nutritionally sound and useful. Others, such as Elizabeth M. Whelan of the American Council on Science and Health, criticize it as restrictive, austere and dreary. The American Medical Association questions the safety and effectiveness of the plan, especially for the diseases it is supposed to help prevent. In a November 1981 news release, the AMA said that researchers at the University of Alberta in Canada had reason to believe that the program offered no more relief from peripheral vascular disease (disease of blood vessels outside the heart) than did the more moderate American Heart Association diet combined with exercise. The AMA said that researchers further reported that the Pritikin plan, because of its lower fat and protein intake requirements, might lead to reduced resistance to infection and poor wound healing. The lower intake of calcium and iron may also make it unsuitable for pregnant women and other women of childbearing age, the AMA said.

Just as the Pritikin plan seems to be in agreement with a contemporary shift in nutritional emphasis from proteins to complex carbohydrates, so originators of diets in the past few years seem to have kept in step with health concerns of their times. For example, in the early 1960s, the rising concern with the avoidance of saturated fat seems to have given credence to a ketogenic diet espoused by Dr. Herman Taller in the book Calories Don’t Count. Taller theorized that the number of calories a person consumes doesn’t matter, and that “the calories of carbohydrate and the calories of unsaturated vegetable oil work quite differently in the system.” His convoluted, unproven theories revolved around the tenet that a person had to eat polyunsaturated fats to be slim. Because the book was being sold in stores alongside capsules of safflower oil, FDA instituted proceedings charging violation of drug regulations against Taller, who was also convicted of mail fraud and conspiracy.

Another approach taken by some diets is that a certain food somehow burns calories to get rid of fat. One version of this is the grapefruit diet in which dieters are instructed to eat grapefruit before each meal and then literally stuff themselves with as much bacon, eggs, meat, fish and vegetables as they like. The diet is based on the erroneous theory that grapefruit contains enzymes that somehow subtract calories by increasing the fat-burning process. The diet is often called the “Mayo Diet,” although the famed Mayo Clinic in Rochester, Minn., steadfastly denies any association with it.

A recent entry into the weight loss sweepstakes is the fructose diet, which capitalizes on the current interest in fructose as an alternative to table sugar (sucrose—half fructose, half glucose). The Fabulous 14-day Fructose Diet is a ketogenic, low carbohydrate, high protein diet that provides approximately 700 to 1,000 calories a day. About 150 of those calories are from fructose.

Another recent and enormously successful weight loss program is Judy Mazel’s Beverly Hills Diet book, which was No. 1 on the New York Times non-fiction best seller list for several weeks in the fall of 1981.

Like other diet hits of the past, it combines sound health advice, such as limiting sodium, with trendy ideas such as the use of bran, sesame seeds, brewer’s yeast and raw butter. Basically, the Beverly Hills Diet is a low calorie fruit diet. For the first week the dieter eats only pineapples, bananas, papayas, mangos, strawberries, apricots, blueberries, watermelon, apples and prunes.

It is not until the 11th day of the diet that something other than fruit is allowed (bagels, butter and corn on the cob), and it is not until the 19th day that a significant source of protein (steak or lobster) is permitted. Then, through the fifth week, protein foods are allowed only one day a week.

The Beverly Hills Diet is based on the false theory that protein and carbohydrate digestive enzymes cannot work together and that while protein enzymes are needed to digest protein, and carbohydrate enzymes for carbohydrates, fruit does not need the body’s enzymes to be digested because it has its own enzymes. Another unfounded claim made by Mazel is that the enzymes in fruit can render other foods less fattening.

“Fat,” Mazel says, “means... undigested food... When your body doesn’t process food, doesn’t digest it, that food turns to fat.”

Mazel claims that in order to digest food properly, a process she calls “conscious combining” must be used. Her rules of conscious combining call for eating proteins only with other proteins, and fats and carbohydrates only with other carbohydrates and fats. Fruits are to be eaten alone. Because of the supposed enzymatic process, once a protein is eaten on a given day, the dieter must continue to eat only protein, with absolutely no carbohydrates or fruit, for the remainder of that day.

In an article in the Nov. 15, 1981, issue of the Journal of the American Medical Association, Drs. Gabe B. Merkin and Ronald N. Shore wrote:

“Not only is there no scientific evidence to support this diet plan, but it also contradicts established knowledge about
Advice Aplenty But It's Really Simple Arithmetic

During the course of just about any year, a person contemplating going on a diet will have more than 100 magazine articles peruse on the subject. Indeed, some magazines seem to reserve space in each issue for a weight loss article. For example, the entries under "diet" in a recent issue of the Reader's Guide to Periodical Literature had a listing that ran from the "At Work Diet" in Mademoiselle to "Your 10-day Midwinter Shape-up Plan" in McCall's.

Of course all that advice doesn't include other plans offered in the popular press, such as the National Enquirer's front page announcement of "Easiest Diet Ever." And it seems that there is always a place—usually near the top—on the non-fiction best seller list for a diet book.

With the woods so full of dubious diets, what is the best type of weight loss program to embark upon?

Nutritionist Marilyn Stephenson of FDA's Office for Nutrition and Food Sciences has evaluated many types of diets and has come to the following conclusion:

"If you follow just about any diet published in magazines or books you will lose weight. This is because these diets, regardless of whether they emphasize calorie counting, will fail in the range of 1,000 to 1,200 calories a day or less, and the ones that differ drastically from the usual way we eat force the dieter to change eating habits, which almost always result in a person's eating less."

"However, it is important in selecting a diet for weight loss, to be sure that you are not endangering your health. One of the best ways I know to do this is to go on a low calorie (1,000 to 1,200 a day) diet that is not extreme in either carbohydrate or protein intake and contains a variety of foods. This can often be done by simply eating smaller portions of the foods you ordinarily eat while minimizing the fat content."

Ms. Stephenson admits that for some people eating less of their usual fare involves more willpower than drastically changing the types of foods they eat. But although it may be harder, in the end it is safer and probably more productive in terms of changing eating habits. Stephenson also advises:

- Consulting a physician and then, if possible, a nutritionist or dietitian before beginning a diet. (It is particularly hazardous for people with specific diseases such as intestinal disorders, diabetes or disease to follow some types of diets.)
- Asking the physician if he or she would advise a vitamin and/or iron supplement, especially if the dieter is contemplating a diet under 1,200 calories.
- Keeping track of calorie intake with special attention to portion size.
- Eating several small meals a day instead of three larger ones.

Once a person is successful in losing weight, how can regaining it be avoided?

This question may have as many specific answers as there are persons who ask it, but in general, according to Stephenson, the most effective way to keep weight down is to continue the new eating habits developed during the weight loss diet while increasing calorie intake to a maintenance level.

For many Americans, this apparently means eating fewer than 1,500 calories a day according to data from the Health and Nutrition Examination Survey, 1971-75 (HANES-1). Reviewing this finding, Dr. Allan L. Forbes, FDA's associate director for nutrition and food sciences, notes that people consuming 1,500 calories a day need to pay particular attention to the amount of nutrients in the foods they eat. For example, green and yellow vegetables are a wise choice because they contain generous amounts of vitamin A and other nutrients but are low in calories.

"Most of the obesity in the U.S.," Forbes says, "results from a relatively tiny imbalance between daily energy intake and expenditure."

This means that only 50 to 100 extra calories daily, if consumed regularly, can add several pounds a year. Therefore, watching those small extra amounts of food will help avoid the unwanted pounds in the first place.

—J. Willis

nutrition." They added: "Before a food can be absorbed into the bloodstream, it must be broken down by specific enzymes manufactured by the body. Enzymes in the food—the focus of Ms. Mazel's attention—are irrelevant to the absorption process. Food not broken down by enzymes will not be absorbed from the intestinal tract. It will pass out with the stool supplying no calories whatever. Contrary to the main contention of the Beverly Hills Diet, then, it is the digested food that has the potential to make you fat. Undigested food cannot possibly be fattening."

In their practices, these physicians have seen three patients on the Beverly Hills Diet with severe diarrhea, muscle weakness and dizziness, and they warn that the diet could result in a form of shock, low blood pressure and ultimately death, although there have been no reports of deaths of persons following the diet.

Dr. Mark Saginor, assistant clinical professor of medicine at UCLA, cautions that the diet has the potential to cause such side effects as diarrhea, gout, kidney stones, heart problems and strokes. Sami Hashim, nutrition professor at Columbia University, would add to these the risk of perforated peptic ulcers.

Diets come and diets go, and weight remains a problem for many in a country such as ours, blessed as it is with relative prosperity and an ample food supply. But resorting to dangerous fad diets is obviously not the way to get better readings from the bathroom scale.

Judith Willis, editor of FDA's Drug Bulletin, lost 35 pounds five years ago over a nine month period, eating 1,000 to 1,200 calories a day. She has not regained the lost weight, nor lost any more.
On Getting The Lead Out Of Food

by Emil Corwin

"Tin cans" are somewhat misnamed. The metal is only 2 percent tin. The other 98 percent is steel. The tin is plated over the steel because tin is less subject to oxidation and resists acid. But while steel is sturdy and tin is relatively safe, there's another metal in most cans that's a problem. That metal is lead, which is used to solder some 20 billion cans of food each year. Lead seals up cans very well, but it's also toxic and some of it gets into the food supply.

Two-thirds of the lead found in canned foods comes from this solder, and this amount, in turn, constitutes one-third of the lead that the average person ingests from food. Other lead intake in humans comes from less easily controlled environmental sources, such as lead-based pesticides, automobile emissions, lead water pipes and paint chips.

Lead in food and drink has long been a concern of health professionals, government agencies such as the Food and Drug Administration and the canning industry. Through cooperative efforts between FDA and industry, the lead in canned foods has been reduced and continues to be reduced. This is the story of how it has been done.

Lead is one of the first metals known to mankind, and its toxic effects have been long recognized. Lead can cause anemia, as well as damage to the kidneys, the central nervous system in children, and to the peripheral nervous system in adults.

The method of preserving food in vessels of "tin" took hold in the United States around 1825. It was the brainchild of Thomas Kensett, called the "father of the canning industry in the United States." At first a hole was punched in the top through which chunks of fruit and vegetables were forced into the can. Lead solder was used to seal this vent hole as well as the side seam of the can.

The big advance in improving the can came at the turn of the century with the introduction of the "sanitary can." Instead of hand-soldering, the lid and bottom were mechanically crimped on and sealed with a rubber compound. Most important, solder was applied early to the side seam, which minimized its contact with food in the can.

The "sanitary can" (after the name of the manufacturer, the Sanitary Can Co.) increased production through rapid closing operations as well as elimination of the lead used to seal the vent hole and ends of the can.

The open-top, three-piece can came into wide use in the 1920s. In this period, the steel industry and canning manufacturers developed can linings of enamel and lacquer to prevent corrosion caused by fruit acids attacking the tin plate.

The yellowish or white enamel coating on the inside of some cans must comply with FDA food additive regulations. The coating is used for a number of food products including beer, carbonated soft drinks, some vegetables and seafood. It protects the contents from metal contamination, preserves their color and flavor and allows longer storage. "Coatings," says the Can Manufacturers Institute, "also prevent rust and corrosion, and in some cases, may reduce the cost of cans by permitting the use of less tin coating."

Probably more progress has been made in the past dozen years in reducing lead levels in food than in the 170 years since Nicolas Appert, a French chef, discovered the process of preserving foods in glass jars.

The very young are much more susceptible to lead exposure; they absorb approximately 40 to 50 percent of dietary lead as compared to 5 to 10 percent absorbed by adults. Because of this greater susceptibility, FDA has placed its main emphasis on the diets of infants and young children. Since recent studies have indicated that lead may cross the placental barrier and affect the developing fetus, FDA has also become concerned about the foods eaten by women of childbearing age.

FDA's program to reduce lead in food began in 1972 with evaporated milk, which at the time was widely used by mothers in preparing infant formula. Evaporated milk cans contained more lead than the conventional three-piece sanitary can, since its seams are traditionally soldered and the vent hole is closed with a solder plug after the can is filled through it. In 1973, the evaporated milk industry entered into a lead reduction program to ensure compliance with the FDA limit of 0.5 parts per million (ppm) lead in the product. As a result, the average lead level in evaporated milk declined from 0.52 ppm in 1972 to 0.08 ppm currently. That's an 85 percent decrease.

The use of evaporated milk has declined in the past 10 years, and now only around 1 percent of young infants consume formula prepared from evaporated milk, thus further reducing exposure to lead from this source. Most infant formula used today is ready mixed preparation in cans. The average lead levels in canned infant formula
Tin cans, such as those shown here at a can-making plant, are only 2 percent tin. They are named for the tin plate that is used over the can’s principal material, steel. Lead is used to solder the seams of these cans and lead is toxic. However, industry and FDA have been working for years with considerable success to reduce the amount of lead that gets into food from the cans.
have been reduced from 0.10 ppm in 1974 to 0.02 ppm today, a decrease of 80 percent. Some of the reduction is because manufacturers have switched most of their production from lead-soldered cans to welded steel cans or seamless two-piece cans.

In another action, manufacturers of infant juices switched from cans to glass jars, resulting in reduction of average lead content from 0.30 ppm in 1973 to about 0.015 today, a 90 percent plus drop. Solid infant foods (fruits, vegetables and meats) have been packed for many years in glass jars; all evaporated milk and most infant formula are still packaged in metal cans.

The dramatic overall decline of average lead levels in infant foods is shown in the chart (right) in parts per million of lead.

Aside from evaporated milk, no “action level” has been established for these categories of food. An action level is the minimum amount of substance in a food at which the agency will take action to remove the food from the market—that is, seize the food or ask the manufacturer to recall it. In 1974, when the average lead level in evaporated milk was 0.52 ppm, FDA proposed a tolerance of 0.3 ppm, the lowest level it believed the industry could reasonably comply with at the time. Today, because of the industry’s success in reducing lead content, FDA is considering setting even lower action levels than 0.3 ppm. Lead action levels are also being considered for food in other categories consumed by infants and young children to further reduce lead levels in their diets.

Results from FDA surveys of canned food for adults show that lead levels in the food have decreased somewhat in recent years. As an example, the average lead level of 13 popular canned adult foods analyzed by FDA in 1974 was 0.38 ppm. In a 1980 survey of about the same number of foods, the mean lead level had dropped to 0.21 ppm. The National Food Processors Association recently completed a study of over 500 samples of 24 typical canned products for adults, and reported an average lead content of 0.23 ppm, very similar to the FDA findings.

### What about the future?

In August 1979, FDA announced that within five years it hoped to reduce lead in food from lead-soldered cans by at least 50 percent. With the progress in reducing lead in foods for infants, FDA has shifted emphasis to reducing lead in canned foods for adults that are also commonly eaten by infants and children.

