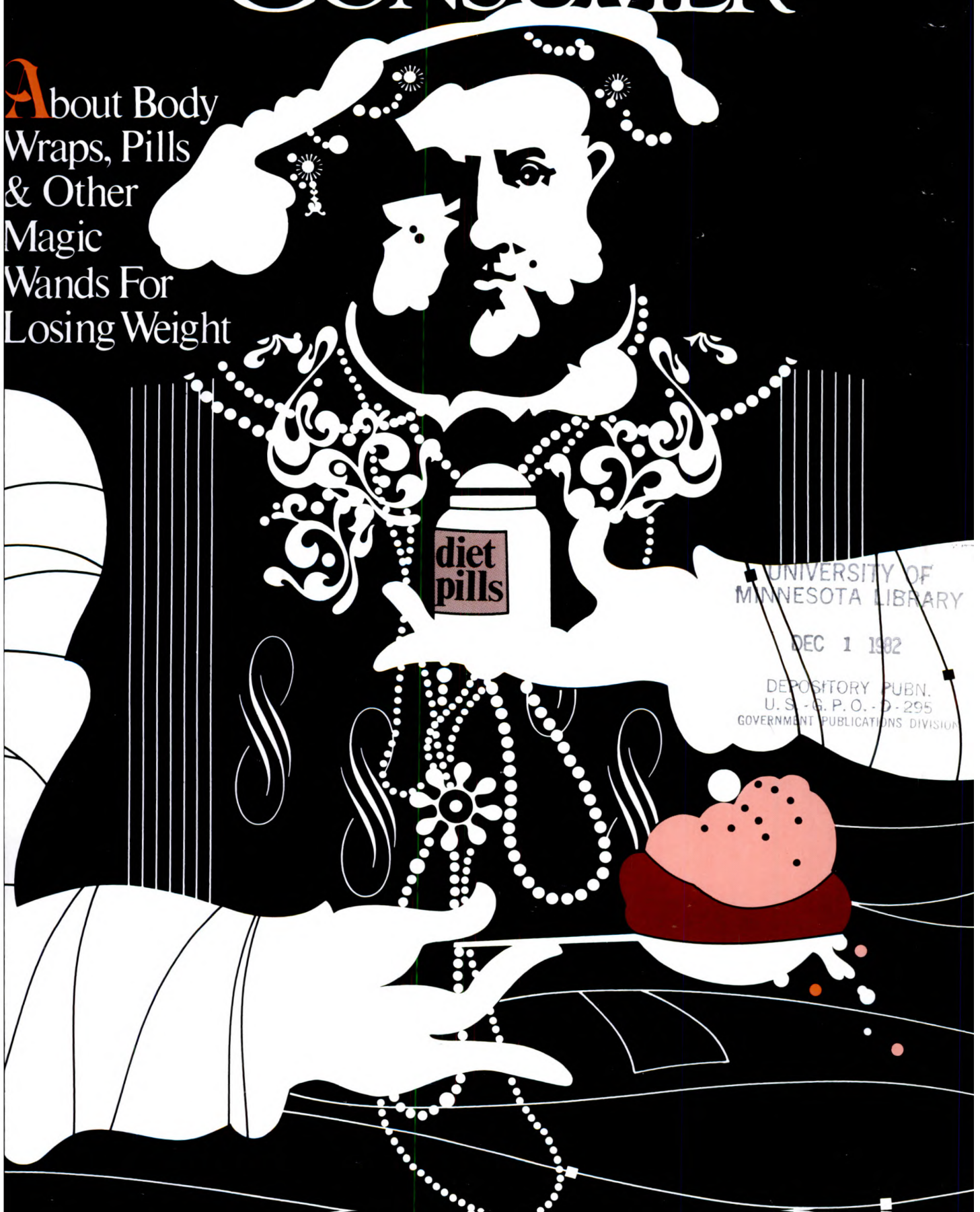


FDA

CONSUMER

November 1982

About Body
Wraps, Pills
& Other
Magic
Wands For
Losing Weight



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Current That Switches Off Pain

Through-the-skin electrical stimulation can relieve some types of chronic or acute pain for some people. For these, personal stimulating devices are available only by prescription.

Recalls, the Media and Motherhood

FDA isn't just crying "wolf" when it sometimes announces to the newspapers and radio-television that a manufacturer is recalling a food or drug product. It means the agency thinks the matter is so urgent that the public ought to know about it immediately. Most of the recalls made each year don't rate this emergency treatment.