Other changes under way to reduce or to eliminate lead in canned foods:

- An increasing number of canners are packing their foods in a seamless, two-piece can, a major innovation. It is estimated that packagers will be using the two-piece can at the rate of 4 billion containers a year by 1985.
- More cans are being made with electrically welded side seams, which eliminates the use of lead solder. The American Iron and Steel Institute believes the welded cans will eliminate soldered cans in the not-too-distant future.
- The manufacturers of infant formula expect by 1982 to be packing their products entirely in welded cans without solder or in seamless two-piece cans.
- The agency will continue to analyze samples of various foods annually for levels of lead as a way of assessing the effect of control measures instituted for canned food by the industry.
- In FDA's current survey, which will continue for at least three years, the agency is analyzing 10 canned foods for adults but also commonly eaten by children—tuna, apple juice, orange juice, string beans, baked beans, tomatoes, applesauce, chicken noodle soup, vegetable soup and fruit punch.

The advances that have been made in reducing lead in canned foods have been described as “one of the best success stories ever” by the industry and government working toward a common goal. The canners, the can makers and the FDA all are optimistic about meeting the goal the agency set in 1979 to reduce lead intake from food by half within five years.

Emil Corwin is a member of FDA’s public affairs staff.
There was a little bit of good news and a lot of bad news in the latest round of panel reports coming out of FDA's review of ingredients in OTC drugs.

The good news was that three ingredients—two for treating acute toxic ingestion (that is, accidental poisoning) and one for treating corns and calluses—were found to be safe and effective.

The bad news was that nothing is available that is good as digestive aids, deodorants for internal use, smoking deterrents, or for insect repellents for internal use or oral treatment of fever blisters. It was recommended that hormones be eliminated from non-prescription skin, hair, scalp and other topically applied products, and mercury compounds were reported to be of dubious value in anti-microbials.

These were the conclusions of two of the 17 panels of experts established by FDA to review the safety and effectiveness of ingredients in all non-prescription drug products. By the end of this review, now in its 10th year, some 800 ingredients in 300,000 drug products will have been under scrutiny.

The nine latest reports, published in the Jan. 5, 1982, Federal Register, bring to 45 the number of panel reports that have been issued for public comment. Still to come are 19 others.

Recommendations of the expert panels are not binding upon FDA. After the agency has evaluated the panels' reports and the public comments on them, monographs (i.e. standards) establishing the acceptable ingredients and labeling for the various products will be published.

Here is the essence of the nine panel reports, starting with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products.

**Corn and Callus Removers**—The panel recommended that these products be used to treat calluses and hard corns only. Hard corns occur on the surfaces of the toe joints. Soft corns are whitish thickenings of the skin usually found on the webs between the fourth and fifth toes.

Salicylic acid is the only ingredient the panel found safe and effective for removing hard corns and calluses. They recommended it be used in concentrations of 12 to 40 percent in pads, plasters and discs, and at concentrations of 12 to 17.6 percent in a collodion base. Collodion is a solution of pyroxylon (nitrocellulose) in a solvent that leaves a transparent film when applied to the skin.

Phenoxyacetic acid and zinc chloride were considered safe by the panel but need additional testing to determine their effectiveness as callus and corn removers. There were no data demonstrating either safety or effectiveness for 13 other ingredients including glacial acetic acid, chlorobutanol, iodine, methyl salicylate and vitamin A.

Labels on the effective products can claim that they are “for the removal of hard corns and calluses,” and should include warnings against use by diabetics or people with poor blood circulation. Labels should not include statements such as: “You are about to make your feet more comfortable,” “Walk easy, walk soft” or “Dissolves corn or callus away.”

**Mercury-Containing Drug Products for Topical Anti-microbial Use**—Mercury has been known to humans a long time and has been used in various ways for treating illness, the panel said, but it usually has been replaced by safer and more effective drugs. Science has shown that, as a class, mercury compounds are of dubious value for anti-microbial use, i.e., to treat bacterial infection. They act primarily by slowing the growth of bacteria. They can kill bacteria but this action is slow.

No mercury compounds were found by the panel to be safe and effective as topical anti-microbials and it recommended that seven mercury compounds be taken off the market. These are calomel, mercuric chloride, ammoniated mercury, merbromin, thimerosal, Ortho-hydroxyphenyl-mercuric chloride and phenylmercuric nitrate. Since mercury is not considered safe and effective, the panel said, no labeling would be recommended.

**Topically Applied Hormone-Containing Drug Products**—Estrogens and progesterone are sometimes ingredients in OTC drug products marketed for topical use as hormone creams and oils with the claim they will improve the appearance of skin and hair. However, the panel concluded that there is no evidence that using products containing hormones at a safe level will do any more good than using a cream
alone. Such products cannot be considered safe and effective for their intended use.

Furthermore, the panel noted, hormones are often found in products sold as cosmetics. This leads the consumer into believing a more youthful appearance will result when in fact the changes that might occur cannot be seen with the naked eye, the panel said.

Six reports resulting from the deliberations of the Advisory Review Panel on Miscellaneous Internal Drug Products were included in the group published in January. Their recommendations:

Drug Products To Treat Acute Toxic Ingestion—An estimated two million accidental poisonings occur each year in the United States and about 60 percent of these involve children under 5. When a child swallows a toxic substance, the means to handle the situation should be available until medical help is obtained.

The panel said that two ingredients, activated charcoal and ipecac syrup, are effective for this purpose and further recommended that a kit containing both be developed.

Labeling for activated charcoal sold alone should include under “indications” the phrase “For the treatment of acute poisoning.” Labels should also contain warning statements that a poison control center, emergency medical facility or physician should be called before the product is used; that the product should not be used in semiconscious or unconscious persons; and that if ipecac syrup has been used, the charcoal should not be administered until the patient has vomited.

Labeling for ipecac syrup alone should indicate that the product is for treatment of acute poisoning and should include a warning that the syrup not be used if the victim has swallowed strychnine, corrosives such as lye, and strong acids or petroleum distillates. Similar labeling would be required on acute toxic ingestion kits.

The panel also noted that no data are available on the safety and effectiveness of alcohol, magnesium hydroxide, potassium arsenite or tannic acid for the treatment of accidental poisoning. Thus, these ingredients should not be used in products intended to treat persons for toxic ingestion.

Smoking Deterrents—“Attempts by confirmed smokers to stop smoking are as numerous as are the different methods used,” the panel said in this report. Unfortunately for those who need some help, the panel had nothing to offer. The group found no ingredients currently available that they considered safe and effective as smoking deterrents. Quinine ascorbate was considered safe but not effective as were a combination of licorice root extract, ground coriander, ground ginger, ground cloves, lemon oil and orange oil, and a combination of methyl salicylate, eucalyptus oil, menthol and thymol.

Recommended by the panel for further testing were lobeline and silver acetate. Lobeline is an alkaloid obtained from the herb Lobelia inflata. Silver acetate is a soluble silver salt. It leaves a nasty, sweet metallic taste in the mouth that makes smoking less desirable.

The panel recommended that, in the event an acceptable smoking deterrent becomes available, its labeling include a statement such as: “A temporary aid to those who want to stop smoking cigarettes,” “Helps you stop the cigarette urge temporarily,” or “A temporary aid to breaking the cigarette habit.” The panel would also require this statement: “This product’s effectiveness is directly related to the user’s motivation to stop smoking cigarettes.”

Drug Products for the Treatment of Fever Blisters—Fever blisters, or cold sores, are recurrent sores on the lips and other areas around the mouth, usually caused by herpes simplex virus. They are not to be confused with canker sores, which occur inside the mouth and may be associated with a variety of viruses, bacteria or fungi.
There are no ingredients in OTC drugs to be taken orally that are safe and effective in treating fever blisters, the panel said. However, three ingredients were found to be safe, although additional testing was recommended by the panel to establish their effectiveness. These are Lactobacillus acidophilus and Lactobacillus bulgaricus, which come from fermented milk cultures, and lysine hydrochloride. Five ingredients, not shown to be either safe or effective, should not be used in oral drugs for the treatment of fever blisters: acetaminophen, caffeine, chlorpheniramine maleate, phenolphthalein and phenylephrine hydrochloride.

Should an effective product be developed, the panel recommended that label claims for it be limited to the phrase, “For the relief of the discomfort of fever blisters (cold sores).” Not acceptable would be such claims as: “For the relief of discomfort of sun blisters,” “Useful for fever blisters of herpetic origin,” or “Arrests the symptoms associated with cold sores and sun blisters on the lips.”

Digestive Aid Products—The Miscellaneous Internal Drug Panel reviewed 24 active ingredients intended to relieve the symptoms of either immediate post-prandial (after meal) upper abdominal distress or intestinal distress or both of these conditions. IPPUAD consists of sensations of bloating, distension, fullness or pressure with upper abdominal discomfort occurring within 30 minutes after a meal. Intestinal distress is abdominal discomfort occurring 30 minutes to several hours after a meal. Because this report was more extensive than the others in the group published in January it will be discussed in greater detail in a forthcoming story in FDA Consumer about the digestive system. It’s enough to say here that none of the ingredients passed muster as both safe and effective for these uses. Of the 19 ingredients intended to relieve post-prandial distress, nine were considered not effective and 10 were recommended for further testing. Of the 18 ingredients for intestinal distress, seven were safe but not effective and two were neither safe nor effective, while nine need further testing, according to the panel.

Deodorant Drug Products for Internal Use—Most body odors can be controlled by adequate personal hygiene. But there are some over which the individual has no control, such as the odors produced by an ostomy—any surgically-created opening for the external discharge of urine or feces—or by incontinence. The panel studied three ingredients intended as deodorants for internal use: bismuth subgallate, activated charcoal and water-soluble chlorophyllin. They found them generally safe for OTC use, but the data weren’t sufficient to establish their effectiveness. Thus the panel called for additional testing.

The panel recommended that if any of these ingredients meet the test of effectiveness, labeling of products containing them include one or both of the following statements: “A colostomy or ileostomy deodorant,” or “An aid to reduce odor from colostomies or ileostomies.” The label should also state, “This product cannot be expected to be effective in the reduction of odor due to faulty personal hygiene.” Activated charcoal products also should be labeled with the warning that the product may decrease the effectiveness of other drugs.

—Annabel Hecht
Advice to pregnant women flows in abundance. It comes from doctors, friends and relatives, and from books, magazines, newspapers, radio and television. All feed her interest and concern over how to bear a healthy child. In recent years, there has been a large volume of publicity—generated, in part, by the federal government—focusing on the potential dangers and hazards pregnant women and their unborn children face from the consumption or over-consumption of alcohol, caffeine, drugs in general and other substances.

But is the message getting across?

A recent report, based on a nationwide survey conducted for the Food and Drug Administration by the polling firm of Louis Harris and Associates, clearly indicates that it is, especially where the consumption of alcohol and caffeine-containing products is concerned. And, as might be expected, the highest level of awareness is among women 18 to 44, the child-bearing years.

However, even though those surveyed showed a high level of awareness to the potential dangers pregnant women face from consuming certain substances, their specific recall—that is, detailed knowledge—on the content of the warnings was not high. Some replied simply that a particular substance "harms the baby" and many others either could not recall the content of the warnings or they resorted to general answers.

More than 1,200 of the 1,499 respondents (80 percent) said they regarded the consumption of alcohol during pregnancy as a serious problem but only a third saw it as being serious enough to warrant direct federal action to deal with the problem. With caffeine, nearly 800 persons (53 percent) said caffeine consumption could be a serious problem during pregnancy but only 25 percent favored the idea of direct federal action.

FDA’s report, titled “Alcohol, Caffeine and Pregnancy: The Public View,” was based on face-to-face interviews with those 1,499 people who were identified as the primary food shoppers for their households. The interviews were conducted between Dec. 1, 1980, and Jan. 12, 1981. Those interviewed included 242 men and 1,257 women, and among the latter were 593 women in the 18 to 44 age group. Also, a little over half of those participating were parents of at least one child. No attempt was made to determine if any of the participants were pregnant at the time or contemplated becoming pregnant.

The basic aim of the survey was to measure public awareness of the possible hazards pregnant women and their unborn children faced from consuming or over-consuming alcohol and caffeine-containing substances (coffee, tea, cola and pepper type drinks and other products), along with drugs in general and other substances.

The survey also sought to find out if the public knew specifically about the possible dangers of alcohol and caffeine consumption during pregnancy—issues that the Department of Health and Human Services and its affiliated agencies have emphasized more heavily in recent years.

Besides the public pronouncements of health officials, an example of the initiative taken at the federal level was the issuance of an instructive pamphlet titled “Alcohol and Your Unborn Baby.” Prepared by the Alcohol, Drug Abuse and Mental Health Administration, the 14-page publication was first printed in 1978. Since then more than four million copies have been distributed. Citing the findings of recent scientific studies, the pamphlet provides a clear warning of the potential hazards from heavy drinking during pregnancy. It also expresses concern, based on some research data, that even low levels of alcohol consumption—two drinks a
What have you recently read or heard of that pregnant women should not eat or drink, or eat or drink too much of?

- Alcoholic beverages
- Caffeine: Coffee, tea, colas
- Tobacco/smoking
- Aspirin/drugs/medications
- Salt/sodium
- Artificial preservatives, colors, flavors, saccharin
- Sugar/sweets
- Fats/cholesterol
- Other
- Haven't heard or read anything
- Not sure

Alcoholic beverages 54%
Caffeine: Coffee, tea, colas 25%
Tobacco/smoking 24%
Aspirin/drugs/medications 14%
Salt/sodium 4%
Artificial preservatives, colors, flavors, saccharin 2%
Sugar/sweets 2%
Fats/cholesterol 1%
Other 4%
Haven't heard or read anything 28%

Not surprisingly, women 18 to 44 years of age were more aware of the publicized warnings than were men and older women. Seventy-two percent of the 1,257 women interviewed for the survey and 77 percent of the 593 women in the 18 to 44 age group needed no prompting in replying that they had read and heard about the advice. Fifty-eight percent of the women in the main childbearing ages specifically mentioned hearing about alcohol and 34 percent about caffeine.

Is alcohol and caffeine consumption during pregnancy viewed as a serious problem? In the case of alcohol, 81 percent of those surveyed replied "yes." Fifty-three percent voiced the same view about caffeine. But the report clearly indicates that the public's perception of something being serious is not necessarily a call for direct federal action. Of the entire group of 1,499 persons, only 27 percent termed the alcohol problem serious enough to require federal involvement. In the case of caffeine, only 13 percent advocated federal action to deal with the issue.

The term "direct federal action" was posed to the respondents in a general way, the interviewers making no attempt to further define the term in talking to shoppers. Among those who did advocate a federal role, most suggested using the mass media or warning labels to better inform the public of the hazards to pregnant women.

Chris Lecos is on FDA's public affairs staff.
FDA's Philadelphia Regional Office has opened a new regional small business desk to help firms obtain information and guidance about the requirements of laws administered by the agency. This is the fifth small business desk to be established by FDA since the program began in 1979.

To streamline government purchasing procedures, FDA and the Department of Defense have consolidated their medical products quality assurance programs. Under the agreement, made public Dec. 24, 1981, FDA will provide Defense with information about firms seeking to sell medical devices such as dental and surgical instruments, bandages and some X-ray equipment. FDA also may conduct inspections of firms and sample and test products offered for delivery. A similar agreement was signed in 1976 for drugs and biological products such as vaccines.

F.D. & C. Yellow No. 6, which has been used since 1929 to color foods such as gelatin desserts, sherbets, sodas, candies and cereals, as well as drug solutions, toothpastes and hair rinses, does not cause cancer, according to a carcinogenesis bioassay conducted by the National Cancer Institute. The report, "Bioassay of F.D. and C. Yellow No. 6 for Possible Carcinogenicity (T.R. 208)," is available from the Public Information Office, National Toxicology Program MD B-2-04, Box 12233, Research Triangle Park, N.C. 27709 (FR Dec. 11, 1981).

Chlorofluorocarbons are essential as lubricants for pharmaceutical rotary tablet press punches and thus are exempt from an Environmental Protection Agency rule prohibiting manufacture, processing and distribution of these aerosol propellants. The ban was imposed because of concerns that the fluorocarbons might destroy the protective ozone layer in the atmosphere (FR Jan. 5, 1982).

Vitamins are chemical nutrient substances necessary in very small amounts for life, growth and health. However excessive amounts do not have a vitamin function in the body, says the American Medical Association. Instead, the vitamins act like drugs. In a new publication, "Vitamin-Mineral Supplements and Their Correct Use," the medical group points out that individuals differ in their response to large amounts of vitamins and that poisoning from overdoses does occasionally happen.

To relieve the Freedom of Information office of an overwhelming paper burden, FDA has proposed changing the time of file retention. Except where denials and appeals are involved, the proposal would authorize disposal of FOI request files two years from the date of FDA's response to the request. This would mean an immediate saving of $42,000 per year at current storage rates and would also allow the agency to keep, for longer periods, those files concerning FOI requests that were wholly or partially denied (FR Jan. 5, 1982).

U.S. school children have fewer tooth cavities today than they did in the last decade, Dr. Janet A. Brunelle of the National Institutes of Health told a meeting of the American Association for the Advancement of Science in January. A survey of 40,000 children aged 5 to 17, examined during the 1979-80 school year, showed the percentage of children without tooth cavities was 37 percent, up 9 percent from the early 1970s. Dr. Brunelle attributed the decrease to more community water fluoridation and increased use of fluoridated toothpastes. Changes in dietary habits also may have contributed to improved dental health, she said.

The Public Health Service is assessing what is known about the safety and effectiveness of single and multiple channel transcutaneous electrical stimulators for the treatment of pain. Anyone who wishes to submit information should write: Medical and Scientific Evaluation Staff, Office of Health Research, Statistics, and Technology, Room 17A-40, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20857 (FR Jan. 11, 1982).

FDA's food additive regulations have been amended to provide for the safe use of ethyl acetate as a solvent in the decaffeination of coffee. The rule, effective Jan. 5, 1982, is based on data contained in a petition filed by the General Foods Corp. (FR Jan. 5, 1982).

A proposal to bolster orange juice solids in frozen concentrated orange juice is being considered by FDA. Florida citrus groups petitioned FDA to amend the standard of identity for frozen concentrated orange juice to increase the minimum percentage of orange juice soluble solids from 11.8 percent to 12.3 percent when reconstituted according to directions. Petitioners want to establish a uniformly high level of soluble solids in frozen concentrate in all citrus producing areas. The Processors Council of the California-Arizona Citrus League says their oranges have greater consumer acceptability at the current level and that a higher level would mean the addition of more orange juice at higher cost to the consumer. Persons who wish to comment may write: Dockets Management Branch (HFA-305), FDA, 5600 Fishers Lane, Rockville, Md. 20857 (FR Jan. 8, 1982).
Chelation Therapy Overdone

by John M. Couric

"There are none so credulous as sufferers from disease." So commented President William Howard Taft nearly 70 years ago about the willingness of the ill to believe medical claims even though unsupported by scientific evidence.

Today many sufferers from arteriosclerosis, hardening of the arteries, continue to confirm the keenness of the late president's observation. Some sufferers, faced with a sometimes painful and even fatal condition that surgery often can help, choose a procedure known as chelation therapy in which no surgery is involved.

This therapy, used on persons suffering from poisoning by heavy metals such as lead, is based on a chemical principle in which certain compounds or chelating agents are introduced into the bloodstream to form bonds with the metals. The compounds so formed then are excreted, ridding the body of the poisonous metals. FDA approves certain drugs for chelation treatment of this type of poisoning but does not approve them for treatment of arteriosclerosis. What's more, such a treatment can be dangerous and fatal.

If EDTA or any other agent dissolves arteriosclerotic plaques abruptly, it would be anticipated that chunks of the calcium and fat-filled plaques would break off and lodge in a smaller blood vessel, blocking it. That's what can happen spontaneously in people who have arteriosclerosis and is a common cause of strokes. In at least one reported case, a patient under chelation therapy died when a calcium embolus, or clot, freed from a large arterial plaque lodged in his brain.

EDTA or disodium edetate is a useful drug in some patients who have severe hypercalcemia, a life-threatening condition caused by an excess of calcium in the blood. It also is used to treat some patients with heart function irregularities caused by poisoning from overdose or accidental ingestion of digitalis. However, FDA cannot permit claims by drug makers that disodium edetate is approved for treatment of hardening of the arteries. The agency first must have substantial evidence in the form of well-controlled clinical studies that the use of this drug in the chelation treatment for arteriosclerosis is both safe and effective. If a physician wishes to investigate the use of disodium edetate in the treatment of arteriosclerosis, he or she could do so by filing an application for an investigational new drug. No physician has.

Although a physician can use any drugs he or she wishes in treating a patient, the drug cannot be illegally labeled. In the case of prescription drugs, the term "labeling" includes advertising. That's why a federal court in Louisiana enjoined Dr. H. Ray Evers, and Meadowbrook Hospital, at Belle Chasse, La., from administering disodium edetate, calcium disodium edetate and other chelating agents to persons referred to the hospital for treatment of arteriosclerosis.

In granting the injunction the court noted that, "although several doctors..."
and a number of individuals testified ... as to the beneficial effects of EDTA chelation therapy for arteriosclerosis," various other authorities testified that the therapy should be limited to cases of lead poisoning and even then there is a great risk. "The court in balancing the value of this testimony is satisfied that the possible benefits of the EDTA therapy ... is far outweighed by the serious actual and potential damage caused by the drug in such therapy."

John M. Couric is a writer-editor in FDA's Bureau of Drugs.

Clammed Up

It was believed to be the stiffest penalty ever handed out for violations of Florida state shellfishing laws. Two men were sentenced to spend 45 weekends in jail, and a third, spared jail because of a lung condition, was fined $1,000. And that was only part of their punishment.

The three had been caught clamming on a portion of the Indian River in Florida that had been closed to shellfishing harvesting by the Florida Department of Natural Resources because of a potential pollution hazard. They were clamming at night—another violation—and the court concluded, after hearing evidence, that they intended to sell the harvest to a seafood company for distribution to area restaurants.

In addition to receiving the jail sentence and fine, the shellfishermen were ordered to work one afternoon a week for the Salvation Army and to pay that organization $15 a week. Brevard County Judge Graham Stikelether also revoked the men's commercial shellfishing licenses for one year, except for two months during the summer when they will be allowed to "seed" (plant small seed oysters or clams) their leased areas under strict supervision of the Florida Marine Patrol. In addition, their boat was confiscated and they were ordered not to go on the Indian River for one year.

Said Judge Stikelether: "My primary concern was for public health. These guys had commercial clamming licenses; they knew they were clamming at night, which is a violation of the law; they knew they were going into an area that has been closed to clamming; and they were going to sell these potentially dangerous clams publicly."

Oysters and clams are filter feeders, which means they strain food from the water ingested into their systems. If the water is polluted, the pollution can concentrate in the shellfish in amounts potentially harmful to humans. Clams and oysters are frequently eaten raw or partially cooked, so it is important that shellfish be harvested only from clean, approved waters.

The part of the river where the three men were caught by the Florida Marine Patrol is near a shoreline that is being rapidly developed into condominiums, shopping centers and subdivisions. It was closed to shellfishing harvesting by the Department of Natural Resources because the safety of the water could not be assured. One of many potential sources of contamination is discharge from a nearby waste water treatment plant. In addition, heavy rains wash polluting substances into the river, resulting in periodic closings of various sections of the river to shellfish harvesting.

In every shellfish-producing state, closings of harvest areas and virtually all other regulations are enforced directly by the states, even though the guidelines for their enforcement programs come from FDA's National Shellfish Sanitation Program (NSSP). FDA does not have the power to arrest violators such as the three men caught in Florida. Therefore, the states' enforcement powers are vital to the success of the NSSP. Each year FDA reviews all state shellfishing sanitation programs. After reviewing Florida's program, FDA's regional shellfishing sanitation specialist in Atlanta concurred with the state's decision to close portions of the Indian River to shellfish harvesting.

Suspects in Prison

An investigator in FDA's St. Louis station went to prison to investigate some suspects.

The suspects were swelled cans of fruit cocktail. The incident was unusual since the agency does not routinely inspect foods or drugs used in correctional facilities. The St. Louis station, however, was prompted to do so when the food service manager at the Mis-
Checking on Blood

Many persons consider their blood a renewable resource with a definite market value, and a commercial blood industry has been built up around them.

At a commercial blood center a person can be paid $10 to $15 for surrendering a pint of blood, then come back in two months and give up another pint for another payment. If it is a plasmapheresis center rather than a whole blood operation, the plasma (fluid) will be extracted while the donor is there and the red cells returned to the donor in a saline solution. Plasma donors can be back within a week, since plasma is there and the red cells returned to the donor.

Whole blood is used for transfusions in surgery or accidents. Blood components are important in the making of human medicines. They include plasma derivatives, used as gamma globulin for immunizations and albumin for treating patients in shock.

There are almost 7,000 blood centers throughout the United States. Since 1975 they have been inspected, licensed and regulated by FDA to ensure that the conduct of their operations results in pure, safe and effective products and in safety for their donors, many of whom are regulars.

In a recent inspection of one such plasma center, Mid-South Blood Services in Charlotte, N.C., many deficiencies were found by FDA’s Atlanta district office.

The center’s staff did not take proper medical histories from donors and accepted some who were in obviously poor health. The center also accepted donors who had been permanently rejected (not allowed to give blood) because of prior exposure to hepatitis or venereal disease.

The center’s staff used non-sterile cotton to clean the puncture site with alcohol, and whole blood was not stored at the proper temperatures.

The facility itself was badly maintained. It had bare wooden floors, exposed beams and loose plaster, and was generally unclean, with evidence of mice and roaches found in several locations.

FDA suspended the center’s license to operate and to ship its products interstate. The center remained closed for two months while the facility and its operation were brought up to standard. FDA then made another inspection, found the violations had been corrected, and allowed Mid-South to resume operation.

Corporate Responsibility

Not all companies wait for FDA to tell them when a product should be removed from the market. A recent instance was Merrell-Dow Pharmaceuticals, a Cincinnati firm that distributes Imferon Injection, an iron supplement made in England.

Imferon is an iron-dextrose compound intended for injection by persons with iron deficiencies who cannot take the supplement orally. It is administered in doses of 2, 5 and 10 milliliters, the level of dosage being extremely important.

Early in 1981, Merrell-Dow began receiving reports of muscle pain, stiffness and fever in patients taking the iron injections. A company review of each case found that the product itself was not at fault, but that the dosage level might be. Merrell-Dow concluded that some patients were getting larger doses than needed, and that some might be receiving Imferon who did not really require it.

The company decided on two courses of action, which it described to FDA’s Cincinnati district office. It would withdraw from the market some 90,000 vials and ampules of Imferon already distributed to 15,000 outlets. It would then strengthen the warning label on the drug, stressing that a thorough diagnosis and laboratory tests should be done by the physician before Imferon Injection is prescribed. This would determine the individual’s need for an iron supplement and establish the proper dose for that person. The label would also state that fatalities might occur if these precautions were not taken.

The drugs returned to the company—valued at $400,000—were destroyed. Future shipments of Imferon from the firm will carry the new warning label with its cautions on dosage.

Food for Hogs

The wad of paper and fuzzy material didn’t belong there in the carton of pasta for a good reason: It was a rodent nest. There were nibble marks on packages of cheese and sausage, hundreds of dark pellets scattered on the floor and shelves, and dead rodents and insects in several locations.

Such was the state of affairs at a small food storage warehouse inspected by FDA’s Seattle district last year. In samples taken by the investigator were rodent excreta pellets, insects and insect excreta. Several packages were rodent gnawed.

Since adulteration and insanitary conditions were noted throughout the warehouse, FDA requested seizure of every food item that could be contaminated by insects or rodents. As a result, a U.S. marshal seized all food not packaged in hermetically sealed
metal or glass containers.
The firm, Pacific Food Importers of Seattle, then had the task of recon-ditioning—that is, separating the salvageable food from the unfit products to be disposed of. A sanitation consultant hired by the firm spent several weeks examining thousands of food containers for evidence of insect or rodent contamination. His efforts were checked by FDA. Adulterated food—valued at nearly $55,000—was converted to hog feed.

Pacific Food Importers also found it necessary to hire a pest control service to eliminate the vermin and make construction repairs to prevent more insects and rodents from entering the food storage area. Food in containers that could be penetrated by rodents or insects is now being stored at another facility.

Veal Un-drugged

A veterinarian in New Jersey who became, in effect, a manufacturer of animal drugs, has agreed to discontinue the line of unapproved antibiotics he had been supplying to farmers who raised calves for veal.

Dr. Robert R. Blease of Stewarts-ville, N.J., doing business as the Vet Med Co., had been manufacturing, packaging and distributing various injectable antibiotics to farmers in New Jersey and other states. Two of his products contained penicillin which, if it remained in the veal, could cause an allergic reaction in persons sensitive to that drug. Blease also had included steroids in his products, and these too could affect some people who ate the veal.