Blood: A Fluid You Can Bank On

It's so vital that there never seems to be enough of it to supply our needs. Around these needs has grown a sophisticated industry that uses whole blood and its major components efficiently, and relatively safely, to improve human health.

When a Broken Lamp Burns

Mercury lamps provide light cheaper than ordinary tungsten bulbs for gymnasiums and other uses, but breaks and defects can release harmful ultraviolet radiation unknown to the persons exposed. FDA standards contain built-in safety factors for mercury lamps where risk of exposure is greatest.

About Body Wraps, Pills and Other Magic Wands for Losing Weight

Sleep oneself slim? "Melt" fat under wraps? Eat food that won't stick to the ribs? Take pills that purge pudge? Hear now the siren songs of the latest batch of weight-reducing gimmicks that can make the heart heavier and the wallet lighter.

Diabetes Is a Controllable Disease With a Growth Factor

Although diabetes mellitus can't be cured, most of its victims can lead relatively normal, productive lives, thanks to modern medicines; yet the incidence of the disease is growing at an alarming rate.

RDAs: Key to Nutrition

A respectable share of the processed foods in the market now carry nutrition labels with information useful for maintaining family health and nourishment. For consumers who take the trouble to read, understand and use them, they provide solid nutrition information.

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Shown here at high magnification is one of the body's guardians against invaders, a white blood cell. Billions of them float in the bloodstream along with red cells—which run in the trillions—and platelets. To learn more about what's in blood and what happens to it inside and out of the body, see Blood: A Fluid You Can Bank On, on page 10.

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Richard S. Schweiker
Secretary, U.S. Department of Health and Human Services

Arthur Hull Hayes Jr., M.D.
Commissioner of Food and Drugs

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Roger W. Miller/Editor

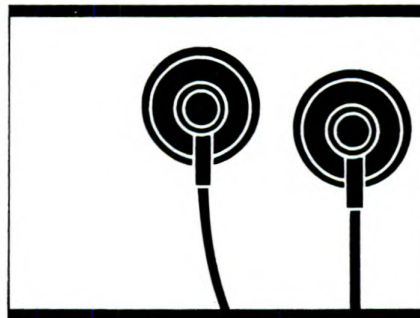
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Jesse R. Nichols/Art Director

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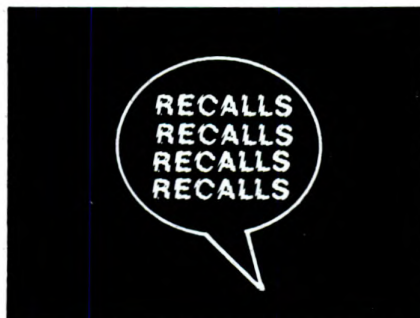
Cover Design: Michael David Brown

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Dangerous Drug Masquerade

Look-alike street drugs have a new look. This time they are masquerading as novelty "cocaine." FDA has warned users of these substitutes that they can be as deadly as the high-priced originals.

The agency has received reports of three deaths associated with injecting or sniffing these substitute white powders, many of which contain local anesthetics such as lidocaine, procaine and tetracaine.

The substitutes are sold openly by mail and in "head shops" as novelty "cocaine" or incense under such names as Toot, Florida Snow, Supercaine, Ultracaine, Base-O-Caine and SuperiorCaine.

Last year's look-alikes were bogus stimulants and sedatives ("uppers" and "downers") containing legal drugs such as phenylpropanolamine, caffeine and ephedrine. (See "On the Trail of Counterfeit Drugs," *FDA Consumer*, December 1981-January 1982.)

The main dangers of the cocaine substitutes are that they can cause blood vessels to collapse, depress heart muscle strength and cause low blood pressure.

Because of cocaine's high abuse and dependency potential, it is regulated under the Controlled Substances Act by the Drug Enforcement Administration. Cocaine substitutes are not controlled under that act and are subject to FDA regulation under the Federal Food, Drug, and Cosmetic Act.

FDA has notified manufacturers of the types of anesthetics used in cocaine substitutes about its concern over this public health problem. The manufacturers are being asked to impose stringent controls over the distribution of the bulk anesthetics to assure that they are offered for sale only to legally authorized firms.

Warning for Pregnant Women

Pregnant and nursing women will be warned to seek professional advice before using most non-prescription drugs, under an FDA proposal. The warning would state: "As with any drug, if you are pregnant or nursing a baby, seek professional advice before using this product."

The warning would be required on over-the-counter (OTC) drugs that are absorbed by the body but would not be required on most externally ap-

plied products such as salves or liniments.