FDA's Newark district investigators filed a complaint with the U.S. attorney for the District of New Jersey, asking that Vet Med be prohibited from introducing these unapproved animal drugs in interstate commerce. On Sept. 4, 1981, Blease entered into a consent decree of permanent injunction, agreeing not to “administer, prescribe or place in interstate commerce” such un-approved drugs for farm users with whom he does not have a valid veterinary practice relationship.

Inflated Claims

During a visit to a beauty trade show in New York City, the proprietor of a New Jersey skin and nail care salon became intrigued with the promotional literature attached to a certain device. Called the “Trimmore System,” it was advertised primarily as a bust developer and consisted of sets of suction cups that were supposed to “stimulate the inner structure of the breasts . . . and develop a better bust-line.”

But that wasn't the only way the device could be used, according to the labeling. Thumbing through the literature, the salon owner saw that the Trimmore supposedly could cure constipation, change body fat to energy, and relieve stress, stiffness and tension. In addition, the claim was made that the device would enhance the body's ability to “combat pollutants that fall on our cities,” “wash out sulphur dioxide and cancer forming particles in the air we breathe,” and “activate latent forces of life and health within us.” The device, according to the labeling, was approved by FDA. The salon owner accordingly queried that agency about the product.

An investigator from the New York district was sent to collect a sample from the importer, RN International, Yaphank, N.Y. Close examination showed that the product, which had been imported from Japan, was suitable only as a mechanical massager. It would not affect the size of the breasts nor fulfill any of the other claims, and, of course, it had not been approved by FDA for anything.

The New York district sent a regulatory letter advising the importer that future shipments of the Trimmore would not be allowed into the United States until the mislabeling is corrected and the importer registers with FDA as a distributor of medical devices. When the firm failed to send a written response promising these corrections, the district requested seizure. Subsequently, a deputy U.S. marshal seized 71 of the Trimmore devices, valued at $12,700.

—Compiled and written by Carol Ballentine, Louise Fenner, Michael Herndon and Richard Thompson.
Seizures and Postal Service Cases

FILED SEIZURE ACTIONS charge violations of the Federal Food, Drug, and Cosmetic Act and are initiated based upon FDA recommendations. A seizure action is commenced by the filing in the U.S. district court where the goods are located. A U.S. marshal is then directed by the court to take possession of the goods, removing the product from commerce, until the matter is resolved.

A total of 16 actions to remove from the consumer market products charged to be violative was reported in November. These actions included 12 of foods: 6 involved charges concerning contamination, spoilage or insanitary handling; and 6 involved charges concerning economic and labeling violations. Others included 4 of drugs.

<table>
<thead>
<tr>
<th>PRODUCT, DISTRICT &amp; DATE FILED</th>
<th>FIRM &amp; PLACE OF BUSINESS</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blackeyed peas/U.S. District Court for the Eastern District of California 9/29/81</td>
<td>San Joaquin Crops Co. Inc./Wasco, Calif.</td>
<td>Product contains rodent and insect filth; held under insanitary conditions.</td>
</tr>
<tr>
<td>Cherry pulp, frozen/U.S. District Court for the Northern District of New York 10/22/81</td>
<td>Clermont Fruit Packers Inc./Clermont, N.Y.</td>
<td>Product contains rotten cherries.</td>
</tr>
<tr>
<td>Cranberry sauce, jellied, canned/U.S. District Court for the Western District of New York 6/9/81</td>
<td>Manufactured from interstate components</td>
<td>Product is contained in rusted and leaking cans.</td>
</tr>
<tr>
<td>Flour mix for chapati/U.S. District Court for the Northern District of California 8/6/81</td>
<td>Bombay Bazar Wholesale Distributors/Berkeley, Calif.</td>
<td>Product contains insects; held under insanitary conditions.</td>
</tr>
<tr>
<td>Flour/U.S. District Court for the District of Puerto Rico 9/21/81</td>
<td>Borinquen Macaroni Corp./Yauco, Puerto Rico</td>
<td>Product held under insanitary conditions; contains rodent filth.</td>
</tr>
<tr>
<td>Flour/U.S. District Court for the Western District of New York 9/22/81</td>
<td>Barry Food Products Inc./Buffalo, N.Y.</td>
<td>Product held under insanitary conditions.</td>
</tr>
<tr>
<td>&quot;Honey&quot; (two lots)/U.S. District Court for the Eastern District of Louisiana 12/10/81</td>
<td>Anthony’s Syrup Co. and/or Oliver Anthony/Philadelphia, Miss.</td>
<td>Glucose and/or corn syrup have been substituted for honey; label of one lot is false and misleading in claiming that the product consists wholly of honey and the label of the other lot is false and misleading in declaring the article to be honey but also having a list of ingredients representing that the food consists in part of corn sweetener and citric acid; label violates the Fair Packaging and Labeling Act because the quantity of contents statement was not expressed in fluid ounces followed in parentheses by a declaration of the largest whole unit.</td>
</tr>
<tr>
<td>&quot;Honey&quot;/U.S. District Court for the Eastern District of Arkansas 10/23/81</td>
<td>James Pilgrim and/or Sleepy Hollow Syrup Co./DeKalb, Miss.</td>
<td>Glucose syrup has been substituted for honey; product labeling is false and misleading in claiming, contrary to fact, that the food consists wholly of honey and is packed for Big Giant Foods, Oklahoma City, Okla.; product is not in compliance with the Fair Packaging and Labeling Act because the quantity of contents statement was not expressed in fluid ounces followed in parentheses by a declaration of the largest whole unit.</td>
</tr>
<tr>
<td>PRODUCT, DISTRICT &amp; DATE FILED</td>
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<tr>
<td>Protein supplement drinks, canned/U.S. District Court for the District of New Jersey 8/14/81</td>
<td>Universal Protein Supplements Corp./Linden, N.J.</td>
<td>Product had had saccharin substituted for sugar; the label lacked the common or usual name of each ingredient because saccharin was not declared; the label lacked the required hazard statement for products containing saccharin.</td>
</tr>
<tr>
<td>“Sesame” oil/U.S. District Court for the District of Hawaii 7/28/81</td>
<td>Taisei Trading Co., Ltd./Kobe, Japan</td>
<td>The valuable constituent, sesame oil, was omitted or abstracted from the product; soybean oil has been substituted for sesame oil; the product’s labeling is false and misleading in representing the product as consisting wholly of sesame oil; and some lots fail to bear the nutrition labeling required by their vitamin claims.</td>
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<tr>
<td>“Sorghum” syrup/U.S. District Court for the Western District of Missouri 11/3/81</td>
<td>Griffin Manufacturing Co./Muskogee, Okla.</td>
<td>Glucose syrup substituted for sorghum; false and misleading labeling claiming article manufactured by Lemuel Roye Farms, Stigler, Okla., which was contrary to fact; false and misleading labeling claiming the article is made from sorghum cane; failure to conform to definition and standard of identity for sorghum syrup; and failure to comply with Fair Packaging and Labeling Act because the quantity of contents declaration was not separated from the printed label information appearing above and below the declaration, and was not expressed in a dual declaration of fluid measure.</td>
</tr>
<tr>
<td>“Sorghum” syrup/U.S. District Court for the Western District of Arkansas 9/18/81</td>
<td>Griffin Grocery Co./Muskogee, Okla.</td>
<td>Glucose syrup has been substituted for sorghum; the product’s labels falsely and misleadingly claimed that the product consisted wholly of syrup from sorghum and that the product was manufactured by Lemuel Roye Farms, Stigler, Okla.; the product fails to conform to the definition and standard of identity for sorghum syrup; failure to comply with Fair Packaging and Labeling Act because the quantity of contents declaration was not separated from the printed label information appearing above and below the declaration; the quantity of contents declarations were in too small type size; and the quantity of contents statement of one of the two lots is not expressed in fluid ounces followed in parenthesis by a declaration of the largest whole unit of net quantity.</td>
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</tbody>
</table>

**DRUGS/Human Use**

<table>
<thead>
<tr>
<th>DRUGS/HUMAN USE</th>
<th>FIRM &amp; PLACE OF BUSINESS</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furosemide tablets/U.S. District Court for the Central District of California 7/14/81</td>
<td>Superpharm Corp./Central Islip, N.Y.</td>
<td>Product is a new drug without an effective approved New Drug Application.</td>
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</tbody>
</table>
False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

August 4, 1981: Against Athena Products, 3176 Marjan Dr., Atlanta, Ga. Satisfactory evidence was presented to the Postal Service that Athena Products, Ltd., and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “Control,” representing the ability to “curb appetites and promote fast weight loss.”

August 10, 1981: Against Cove Pharmacal Sales, 95M South Hoffman Lane, Central Islip, N.Y. Satisfactory evidence was presented to the Postal Service that Cove Pharmacal Sales and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “PPA Plus Diet Capsules.” The ad states, in part, “works so fast—the very first weekend alone you lose a full pound (of fluid and fat) every 8 hours! In fact—because you actually neutralize all the calories in the food you eat—you grow slimmer and slimmer from meal to meal . . . and stay slim for the rest of your life.”

August 12, 1981: Against R. J. Fitzgerald, 521 Fifth Ave., New York, N.Y. Satisfactory evidence was presented to the Postal Service that R. J. Fitzgerald and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “Sexy Slim #10.” The ad states, in part, “one pill in the morning will quickly wash the fat down the drain. 10, 25, 50, 100 or more pounds easily safely . . . are you a round fat zero? Be a beloved sexy slim 10!”

August 31, 1981: Against Standard Research Labs, P.O. Box 9547, Ft. Lauderdale, Fla. Satisfactory evidence was presented to the Postal Service that Standard Research Labs and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “Procaine Vitamin,” representing the ability to “increase energy levels and stamina, as well as a greater sense of well being.”

August 31, 1981: Against Standard Research Labs, P.O. Box 5009, Pompano Beach, Fla. Satisfactory evidence was presented to the Postal Service that Standard Research Labs and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “Procaine Creme,” an anti-aging treatment.

September 30, 1981: Against Perry’s Distributors, 25 N. Beaver St., York, Pa. Satisfactory evidence was presented to the Postal Service that Perry’s Distributors and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising “Stimulants.” These stimulants are being sold as look-alike narcotics.

September 30, 1981: Against R & K Sales, P.O. Box 12589, Knoxville, Tenn. Satisfactory evidence was presented to the Postal Service that R & K Sales and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising “Stimulants,” representing the ability to “lose unsightly fat in days—without grueling exercise or starvation diets . . . they exert gentle but firm pressure which actually massages away layers of fat on your hips, waist, thighs, and bottom.”

September 26, 1981: Against Cosmetics Labs, P.O. Box 1044, Deerfield Beach, Fla. Advertising and sale through the mail of the product “Staminol.” The ad states, in part, “if you’re feeling tired and run down, then Staminol just might be your ‘endurance insurance.’”

August 20, 1981: Against R & K Sales, P.O. Box 12589, Knoxville, Tenn. Advertising and sale through the mail of the product ““Herbal Concepts,” representing the ability to cause weight loss. “At last, a positive cure! Proof that cellulite can be cured! Proof that you don’t have to live with cellulite! This is the only technique we know of that will positively cure cellulite, and prevent its recurrence permanently.”

August 25, 1981: Against Cosmetics Labs, P.O. Box 1044, Deerfield Beach, Fla. Advertising and sale through the mail of the product “Creme,” an anti-aging treatment.

August 25, 1981: Against James O. Anderson, Waco, Ky. Advertising and sale through the mail of the product “Stimulants.” These stimulants are being sold as look-alike narcotics.

August 25, 1981: Against Braswell, P.O. Box 11627, Atlanta, Ga. Satisfactory evidence was presented to the Postal Service that Braswell and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “The South American Diet,” representing the ability to lose weight. “A painless way to diet that sheds pounds quickly and safely.”

August 28, 1981: Against Cosmetics, P.O. Box 11627, Atlanta, Ga. Satisfactory evidence was presented to the Postal Service that Cosmetics and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the products “Will Power” and “Fat Off.” The ads state, in part, “created expressly to decrease appetite” and “designed to make your body burn off your own fat.”

August 28, 1981: Against California Medical Research, P.O. Box 4855, San Diego, Calif. Advertising and sale through the mail of the product “CMR Contour Creme,” representing the ability to “Take off bloated cellulite and ugly inches without pills, shots, exercise or hunger.”

September 30, 1981: Against Cosmetics, P.O. Box 9669, Atlanta, Ga. Satisfactory evidence was presented to the Postal Service that Cosmetics and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the products “1980 Diet System,” representing the ability to “help you achieve the slim, lithe figure you know you’ve always wanted.”

September 30, 1981: Against Braswell, P.O. Box 11627, Atlanta, Ga. Satisfactory evidence was presented to the Postal Service that Braswell and their agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “Guarana,” representing the ability to “eliminate hunger, causes euphoria, even while dieting, sharpens mental acumen and increases physical stamina.”

September 30, 1981: Against American Health Products, P.O. Box 9669, Atlanta, Ga. Satisfactory evidence was presented to the Postal Service that American Health Products and their representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product “Formula—12 Creme.” The ad states, in part, “there’s a smooth way to get rid of cellulite . . . if you want to get rid of those stubborn cellulite lumps and bumps that just won’t seem to go away no matter how much you diet . . .”

False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

Complaints Filed by Law Department Under 39 U.S.C. (False Representation)
NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Shrimp, peeled and deveined, at New York, S. Dist. N.Y.
Charged 9-28-79: when shipped by Sunrise Foods Co., Kaohsing, Nationalist China, the article, labeled in part, "Early Dawn Peeled and Deveined — Individually Quick Frozen Shrimp . . . Packed For: AJC Intl. Atlanta, Ga., Product of Taiwan," contained the poisonous and deleterious substance salmonella micro-organisms, which might render it injurious to health—402(a)(1); and the article contained decomposed shrimp—402(a)(3). The article was claimed by AJC International Inc., Atlanta, Ga. A consent decree of condemnation authorized release to the claimant for export to the original foreign supplier. (F.D.C. No. 62449D; Import S. No. 216356; N.J. No. 1)

Chocolate liquor, other cocoa product stocks, and other food stocks, at Bronx, S. Dist. N.Y.
Charged 11-4-81: when shipped by Pleasant Valley Vegetable Co-op, Oxnard, Calif., the article contained the non-conforming pesticide chemical monitor (methamidophos) and no tolerance or exemption from a tolerance had been granted for such pesticide chemical in or on spinach; 402(a)(2)(B). Consent decree ordered destruction. (F.D.C. No. 63593; S. No. 82-249-967; N.J. No. 2)

Beans, kidney, black-eyed peas, and pinto beans, at Bronx, S. Dist. N.Y.
Charged 12-12-80: while held by Pelham Dairies Inc., Bronx, N.Y., the articles had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62893; S. No. 81-138-215; N.J. No. 3)

FOOD/Contamination, Decomposition and Insanitary Handling

Spinach, bunches, Pleasant Valley, at Chicago, N. Dist. I11.
Charged 7-31-80: while held by Northern Shipping Co., Philadelphia, Pa., some of the articles contained mold and insect filth, and one lot of cocoa butter contained calcium hydroxide — 402(a)(4); one lot of tea and two lots of cocoa beans lacked a label containing a quantity of contents statement — 403(e)(2); the labels of the tea, the cocoa beans and the cocoa butter lacked the name and place of business of the manufacturer, packer or distributor and lacked the common or usual name of the food — 403(e)(1); and the label of the chocolate liquor had mandatory information (i.e., name and place of business of the manufacturer, packer or distributor and lacked the common or usual name of each ingredient) which was inconspicuous since such information did not appear on the label in the English language — 403(f). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63109; S. No. 80-288-331; N.J. No. 4)

Pecan logs, nut logs, and milk-chocolate creamsticks (lemon, orange & coconut), at Salt Lake City, Dist. Utah.
Charged 3-20-81: while held by Maxfield Candy Co., Salt Lake City, Utah, the articles had been prepared and packed under insanitary conditions; 402(a)(4). The articles were claimed by the manufacturer who denied that the articles were adulterated or that the articles had been introduced into or held for sale after shipment in interstate commerce, and who asserted that the government had waived its rights and/or was estopped because of government assurance that the seized articles were not contaminated and were not injurious to health. The government moved against hearing testimony about the absence of filth in a portion of the seized articles on the grounds of irrelevancy, since it is only necessary for the government to prove the existence of insanitary conditions that create a reasonable possibility of contamination. Subsequently, the claimant believed that the shelf life of the seized articles had expired. For the purposes of settlement of the action, the claimant consented to a decree ordering the articles destroyed. (F.D.C. No. 63415; S. No. 81-243-343 et al.; N.J. No. 7)

Rice, and dog food, at Statesboro, S. Dist. Ga.
Charged 10-1-81: while held by T. J. Morris Co., Statesboro, Ga., the rice contained rodent filth and both articles had been held under insanitary conditions; 402(a)(3) and (4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63425; S. No. 81-239-129 et al.; N.J. No. 8)

Rice, and dog food, at Statesboro, S. Dist. Ga.
Charged 10-1-81: while held by T. J. Morris Co., Statesboro, Ga., the rice contained rodent filth and both articles had been held under insanitary conditions; 402(a)(3) and (4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63425; S. No. 81-239-129 et al.; N.J. No. 8)

FOOD/Economic and Labeling Violations

Charged 5-12-81: when shipped by Oliver Anthony, t/a Anthony's Syrup Co., Philadelphia, Miss., the articles had had glucose substituted for honey, sorghum syrup and cane syrup — 402(b)(2); the articles' labels were false and misleading in representing that the foods consisted wholly of honey, sorghum syrup or cane syrup — 403(a)(1); and the articles labeled "sorghum" syrup and "cane" syrup failed to conform to the respective definitions and standards of identity for sorghum syrup and cane syrup, since the articles were made with syrups derived from sources other than sorghum cane and sugarcane — 403(g)(1); and all of the articles except one lot of canned sorghum syrup were in violation of the Fair Packaging and Labeling Act because of failure to bear quantity of contents statements in prescribed terms—15 U.S.C. 1453(a)(3)(A)(i). Default decree ordered destruction by delivery to a charitable institution for use and not resale. (F.D.C. No. 63439; S. Nos. 81-260-910/3; N.J. No. 9)

Charged 6-24-81: when shipped by Dewey Clark, Philadelphia, Miss., the article had had corn syrup substituted for maple syrup — 402(b)(2); the article's labeling falsely and misleadingly represented that the food consisted wholly of maple syrup — 403(a)(1); and the...
article failed to conform with the definition and standard of identity for maple syrup because the article was made with syrup from a source other than the maple tree — 403(g)(1). Default decree of condemnation ordered appropriate disposal. (F.D.C. No. 63444; S. No. 81-258-822 et al.; N.J. No. 10)

Protein supplement drinks, canned, at Linden, Dist. N.J.
Charged 8-14-81: while held by Universal Protein Supplements Corp., Linden, N.J., a powdered mix was blended, using interstate ingredients, which was subsequently manufactured into the liquid article and canned locally. The article, labeled in part, “Zero + 32 . . . A Nutritious 32 Gram Protein Drink . . . Strawberry [or ‘Vanilla Malt,’ or ‘Chocolate’ or ‘Banana’] Manufactured for Universal Protein Supplements, Linden, N.J.,” had had saccharin substituted for sugar — 402(b)(2); the label lacked the common or usual name of each ingredient because saccharin was not declared — 403(i)(2); and the label lacked the required hazard statement for products containing saccharin — 403(o)(1). Default decree ordered destruction. (F.D.C. No. 63518; S. Nos. 81-286-451/4; N.J. No. 11)

**DRUGS/Human Use**

**Allopurinol tablets,** at City of Commerce, C. Dist. Calif.
Charged 1-28-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62841D; S. No. 80-244-617 et al.; N.J. No. 12)

Allopurinol tablets, chlorthalidone tablets, diethylpropion HCl tablets, furosemide tablets, hydroxyzine pamoate capsules, spironolactone tablets, and trimethoprim with sulfamethoxazole tablets, at Tulsa, N. Dist. Okla.
Charged 1-28-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. A consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62760; S. No. 80-211-723; N.J. No. 13)

Charged 3-6-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62805; S. No. 80-208-569; N.J. No. 14)

Allopurinol tablets, doxylamine succinate with Be tablets, and prochlorperazine capsules, at Valley Stream, E. Dist. N.Y.
Charged 4-25-79: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Consent decree ordered destruction. (F.D.C. No. 62258; S. No. 79-184-604; N.J. No. 15)

Amygdalin injectable and amygdalin tablets, at Buffalo Grove, N. Dist. Ill.
Charged 8-17-78: when shipped by M&R Electronics, Graham, Texas, the injectables, which were labeled in part, (via) “Amygdalin CytoPharma 3g. 10 ml. CytoPharma De Mexico, SA.,” and the tablets, which were in unlabeled plastic bags, had accompanying labeling (e.g., air bill listing the shipment as “Electronics” from M&R Electronics) which was false and misleading — 502(a); the articles' labeling lacked: (1) the name and place of business of the manufacturer, packer or distributor, and (2) lacked accurate quantity of contents statements — 502(b)(1) and (2); the labeling lacked the established name of the drugs — 502(e)(1)(A)(i); the labeling lacked adequate directions for use and was not exempted — 502(k)(1); the labels failed to bear the required prescription legend — 503(b)(4); and the articles were new drugs without an effective approved New Drug Application — 505(a).

The articles were claimed by John E. Roche, M.D., Bridgeview, Ill., who denied knowledge concerning the misbranding charges, denied that the articles were new drugs within the meaning of 21 U.S.C. 321(b), and claimed that under the April 8, 1977, order in Rutherford v. U.S.A., the claimant, as a physician for five terminally ill cancer patients with certain executed affidavits, was entitled to the protection of that order.

At a hearing before the court, the claimant argued that patient affidavits had been provided and that the government had sufficient time to study them. The government argued that the affidavits did not appear to be in order and sought time for discovery.

The government prepared written interrogatories for service on the claimant. Subsequently, the claimant withdrew his claim and answer. Ultimately, a default decree of condemnation ordered the articles destroyed. (F.D.C. No. 61890; S. Nos. 78-180-963/4; N.J. No. 16)

Chlorpropamide tablets, at City of Industry, C. Dist. Calif.
Charged 6-13-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63057; S. No. 80-245-421; N.J. No. 17)

Chlorpropamide tablets, at Ft. Lauderdale, S. Dist. Fla.
Charged 6-5-80: when shipped by Darby Drug Co. Inc., Rockville Centre, N.Y., the article, labeled in part, “Chlorpropamide Tablets . . . Manufactured by Chelsea Laboratories, Inc., Inwood, N.Y., . . . A Division of Rugby Laboratories, Inc.,” was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 62924; S. No. 80-193-659; N.J. No. 18)

Chlorpropamide tablets, at New Britain, Dist. Conn.
Charged 12-28-78: when shipped by Premo Pharmaceutical Laboratories Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The shipper claimed the article, denied the charge and asserted that the government was estopped, but admitted certain specified facts. The government filed a motion for summary judgment of condemnation and destruction asserting that all the requisite facts had either been admitted by Premo or previously decided adversely to Premo. The court granted the government's motion for summary judgment and ordered the article destroyed. (F.D.C. No. 61997; S. No. 79-135-717; N.J. No. 19)

Chlorpropamide tablets, at Port Washington, E. Dist. N.Y.
Charged 12-20-78: when shipped by Premo Pharmaceutical Laboratories Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by the shipper who denied the charge and asserted that the government was estopped as a result of its arbitrary and capricious action in the regulation of "new drugs." Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 61999; S. No. 79-135-713; N.J. No. 20)

Charged 2-13-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62819L; S. No. 80-208-582; N.J. No. 18)

Chlorhaldione tablets, furosemide tablets, allopurinal tablets, and trimethoprim with sulfamethoxazole tablets, at Brooklyn, E. Dist. N.Y.
Charged 6-13-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by Premo or previously decided adversely to Premo. The court granted the government's motion for summary judgment and ordered the article destroyed. (F.D.C. No. 61997; S. No. 79-135-717; N.J. No. 19)

The articles were claimed by Premo Pharmaceutical Laboratories Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The shipper claimed the article, denied the charge and asserted that the government was estopped, but admitted certain specified facts. The government filed a motion for summary judgment of condemnation and destruction asserting that all the requisite facts had either been admitted by Premo or previously decided adversely to Premo. The court granted the government's motion for summary judgment and ordered the article destroyed. (F.D.C. No. 61999; S. No. 79-135-713; N.J. No. 20)
Furosemide tablets, hydroxyzine HCl tablets, allopurinal tablets, furosemide tablets, hydroxyzine pamoate capsules, and trimethoprim with sulfamethoxazole tablets, at Ormond Beach, M. Dist. Fla. Charged 2-27-79: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the Eastern District Court of New York for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62203; S. No. 79-166-559; N.J. No. 30)

Furosemide tablets, and chlorothalidone tablets, at Cleveland, N. Dist. Ohio. Charged 2-4-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper who denied the charge. The government served written interrogatories on the claimant. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62791; S. No. 80-208-554; N.J. No. 31)

Furosemide tablets, and trimethoprim with sulfamethoxazole tablets, at Philadelphia, E. Dist. Pa. Charged 3-6-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62804; S. No. 80-208-568 et al.; N.J. No. 32)

Guaiacol combination injection, at Carolina, Dist. P.R. Charged 1-29-81: when shipped by Carter-Glogau Laboratories Inc., Glendale, Ariz., the article, labeled in part, "Injection Guaiacof ... guaiacol ... aqueous solution ... with water for injection ... Manufactured for: David Hurst, Inc., Hato Rey, Puerto Rico," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 63296; S. No. 81-274-502; N.J. No. 33)

Hydroxyzine HCl tablets, allopurinal tablets, chlorothalidone with reserpine tablets, diethylpropion HCl tablets, hydroxyzine pamoate capsules, and spirinolactone with hydrochlorothiazide tablets, at Brooklyn, E. Dist. N.Y. Charged 11-7-79: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62450; S. No. 79-162-182 et al.; N.J. No. 34)

Hydroxyzine HCl tablets, allopurinal tablets, diethylpropion HCl tablets, furosemide tablets, hydroxyzine pamoate capsules, and trimethoprim with sulfamethoxazole tablets, at Elmhurst, E. Dist. N.Y. Charged 2-29-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62832; S. No. 80-208-588; N.J. No. 35)

Hydroxyzine HCl tablets, and furosemide tablets, at Orlando, M. Dist. Fla. Charged 2-8-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the articles destroyed. (F.D.C. No. 62803; S. No. 80-208-567; N.J. No. 36)

K.H.3 procarbazine HCl & hematoporphyryine capsules, three seizure actions, at Brownsville, S. Dist. Texas; Hidalgo, S. Dist. Texas; and Laredo, S. Dist. Texas. Charged 5-2-80 and 5-5-80: when shipped by International Bonded Warehouses Inc., Laredo, Texas, the article, labeled in part, "K.H.3 Schwarzhaup . . . zur Rewitalisierung und Regeneration . . . Kapseln . . . Schwarzhaup * Koln," was a new drug without an effective approved New Drug Application; 505(a). The article was claimed by the dealer who denied the charge. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62938, 62935 and 62936; S. Nos. 80-192-974/5 and 80-122-314; N.J. No. 37)

Elmwood Park, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The articles were claimed by the shipper. Pursuant to stipulation, the action was transferred to the District Court of New Jersey for consolidation for trial with a similar action. Subsequently, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 62841F; S. No. 80-244-617 et al.; N.J. No. 38)

Salicylamide, acetaminophen and antihistamine combination tablets, at Birmingham, N. Dist. Ala. Charged 5-1-81: the article, which was labeled in part, “Soporific Tablets Non Prescription Sleep Aids” and which had been shipped by W. W. Sales Inc., Elkhon, Md., was a new drug without an effective approved New Drug Application — 505(a); the article (whose tablets bore the embossed logo “Lemmon 714”) was an imitation of another drug (Quaalude tablets) — 502(i)(2); and the article was a counterfeit drug, since without authorization the article bore the trade name, other identifying marks, imprint or likeness of a manufacturer other than the actual manufacturer, and thereby was falsely represented to be the product of such manufacturer — 201(g)(2). Default decree ordered destruction. (F.D.C. No. 63464; S. No. 81-163-643; N.J. No. 39)

DRUGS/Veterinary Use

Diethylstilbestrol (DES) implant pellets, at Omaha, Dist. Neb. Charged 5-7-80: while held by Ronald L. Rosberg, Omaha, Neb., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the article’s use or intended use; 501(a)(5).

The article was claimed by Foxley & Co. (employer of Ronald L. Rosberg), Omaha, Neb., which denied the charge and served written interrogatories on the government. The government served requests for admissions and written interrogatories on the claimant. The claimant moved for a stay pending the outcome of another action involving diethylstilbestrol in the District of Columbia Circuit Court of Appeals. Subsequently, pursuant to stipulation the stay was lifted. The claimant moved for summary judgment and the government subsequently moved for summary judgment. The court granted the government summary judgment, saying:

"Pursuant to the warrant for arrest issued by this court, the above-captioned articles of drug were seized on May 16, 1980, by the U.S. marshal for this district. Foxley & Co. (hereinafter claimant) there after intervened in the action by filing a claim to the seized articles and an answer to the complaint. Based upon a stipulation by and between the United States and claimant, this court ordered that claimant be appointed custodian for the seized articles pending further court order.

"On the basis of the pleadings, answers to interrogatories, admissions on file and supporting affidavits, the parties have now cross-moved for summary judgment pursuant to Fed.R.Civ.P. 56. It is settled that summary judgment motions are appropriate in libel actions brought pursuant to the Act, United States v. 14 Cases, Etc., 'Naremco Medi-Matic,' 374 F.Supp. 922, 926 (W.D.Mo. 1974); United States v. Article of Device... Cameron Spiler, 261 F.Supp. 243, 244 (D.Neb. 1966).

"In the brief in support of its motion for summary judgment, the United States essentially argues that: (1) there is no genuine issue as to the fact that the seized articles are new animal drugs which are unsafe and, therefore, adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act; (2) the seized articles of drug are ‘held for sale’ by claimant as a matter of law since they are being held for a purpose other than the personal consumption of the ultimate consumer; and (3) whether the seized articles were legally adulterated when purchased and received by claimant is immaterial to this proceeding in view of the act’s purpose to reach adulterated articles at all stages of commerce.

"In the brief in support of its motion for summary judgment, the claimant essentially argues as follows: (1) claimant’s purchase of the seized articles, which occurred prior to the effective date of the decision by the FDA Commissioner to withdraw approval of New Animal Drug Applications for DES, was lawful; (2) the articles of drug containing DES purchased and received by claimant have not been ‘held for sale’ after October 31, 1979; (3) claimant is not in violation of the FDA’s ban on the use of DES animal drugs since claimant has not implanted any cattle since the effective date of said ban (November 1, 1979); and (4) claimant’s mere possession of the article of drug in question is not presently illegal.

"The chosen starting point for analysis of the above described cross motions for summary judgment is 21 U.S.C.A.§334(a)(1), which in pertinent part provides: ‘Any article of food, drug, or cosmetic that is adulterated or misbranded...while held for sale (whether or not the first sale) after shipment in interstate commerce...shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States...within the jurisdiction of which the article is found.’

"To obtain a judgment of condemnation of a seized article of drug under 21 U.S.C.A.§334(a)(1), therefore, the government must prove that the item seized is (1) a new animal drug (2) which is adulterated (3) while held for sale (4) after shipment in interstate commerce. The court now turns to a brief discussion of each of these requisite elements as applied to the case at bar.

New Animal Drug

"This court finds, and claimant does not contest, that the articles of drug containing DES, which were seized on May 16, 1980, constitute a new animal drug within the meaning of 21 U.S.C.A.§321(w). . . .

Adulteration

"A new animal drug is deemed to be adulterated [21 U.S.C.A.§351(a)(5)] for purposes of the act if it is unsafe [21 U.S.C.A.§360b(a)(1)(A)]. And such a drug is deemed to be unsafe unless there is in effect an approval of a New Animal Drug Application filed pursuant to 21 U.S.C.A.§360(b) with respect to the use or intended use of such drug, or a notice of claimed investigational exemption under 21 U.S.C.A.§360(b) is on file for the drug in question.

The claimant, Foxley & Co., had admitted that there is no approved New Animal Drug Application in effect for the articles of drug seized in this action. . . . Further, claimant has filed no notice of claimed investigational exemption under 21 U.S.C.A.§360(b)(j) and Regulation 21 C.F.R.§511.1 (1980) with respect to the articles of drug in question. . . . As a result the court finds that the new animal drug seized herein is unsafe, and thus adulterated, within the meaning of the act.

Held for Sale

"Title 21, U.S.C.A.§334(a)(1) requires inter alia that adulterated articles sought to be condemned must have been ‘held for sale’ after their shipment in interstate commerce. Claimant apparently contends the United States has failed to demonstrate as a matter of law that the DES animal drugs in claimant’s possession were held for sale at the time of seizure. In support thereof, claimant has submitted the affidavit of Jerald E. Swanson, D.V.M., an employee of Foxley Cattle Co. Dr. Swanson’s affidavit states in part: ‘The DES seized has not been held for resale by Foxley Cattle Co. nor implanted in any cattle owned by Foxley Cattle Co. after October 31, 1979 ...’ Claimant has also represented that, at the time of seizure, the articles of drug containing DES were being held for return to their manufacturer in exchange for a refund of the purchase price. . . .

"It is well established that the terms ‘while held for sale’ as they appear in the Federal Food, Drug, and Cosmetic Act have been given by courts an expansive rather than a technical construction. United States v. 10 Cartons ... Hossey Tablets, 152 F.Supp. 360, 364-65 (W.D.Pa. 1957). Indeed, whenever there is a problem of construction involving the federal food and drug law, the duty of courts is to liberally construe provisions of the act, being mindful of its overriding purpose to protect the lives and health of the public. Meserey v. United States, 447 F.Supp. 548, 553 (D.Nev. 1977). In United States v. Sullivan, 332 U.S. 689, 696-97 (1948), the Supreme Court explained that the words ‘while such article is held for sale after shipment in interstate commerce’ apparently were intended by Congress ‘to extend the act’s coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer.’
“Courts have construed the ‘held for sale’ clause to cover situations in which adulterated or misbranded articles are held by a retailer, United States v. Sullivan, supra; a wholesaler, DeFrees v. United States, 270 F.2d 730, 731 (5th Cir. 1959), cert. denied, 362 U.S. 944 (1960); and a bailee, United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 92 (1964). Physicians holding drugs for use in their practice may hold drugs for sale within the meaning of 21 U.S.C.A. §331(k). United States v. Evers, 643 F.2d 1043, 1050 (5th Cir. 1981). Devices, held by medical practitioners and used in the treatment of patients, are properly considered ‘held for sale.’ United States v. Diapulse Corp. of America, 514 F.2d 1097, 1098 (2d Cir.), cert. denied, 423 U.S. 838 (1975); United States v. Article of Device . . . Cameron Spitler, supra, 261 F.Supp. at 246. Owners of a bakery have been convicted of violating the act by holding adulterated flour for sale even though they planned to sell bread and rolls made from the flour rather than the flour itself. United States v. Cassaro, Inc., 443 F.2d 153, 155 (1st Cir. 1971).

“This court subscribes to the view that an article of drug or device is ‘held for sale’ if it is used for any purpose other than personal consumption. United States v. Articles of Device [Acuflex; Pro-Med], 426 F.Supp. 366, 368 n.3 (W.D.Pa. 1977); see United States v. Article of Device . . . Cameron Spitler, supra. The animal drugs containing DES at issue here clearly were not being held for personal consumption by an ultimate consumer, and were, therefore, ‘held for sale’ under 21 U.S.C.A. §334(a)(1). This conclusion is reinforced by the statement in Jerald E. Swanson’s affidavit that, on December 20, 1979, claimant shipped 100,000 pellets of DES to Mexico, which shipment was subsequently returned to Foxley Cattle Co.

Shipment in Interstate Commerce

“As previously noted, 21 U.S.C.A. §334(a)(1) requires that the adulterated drugs sought to be condemned have been held for sale ‘after shipment in interstate commerce.’ Claimant herein admits that, prior to their seizure on May 16, 1980, the articles of animal drug in question had been shipped in interstate commerce. . . . Claimant asserts, however, that at the time it received the DES animal drugs, there was no legal restriction on their use, with the result that the nexus between the drug item and commerce, necessary to invoke federal jurisdiction, United States v. Articles of Drug, 385 F.2d 575, 585 (3d Cir. 1978), is not present in this case.

“Claimant’s argument misses the mark. The language employed by Congress in 21 U.S.C.A. §331(k) and §334(a)(1) broadly prohibits misbranding or adulterating articles held for sale after interstate shipment, without regard to, inter alia, how long after the shipment the misbranding/adulteration occurred or how many intrastate sales had intervened. United States v. Sullivan, supra, 332 U.S. at 696. ‘Once an article is misbranded, it has violated the law and is subject to seizure at any time thereafter and no subsequent action can purge it from the violation.’ United States v. Article of Device . . . Cameron Spitler, supra, 261 F.Supp. at 246; see United States v. 1,800.2625 Wine Gallons, 121 F.Supp. 735, 738 (W.D.Mo. 1954). The above quoted principle applies to adulterated articles of drug as well as to misbranded articles of device.

“It has been admitted by claimant that the seized animal drugs are presently adulterated after shipment in interstate commerce. The fact that the seized articles may not have been legally adulterated before their shipment to, or receipt or use by, claimant is immaterial to the propriety of a judgment of condemnation under the act. The act was designed to safeguard the consumer from the time the article is introduced into the stream of interstate commerce all the way to the moment of delivery to the ultimate consumer. United States v. Wiesenfeld, supra, 376 U.S. at 92.

“In its brief in support of motion for summary judgment, claimant notes that this litigation arose after issuance of the FDA Commissioner’s decision on withdrawal of approval of New Animal Drug Applications for DES, 44 Fed.Reg. 54852, which became effective June 29, 1979. Predicating its argument on the commissioner’s decision, claimant notes that the federal laws covering adulterated substances simply did not apply to DES animal drugs prior to June 29, 1979, and that it is not illegal to possess DES which was purchased before, and not used after, the effective dates specified in the commissioner’s determination.

“Claimant’s argument is without merit. In plain, direct and unambiguous language, 21 U.S.C.A. §334(a)(1) provides that any adulterated article of drug which is held for sale after shipment in interstate commerce is subject to seizure and condemnation. Absent a clearly expressed legislative intention to the contrary, the language of a statute must ordinarily be regarded as conclusive. Consumer Product Safety Comm’n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980). Courts are not at liberty to modify by judicial construction the plain words of a statute or to depart from a statute’s clear meaning under the guise of interpretation. Adams v. Morton, 581 F.2d 1314, 1320 (9th Cir. 1978); Baker v. United States, 460 F.2d 827, 831 (8th Cir. 1972). In situations where, as here, a statute’s provisions are clear and unequivocal on their face, ‘this court must follow the dictates of that statute.’ Sturdevant v. Wilber, 464 F.Supp. 327, 332 (E.D.Wis. 1979).

“Considering that the articles of drug at issue in this action constitute a new animal drug that is adulterated while held for sale after shipment in interstate commerce, the court finds that there is herein no genuine dispute as to any material fact and that the United States is entitled to judgment as a matter of law.” (F.D.C. No. 63002; S. No. 80-165-948; N.J. No. 40)
false and misleading in claiming compliance with the regulation's standards, and in claiming that the device would deliver the radiation exposure stated in the instruction manual—502(a); and the article's quality fell below its purported quality—501(c). Consent decree authorized release to possessor for reconditioning. (F.D.C. No. 62558; S. No. 79-152-930; N.J. No. 43)

X-ray system, Traceray III, three seizure actions, at Morris, Dist. Minn., destroyed the 300,000 pounds of brined cherries which had been on inspection and inspection of specified government evidence, moved to compel an inspection of specified government evidence, moved to compel an election as to the various counts of the criminal information and for separate trials and moved to suppress inspectional and other evidence in claiming that the circumstances used for the manufacturing, processing, packing and holding of such drugs did not conform to and were not operated and administered in conformity with current good manufacturing practice; that FDA inspections of the defendants' plant revealed a number of specified deficiencies; that FDA analyses of samples found that the samples contained particular matter indicative of inadequate processing for the manufacture, processing, packing and holding for sale, after interstate shipment of components, certain articles which were labeled as "Sterile Diluent for Allergic Extracts" and as "Sterile Empty Vials" which were intended as components of various drug systems, and (b) distributing such articles (drugs) in interstate commerce; that the circumstances used for the manufacture, processing, packing and holding of such drugs did not conform to and were not operated and administered in conformity with current good manufacturing practice; that FDA inspections of the defendants' plant revealed a number of specified deficiencies; that FDA analyses of samples found that the samples contained particular matter indicative of inadequate processing and testing; and that the defendants were well aware that their operations failed to conform with current good manufacturing practice; 501(a)(2)(B).

A consent decree of permanent injunction enjoined the complained of violation and enjoined continued drug production unless and until a number of specified corrections were undertaken. (Inj. No. 870; S. No. 78-100-869 et al.; N.J. No. 48)

Overisel Feed Supply Co., and Adrian Slager, president Holland, W. Dist. Mich. Charged 12-4-78 in a complaint for injunction: that the defendants manufactured, processed, packed, and labeled and held various medicated and non-medicated animal feed mixtures containing interstate components; that the circumstances used for the manufacture, processing, packing and holding of the medicated animal feed mixtures failed to conform with current good manufacturing practice; that certain medicated animal feeds differed in purity, quality and strength from their purported purity, quality and strength due to cross-contamination or sub-potency; that FDA analysis of a specified medicated feed showed sub-potency in chlorotetracycline content; that FDA analysis of bagged "non-medicated" animal feed mixture revealed contamination with 2.5 parts per million (ppm) sulfamethazine, and FDA analysis of unbagged material (from the floor chute after flushing) revealed 28 ppm sulfamethazine; that non-medicated animal feed mixtures contained non-conforming new animal drugs; that non-medicated animal feed mixtures had been prepared, packed and held under insanitary conditions whereby they might have been rendered injurious to health; that FDA inspections disclosed a number of specified serious deviations from current good manufacturing practice; and that the defendants were well aware that their activities were in violation of the Federal Food, Drug, and Cosmetic Act; 501(a)(2)(B), 501(c), 402(a)(2)(D) and 402(a)(4).

The defendants opposed the government's action. However, after a hearing, the court granted a temporary restraining order and a preliminary injunction enjoining the defendant, but permitting the manufacture of non-medicated feed provided that FDA had certified that all equipment had been adequately cleaned. Over the next two years, FDA inspected the firm's plant three times and determined that the terms of the injunction were being met. Subsequently, pursuant to stipulation of the parties, the action was dismissed. (Inj. No. 863; S. No. 78-121-217; N.J. No. 49)

Briggs-Aitchison Co. Inc., and Thomas Aitchison, president, Wenatchee, E. Dist. Wash. Charged 10-16-78 in a complaint for injunction: that the defendants processed, packed, held and distributed in interstate commerce brined cherries, which contained insect filth and which had been prepared, packed and held under insanitary conditions; that FDA inspections disclosed a number of specified insanitary conditions; that FDA analysis revealed the presence of insects on the cherries; and that the defendants had been repeatedly warned of the insanitary conditions in a building accessible to rodents and insects; and the peanuts, roll mix, brownie mix, and gingerbread mix were contaminated with rodent or insect filth; 402(a)(3) and (4). Guilty plea by corporation; $1,000 fine on count 1, sentence suspended on other counts; probation for one year. Guilty plea by William Cleo Cheek Jr. to two counts; $500 fine on count 1; suspended sentence on other "goober" peanut count; and probation for one year. Guilty plea by William Cleo Cheek Jr. to two counts; $1,000 fine on count 2; suspended sentence on other sugar count; and probation for one year. (F.D.C. No. 63244; S. No. 79-137-524 et al.; N.J. No. 45)

Polar Bear Ice Co., Inc., t/a Alexandria Ice & Cold Storage Inc., and Robert A. Moore, president, at Alexandria, W. Dist. La. Charged on or about 4-23-81: corn grits, whole wheat flour (two lots), macaroni and corn meal were held under insanitary conditions in a building accessible to rodents and were contaminated with rodent filth; 402(a)(3) and (4). The defendants moved for a bill of particulars, moved for discovery and inspection of specified government evidence, moved to compel an election as to the various counts of the criminal information and for separate trials and moved to suppress inspectional and other evidence. The defendants also requested that the government serve notice of its intention to use any properly discoverable evidence. Subsequently, the corporation pleaded guilty and was fined $1,250. The individual pleaded guilty to the count involving corn grits; sentence was suspended and the individual was placed on probation for two years. (F.D.C. No. 63241; S. No. 79-171-779 et al.; N.J. No. 46)

Notices of Judgment on Miscellaneous Actions

Hearing aid device labeling, conditions for sale, and regulations promulgated by FDA, at Washington, D.C. Charged 7-28-77 by American Speech & Hearing Association, Rockville, Md., and Maurice H. Miller, Ph.D., Audiology Chief of a hospital, New York, N.Y., against H.E.W. Secretary Joseph A. Califano Jr., FDA Commissioner Donald Kennedy, and the Food and Drug Administration in a complaint for declaratory and injunctive relief: that the ASHA, national scientific and professional organization for speech pathologists and audiologists, sued as an incorporated
organization on its own behalf and on behalf of its approximately 3,500 member audiologists; that the ASHA and its member audiologists, including Maurice H. Miller, were adversely affected and aggrieved by proposed April 21, 1976, FDA regulations, entitled "Hearing Aid Devices: Professional and Patient Labeling and Conditions for Sale," because: (a) the regulations did not authorize evaluation by an audiologist as a condition of hearing aid sale, and (b) the regulations would pre-empt state laws which make evaluations by an audiologist a condition of hearing aid sales; that the FDA regulations required prospective hearing aid purchasers to have a medical examination by a licensed physician (but the medical examination could be waived by persons 18 or over except those demonstrating certain specified otological abnormalities) and the FDA regulations did not require hearing aid purchasers to obtain an audiological evaluation of their hearing loss (although numerous states had made an audiologist's evaluation a condition of hearing aid sales, either as a supplement or alternative to a physician's examination); that the regulations (as proposed by FDA) contained a "Non-Pre-emption Statement" which permitted state and local governments to establish more stringent conditions for sale of hearing aids than were prescribed by the FDA regulation; that FDA's final Feb. 15, 1977, rules retained the requirement of a medical examination and retained the right of waiver by any person 18 or over; including those demonstrating otological abnormalities, but, due to enactment of the Medical Device Amendments of 1976, the "Non-Pre-emption Statement" was nullified so that the final rules were the opposite of the proposed rules in that state and local legislation relating to hearing aids was pre-empted; that FDA's action in limiting the phrase "practitioner" to mean "a qualified practitioner licensed by law to administer or use such device" to mean "physician" and to exclude licensed audiologists was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law. FDA's inclusion of the "Non-Pre-emption Statement" in the proposed rules despite the pendency of the Medical Device Amendments misled and deceived readers into believing that the rules would not pre-empt state and local legislation requiring examinations by audiologists; that the termination of the comment period for the proposed rules, prior to the adoption or even proposal of regulations on exemption from pre-emption, deprived the plaintiffs of a fair opportunity to comment on the proposed rules for hearing aids; and that the court should declare invalid FDA's final rules, enjoin the taking effect of the rules, require a new rule making proceeding, and declare invalid FDA's interpretation of the word "practitioner.

The Hearing Industries Association, a national trade association of firms engaged in the manufacture, import and distribution of hearing aids, moved for leave to intervene in the action to protect the interests of HIA and its member firms. The motion of HIA to intervene was granted.

The court denied ASHA's motion for a preliminary injunction, saying:

"In this suit for declaratory and injunctive relief the American Speech and Hearing Association, a national association of audiologists and speech pathologists, and Maurice H. Miller, a member of ASHA, seek to prevent the Food and Drug Administration from issuing final rules governing the manufacture and distribution of hearing aid devices. The rules were due to become effective on August 15, 1977. Briefs were filed on an expedited schedule, and a hearing was held on August 12, 1977, at which time the court granted leave to intervene as a defendant to the Hearing Industries Association.

"The sequence of events precipitating this lawsuit is straightforward. Presently, the marketing of hearing aid devices is regulated, if at all, by the states. Forty-one states have such rules, but their provisions vary widely. For example, in some states that regulate the devices, an examination by a specialist physician or an audiologist or both is required as a condition precedent to obtaining a hearing aid; some states require no examination at all. Rules in some states apply only to certain age segments of the population.

"In March 1974 the defendant, Department of Health, Education, and Welfare, established a task force to study the problems relating to the marketing of quality hearing aids throughout the United States. Comments were solicited, public hearings held and a report prepared. As a result of the task force findings, and acting pursuant to its authority under 21 U.S.C. §371(a) (1970) and 21 C.F.R. §2.120(a)(1) (1976), the FDA undertook to develop national rules. Proposed rules were published in the Federal Register on April 21, 1976, and a 60 day comment period was provided. 41 Fed. Reg. 16756 (1976).

"Section 801.421(a) of the proposed rules required an examination, subject to waiver in certain instances, by a licensed physician prior to issuance of a hearing aid to a user. It also provided that "[s]ate and local governments may make more stringent conditions for sale of hearing aids." Thus, those state rules requiring an examination by an audiologist in addition to one by a physician were left intact.

"On May 28, 1977, however, during the comment period for the proposed rules, Congress passed the Medical Device Amendments of 1976, Pub. L. No. 94-295,[1977] U.S. Code Cong. & Ad. News (90 Stat. 539). The amendments mandate pre-emption of state and local requirements with respect to medical devices (including hearing aids) which are "different from, or in addition to" any requirements established by the FDA. 21 U.S.C.A. §360k(a) (West 1977 Supp.). However, the amendments do allow the FDA, by regulation issued after notice and an opportunity for an oral hearing, to exempt a state or local medical device requirement from pre-emption under such conditions as the FDA may "prescribe if the requirement is (1) more stringent than the federal requirements applicable to the device or (2) required compelling local conditions and compliance with it would not cause the device to be in violation of any other federal requirement. Id. §360k(b). On June 4, 1976, the FDA published in the Federal Register a notice of the new amendments, 41 Fed. Reg. 22620 (1976). However, no mention was made of either the effect of the amendments on the proposed hearing aid rules or the FDA's intention to issue any regulations governing exceptions.

"The hearing aid rules were promulgated in final form on February 15, 1977, to become effective on Aug. 15, 1977. 42 Fed. Reg. 9286 (1977). The requirement of prior examination by a physician was retained, but, due to the intervening enactment of the Medical Device Amendments, providing pre-emption, no allowance was made for differing state and local regulations.

"Plaintiff ASHA filed petitions for stay and for reconsideration of the final rules with the FDA on March 17, 1977, thus exhausting its administrative remedies. The petitions were denied June 14, 1977, and on the same day the FDA issued proposed rules for exemption of state medical device requirements. Id. at 30380. Final exemption rules have not yet been promulgated.

"Plaintiffs' legal claim is two fold. First, plaintiffs object to use of the word 'physician' in the final rule requiring a written statement by a physician as a condition precedent to the purchase of a hearing aid. The rule was promulgated pursuant to 21 U.S.C.A. §360j(e)(1)(A) (West 1977 Supp.), which provides: 'The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . . only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device. . . . (emphasis supplied.)' Plaintiffs contend that in several states audiologists are 'practitioner[s] licensed by law to administer or use' a hearing aid. Therefore, it is argued, use of a term more restrictive than 'practitioner' in the regulation is arbitrary and in contravention of the statute. The extent to which this semantic shift affects plaintiffs is unclear from the present record; evidence on the functions and employment of audiologist was insufficient and contradictory.

"Plaintiffs also challenge the procedure followed in promulgating the final hearing aid rules. Defendants are charged with failure to give notice of the 'drastic alteration' of the proposed rules by pre-emption provision of the amendments, with not affording sufficient time after passage of the amendments for comment on the proposed regulations, and with delaying publication of proposed medical device exemption rules until after issuance of the final hearing aid regulations. Plaintiffs allege that these actions violated the notice and comment provision of the Administrative Procedure Act, 5 U.S.C. §553 (1970), . . . thus depriving them of an opportunity for meaningful participation in the formulation of the final rule. In opposition, defendants deny that any APA violations occurred. They note further that ASHA, which employs professional lobbyists and which was involved in the evolution
of the amendments, had actual notice of the new law and therefore could not have been prejudiced by the FDA's inaction. Defendants represented to the court that pending implementation of final exemption rules the FDA is actively considering individual state exemption requests on an ad hoc basis.

"There is no question that plaintiffs have raised serious legal questions as to the propriety of the FDA's actions. However, this alone does not warrant interim injunctive relief. Something more must appear. 'An order maintaining the status quo is appropriate when a serious legal question is presented, when little if any harm will befall other interested persons or the public, and when denial of the order would inflict irreparable injury on the movant.' Washington Metropolitan Area Transit Commission v. Holiday Tours, slip op. at 6, C.A. No. 76-1500 (D.C. July 5, 1977), interpreting Virginia Petroleum Jobbers Ass'n v. FCC, 259 F.2d 921 (D.C. Cir. 1958).

"The plaintiffs' showing of irreparable injury was inadequate. When questioned by the court, plaintiffs pointed to the 'confusion' that would accompany implementation of the rules and the loss of business that audiologists might suffer. The first claim is frivolous; the second is not persuasive. While the court does not hold that economic injury can never constitute sufficiently irreparable injury to warrant injunctive relief, cf. Independent Bankers' Ass'n v. Smith, 534 F.2d 921, 950 (D.C. Cir. 1976), cert. denied, 45 U.S.L.W. 3253 (1977), the plaintiff must come forward with something more than a conclusory allegation. Counsel could not, at this stage of the proceedings, establish what portion of plaintiffs' business would be adversely affected by the rules, or why the injury would be irreparable if the rules became effective. Perhaps such a showing will be made in a hearing on the merits after appropriate discovery, but on the present record there is insufficient evidence to establish the irreparable injury that would warrant the granting of preliminary relief."

The plaintiffs appealed the denial of a preliminary injunction and moved for a stay of the effective date of the final rules. The Court of Appeals denied the motion because it appeared that FDA was currently considering requests for exemption from pre-emption on an ad hoc basis, and that consequently the denial of a stay would not adversely affect local governments.

As to ASHA's still pending request for a permanent injunction, the government and the other defendants moved to dismiss on the grounds that ASHA had failed to state a claim upon which relief could be granted. HIA joined in the defendants' motion; and the plaintiffs countered with their own motion for summary judgment. After a hearing before the court, the court took the case under advisement. HIA, the intervenor, filed a synopsis to the document in question and included an attachment, 1, a letter of Nov. 22, 1977, from the intervenedor's counsel. Upon motion of ASHA, the court struck such letter from the record.

In ruling on cross motions of summary judgment, the court upheld the FDA and granted summary judgment against ASHA, saying:

"The material facts are not in dispute. Prior to implementation of the challenged regulations, the marketing of hearing aid devices was regulated, if at all, by the states. Abuses were prevalent. Although 43 states had rules governing some aspect of hearing aids, the provisions varied widely in both force and scope. In some states an examination by a physician specializing in hearing disorders or an audiologist was required as a condition precedent to obtaining a hearing aid. Some states required no examination at all. Rules in some states applied only to certain age segments of the population.

"In March 1974 the defendant, Department of Health, Education and Welfare, established a task force to study problems relating to the marketing of quality hearing aids throughout the United States. Comments were solicited, public hearings held, and a report prepared. As a result of the task force findings, and acting pursuant to its delegated authority under 21 U.S.C. § 377(a) (1970) and 21 C.F.R. § 21.120(a)(1) (1976), the FDA undertook to develop national rules. Proposed rules were published in the Federal Register on April 21, 1976, and a 60 day comment period was provided. 41 Fed. Reg. 16756 (1976).

"Section 801.421(a) of the proposed rules required an examination, subject to waiver in certain instances, by a licensed physician prior to issuance of a hearing aid to a user. It also provided that 'a state or local governments may make more stringent conditions for sale of hearing aids.' Thus, those state rules requiring an examination by an audiologist in addition to one by a physician were left intact.

"On May 28, 1977, however, during the comment period for the proposed rules, Congress passed the Medical Device Amendments of 1976. . . . The amendments mandate pre-emption of state and local requirements with respect to medical devices (including hearing aids) that are 'different from, or in addition to' any requirements established by the FDA. . . . The amendments do allow the FDA, by regulation issued after notice and an opportunity for oral hearing, to exempt a state or local medical device requirement from pre-emption under such conditions as the FDA may prescribe if the requirement is (1) more stringent than the federal requirements applicable to the device, or (2) required by compelling local conditions and compliance with it would not cause the device to be in violation of any other federal requirement. . . . On June 4, 1976, the FDA published in the Federal Register a notice of the new amendments, 41 Fed. Reg. 22620 (1976), but it made no mention of either the effect of the amendments on the proposed hearing aid rules or the FDA's intention to issue any regulations governing exemption.

"The hearing aid rules were promulgated in final form on February 15, 1977, to become effective on August 15, 1977. 42 Fed Reg. 9286 (1977). The requirement of prior examination by a physician was retained, but, due to the intervening enactment of the Medical Device Amendments, the allowance for differing state and local regulations was deleted.

"Plaintiff ASHA filed petitions for stay and for reconsideration of the final rules with the FDA on March 17, 1977, thus exhausting its administrative remedies. The petitions were denied June 14, 1977, and on the same day the FDA issued proposed rules for exemption of state medical device requirements. . . . Final exemption rules have not yet been promulgated.

II.

"Plaintiffs argue that promulgation of the rules was so fraught with procedural irregularity that the rules must be repromulgated and made subject once again to a comment period. The crux of the argument centers around passage of the Medical Device Amendments midway through the comment period for the proposed rules. The amendments' pre-emption of all state regulation of hearing aid devices is said to have so changed the proposed rules that the regulatory scheme as adopted was no longer the same as that originally proposed. Therefore, the argument continues, the FDA violated both the APA, 5 U.S.C. § 553 (1970), and its own regulations, 21 C.F.R. § 10.40(b)(2) (1977), in failing to (1) issue a notice drawing attention to the intervening legislative change, and (2) extend the comment period to provide a full 60 days after the enactment of the amendments for submission of comments.

"Plaintiffs agree that unless the amendments wrought a 'major substantive difference' between the regulation as proposed and as ultimately adopted, there was no requirement of notice or of an extension in the comment period. . . . In this case, unlike those cited by plaintiff, the regulatory scheme itself remained intact; at most the amendments altered only the scope of the rules by automatically pre-
empting, at least temporarily, the laws of certain states that otherwise would have been exempt. It is questionable whether this type of change qualifies as a 'substantive difference.' It is also questionable whether it can be considered to have been 'major.' Under the rules as originally proposed those states with more stringent requirements would have been automatically exempt from the rules. Now those same states are eligible for exemption upon application to and consideration by the FDA. The difference appears to be largely one of temporary delay.

"Even assuming that the change could be considered to have worked a 'major substantive difference,' no procedural violation occurred. Neither the APA nor any authority cited by plaintiff required an agency to publish in the Federal Register notice that an act of Congress has been passed or an analysis of its impact on rules under consideration. 'The statute itself is notice to all' of its provisions and impact. . . . Plaintiffs seek to avoid the operation of this maxim by pointing out, first, that subsequent to passage of the amendments the FDA did issue a notice regarding the effect of the amendments on the proposed rules but failed to mention the pre-emptive effect and, second, that the proposed pre-emption provision was merely 'a gratuitous piece of legal advice' that actively misled parties interested in the regulation after the amendments were adopted. FDA's failure to give notice, although unfortunate, does not rise to the level of reversible error. There is no evidence that anyone was misled. All of the comments received by FDA after enactment of the amendments, including the comment submitted by ASHA, concerned the question of pre-emption, and all correctly interpreted the effect of the new statute.

"Nor is there any violation in the FDA's failure to extend the comment period. Twenty-four days remained after the amendments were passed. The APA, 5 U.S.C.§553 (c) (1970), requires only that interested persons be given 'an opportunity' to comment on proposed rules. FDA's own regulations suggest 60 days for comment but require no more than 10. 21 C.F.R.§10.40(b)(2) (1977). The agency had 60 days from the time it promulgated the proposed rules. Even without an extension, 24 days remained in the comment period after passage of the amendments. This was sufficient to satisfy both the APA and FDA's own regulations. It is interesting to note that of the 500-odd comments received by the FDA on all aspects of the hearing aid regulations, only five were received in the last 24 days, thus suggesting that the interested public had long since exhausted its comments. Moreover, FDA's regulations provide for extension of the comment period upon application to the FDA Commissioner by any agency to publish in the Federal Register notice that an act of Congress has been passed or an analysis of its impact on rules under consideration. 'The statute itself is notice to all' of its provisions and impact. . . . Plaintiffs seek to avoid the operation of this maxim by pointing out, first, that subsequent to passage of the amendments the FDA did issue a notice regarding the effect of the amendments on the proposed rules but failed to mention the pre-emptive effect and, second, that the proposed pre-emption provision was merely 'a gratuitous piece of legal advice' that actively misled parties interested in the regulation after the amendments were adopted. FDA's failure to give notice, although unfortunate, does not rise to the level of reversible error. There is no evidence that anyone was misled. All of the comments received by FDA after enactment of the amendments, including the comment submitted by ASHA, concerned the question of pre-emption, and all correctly interpreted the effect of the new statute.

Plaintiffs' attack on the hearing aid regulations is not limited to alleged procedural irregularities, but extends to the substance of the rule as well. The substantive question centers around §801.421(a), which requires, unless waived, a medical evaluation by a physician of the individual suffering from a hearing disorder prior to the sale of a hearing aid. Plaintiffs contend that the requirement that the pre-sale evaluation be conducted by a physician rather than by any practitioner licensed to administer hearing aid devices violates an express provision of the Medical Device Amendments and in any event is arbitrary and capricious.

"At the very heart of the substantive dispute is the fact that FDA's requirement of examination by a physician as opposed to an audiologist has threatened an important facet of the audiologist's role in the hearing aid delivery system. For this reason it is helpful, in evaluating the strength of plaintiffs' claim, to understand something of the audiologist's function. A clinical audiologist is a graduate-school-trained 'individual qualified to provide professional assistance concerning communication problems associated with hearing impairment.' 41 Fed. Reg. 16757 (1976). Such assistance includes prevention, identification, evaluation and rehabilitation of people with auditory disorders. Approximately 95 percent of all practicing audiologists are members of plaintiff ASHA, which requires that all members who offer clinical services meet certain qualifications and pass certain tests. Twenty-nine states license audiologists, who may work alone, in conjunction with or under the supervision of a doctor, or in a school or clinic. By and large they do not sell or install hearing aids, and in any event are prohibited by their Code of Ethics from extracting a profit from these services. Ordinarily an audiologist who diagnoses an individual's need for a hearing aid will perform diagnostic tests to determine the nature of the hearing problem and the proper qualities a hearing device should have. The individual is free to approach a hearing aid dealer of his choice. The hearing aid dealer will perform other tests, make an ear mold, and fit the hearing aid.

"Section 2 of the amendments . . . provides in relevant part: The Secretary may by regulation require that a device be restricted to sale, distribution, or use. . . . (A) upon the written or oral authorization of a practitioner licensed by law to administer or use such a device, or (B) upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Plaintiffs argue that the regulation in question is invalid under subsection (A), which, in plaintiffs' opinion, requires any regulation mandating pre-sale authorization by a licensed practitioner to apply equally to all licensed practitioners. In most states audiologists, physicians, and hearing aid dealers are all licensed practitioners within the meaning of the statute. Thus, under subsection (A), it is argued, a rule requiring authorization by a physician is invalid because it excludes other licensed practitioners.

"Plaintiffs' argument has several flaws. First, it is incorrect to characterize it as one of exclusion: neither audiologists nor dealers are barred from doing anything, nor are they deprived of their status as practitioners. Second, at least in the context of hearing aid sales, plaintiffs' construction of the term 'practitioner' leaves subsection (A) devoid of meaning. Hearing aids are always sold by 'licensed practitioners' who, by the very act of selling have 'authorized' the sale. The type of restriction comprehended by plaintiffs' interpretation of subsection (A) imposes no restriction at all. Courts are admonished against construing a statute so as to deprive it of effectiveness or meaning. . . . To do so the Court must find that subsection (A) permits the FDA to distinguish among different types of practitioners and thus to authorize the type of regulation at issue.

"This result accords with plain sense. The purpose of the amendments was to empower the Secretary of his judgment to root out the abuses exist under the present regulation of medical devices . . . . The regulation at issue is so obviously directed toward that goal that the Court would have to ignore the most fundamental tenets of statutory interpretation to void it. . . . Plaintiffs' narrow argument does not commend such a course.

"Plaintiffs argue next that even if the regulation does not violate section 2 of the amendments, it is nonetheless arbitrary and capricious and thus voidable under section 10 of the APA, 5 U.S.C.§706(2)(A) (1970). Under the amendments the regulation is valid only if 'there cannot otherwise be reasonable assurance of [the] safety and effectiveness' of hearing aid devices. Yet if this is so is it not irrational to make the examination requirement waivable in a large number of cases? And is it not irrational to allow the required examination to be performed by any physician, a class that includes podiatrists, gynecologists and others with little familiarity with hearing disorders, yet at the same time exclude audiologists, whose expertise is in this area?

"These are thoughtful questions. The record shows, however, that they were carefully considered by the FDA prior to enactment. The regulation is accompanied by detailed and conscientious findings of fact that justify the rule adopted. The seeming contradictions are actually the result of compromises between the competing demand of economy and safety. After extended and careful study, the FDA found a medical evaluation to be essential for proper diagnosis and treatment. It also found that audiologists were unable to 'differentiate, diagnose, evaluate and treat the medical cause or causes of a hearing impairment.' 42 Fed. Reg. 9288 (1977). Examinations were
authorized by all physicians because of the scarcity of otologist, otolaryngologists and other physicians specializing in hearing disorders. A required audiological examination in addition to that of a physician was rejected as too expensive and of dubious incremental benefit. The waiver provision was included to accommodate certain religious and personal beliefs as well as those with the most limited access to physicians. Those eligible to waive the examination may do so only upon signing a form strongly advising against waiver. The court is far from convinced of the wisdom of the compromise adopted, but is mindful of the limited scope of its review and the deference due to the informed experience and judgment of the agency to whom Congress delegated appropriate authority. . . . Because the regulatory choice made in this case cannot be termed unprecedented, it is upheld.

"Finding plaintiffs' arguments inadequate as a matter of law to void the hearing aid regulations, the court hereby denies plaintiffs' motion for summary judgment and grants summary judgment to defendants."

ASHA appealed the grant of summary judgment to the government. However, pursuant to stipulation of the parties, the appeal was dismissed. (Misc. No. 444; N.J. No. 50)

Hearing aid devices, professional and patient labeling and conditions for sale, and FDA regulations, at Lauderhill, S. Dist. Fla.

Charged 8-1-77 by Morris Levin, an individual in the hearing aid business, against FDA Commissioner Donald Kennedy, in a complaint for injunction: that U.S. residents could purchase, without a physician's written permit, cigarettes, alcoholic products and sporting equipment for golf, tennis and bowling, although thousands died annually from problems incurred in the use of such products; that FDA regulations on Hearing Aid Devices [which required a physician's written medical evaluation, unless waived] were discriminatory towards the plaintiff and others like him in the same business and were in violation of the equal rights guaranteed in the 14th amendment to the Constitution; and that an injunction should be issued to prevent enforcement of the regulations.

The government moved to dismiss on the grounds of failure to state a claim upon which relief could be granted. The court agreed with the government and dismissed the plaintiff's complaint, saying: "This case is before the court on the motion of defendant Dr. Donald Kennedy to dismiss plaintiff's complaint for failure to state a claim upon which relief may be granted. Plaintiff Morris Levin alleges in his complaint that he is being denied equal protection of the law in violation of the 14th Amendment in that defendant as Commissioner of the Food and Drug Administration has issued regulations concerning the hearing aid industry of which plaintiff is a member, 21 C.F.R. §§801.420 and 801.421, but has not issued such regulations in regard to other more dangerous industries. With all due regard to plaintiff's pro se status, Haines v. Reiner, 404 U.S. 519 (1972); Guerrero v. Hauck, 502 F.2d 970 (5th Cir. 1974), the court agrees with defendant's assessment of plaintiff's complaint and shall dismiss it.

"Plaintiff does not contend that the FDA lacks authority to issue regulations concerning hearing aids and indeed there can be little question that the FDA does have explicit statutory authority to do so. 21 U.S.C. 371(a), 360(e), 360(i), 352(f), 352(a), 321(n). There is also little question but that the authorizing statutes have a legitimate governmental purpose, the protection of the public health. United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784 (1969).

"Plaintiff, of course, is incorrect to invoke the 14th Amendment as the basis of his claim because that amendment is applicable only to state action, United States v. Price, 383 U.S. 787 (1966) and not to action by the federal government. Taylor v. United States, 320 F.2d 843 (9th Cir. 1963). It is true, however, that the due process clause of the 5th amendment has been held to incorporate the conception of equal protection contained in the 14th Amendment, Bolling v. Sharpe, 347 U.S. 497 (1954) and the mode of analysis employed by the Supreme Court in analyzing 14th Amendment and 5th Amendment equal protection cases is precisely the same. Weinberger v. Wiesenfeld, 420 U.S. 636 (1975). The court, therefore, shall proceed on the assumption that plaintiff intended to invoke the 5th Amendment.

"In the area of social and economic legislation the courts have always used the traditional 'rational basis' standard in determining whether legislation or administrative regulation pursuant thereto was permissible under the concept of equal protection. Dandridge v. Williams, 397 U.S. 747 (1970). This standard simply stated holds that if a given classification of a statute or regulation is rationally related to a legitimate governmental purpose that classification is permissible. City of New Orleans v. Duke, 427 U.S. 297, 96 S.Ct. 2513 (1976).

"Under this standard legislative classifications are effectively entitled to a presumption of reasonableness and constitutionality and discriminatory classifications will be sustained if any state of the facts can reasonably be said to justify the classification. Allied Stores of Ohio, Inc. v. Bowers, 358 U.S. 522 (1950).

"The regulation of hearing aids seems an almost paradigmatic example of social and economic legislation and the court shall apply the rational basis standard. Giving plaintiff the benefit of the doubt the classification involved in the instant regulation is the classification between individuals in the hearing aid industry who are regulated by the FDA and those individuals in other industries who might be so regulated but are not so regulated. Such classification under the traditional standard is not irrational so long as the regulation involved aims at the achievement of a permissible governmental purpose because the legislature or, as here, the agency might reasonably believe that a solution to the public health problems of the hearing aid industry is possible now whereas the problems of other industries require more time or money to solve. It might reasonably believe that an attempt to solve all problems would result in the solution of none and the defeat of the government's purpose in the regulation of any industry. It is firmly established that reform may proceed step-by-step. Williamson v. Lee Optical of Oklahoma, 348 U.S. 483 (1955). Accordingly, as the court has already found as a matter of fact that a legitimate governmental purpose is involved in the instant case, the court finds that the classification in the instant case is rationally related to a legitimate governmental purpose and that the defendant has not violated plaintiff's right to equal protection. Accordingly, it is ordered and adjudged that defendant's motion to dismiss is granted and that plaintiff's complaint is dismissed."

(Misc. No. 448; N.J. No. 50)
Some Poisons Come in Pretty Packages

We don't usually think of perfumes, colognes, soaps, detergents, cold medications, vitamins and minerals as poisons. But when these items get into the mouths — and stomachs — of small children they can be poisonous. The children are often attracted by the alluring containers that hold these goods. So seduced, the youngsters are then challenged to open the container. Then it's a short trip to the mouth. These items have to be kept out of the reach of children, just as common poisons and stronger medications have to be stored beyond the grasps of ever-curious toddlers. March 21-27 is National Poison Prevention Week, a good time to remember that a child's world is full of pretty poisons.