For certain OTC drugs, FDA had previously established specific warnings for use by pregnant or nursing women. These warnings were based on scientific data that suggested a potential hazard to developing or newborn children. For those drugs, the specific warnings would apply, rather than the standard warning proposed.

But even when there are no data to suggest that particular OTC drugs present a potential hazard, there also may be no data demonstrating that such drugs are safe when used by pregnant or nursing women.

The proposal appeared in the Sept. 7 *Federal Register*. FDA accepted public comments on the proposal for 30 days.

The state of California had previously set a similar warning for non-prescription drugs sold in that state.

'Legal Stimulants' Seized

At the request of the Food and Drug Administration and the Department of Justice, U.S. marshals seized thousands of so-called "legal stimulants" containing non-prescription drug ingredients at three manufacturers during the last two weeks of August.

The seizures followed FDA's notification of 16 manufacturers in August that they must discontinue marketing drugs containing the combination of caffeine (a stimulant), phenylpropanolamine (an appetite suppressant) and ephedrine (a decongestant). FDA advised the manufacturers that the triple combination requires approval by FDA before it can be marketed.

The products, advertised as "100 percent legal" pep pills and speed, have been distributed nationwide and promoted through ads in campus newspapers, the mail and handbills at truckstops, schools and rock concerts.

FDA medical experts determined that the combination of the three ingredients is irrational and not generally recognized as safe and effective for use under the conditions suggested in the labeling. In combination, or when taken in excessive doses, these ingredients may cause illness or death. They may, for example, raise blood pressure to the point of causing cerebral hemorrhage.

The seizures were made after FDA investigators found drugs with these three ingredients at the plants. The three firms were: B. T. Products Inc., Tampa, Fla.; Pharmafair Inc., Hauppauge, N.Y.; and Pharmaceutical Dynamics Inc., Hauppauge, N.Y.

The seizures netted over one million finished capsules and tablets and more than \$100,000 worth of machinery used in their manufacture.

Nearly a year earlier, U.S. marshals and FDA agents had seized large quantities of "look-alike" pep pills containing various combinations of these ingredients at nine factories in five states. The seizures were requested by FDA because the drugs were counterfeits of various abused prescription-controlled substances commonly sold on the street. Currently, at least 35 states have passed legislation concerning the distribution of the "look-alike" pills. (See "On the Trail of Counterfeit Drugs" in the December 1981/January 1982 *FDA Consumer*.)

Since then, the non-look-alike drug products containing the same ingredients had become increasingly popular. These products no longer look like amphetamines or other controlled substances but are being sold on an illicit market of their own.

FDA has worked closely with the Drug Enforcement Administration, U.S. Postal Service and other federal agencies, and has encouraged and supported state attempts to deal with this drug abuse problem.

Underarm Safety

Aluminum chlorohydrate in aerosol form is safe as an antiperspirant, FDA has decided. This means that this ingredient won't have to undergo further testing to assure its safety, as an advisory panel of experts recommended back in 1978. Because of concern that continued use of aerosol sprays may present a potential health hazard, the panel had called for long-term inhalation studies with animals. The panel's recommendations were discussed in "Aerosol Antiperspirants: Under a Cloud" in the November 1978 *FDA Consumer*.

FDA's decision regarding aerosol antiperspirants was made public by the Aug. 20 *Federal Register* publication of a proposed monograph, or standard, for this class of over-the-counter (OTC) drugs. The

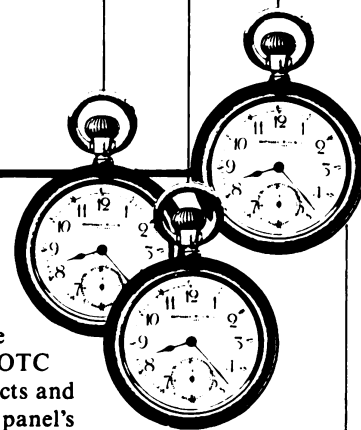
agency's conclusions were based on an evaluation of the recommendations of the Advisory Review Panel on OTC Antiperspirant Drug Products and on public comments on the panel's report. The antiperspirant monograph was one of three proposed during August. Monographs for anthelmintic and cholecystokinetic drug products were published Aug. 24.

FDA agreed with the antiperspirant panel's recommendations that non-aerosol forms of aluminum chlorohydrates, aluminum chloride, aluminum zirconium chlorohydrates and buffered aluminum sulfate also should be considered safe and effective antiperspirant ingredients. However, the agency did not accept a panel recommendation that a minimum effectiveness statement must appear on the label of these products. Such a statement would not serve its intended purpose, said FDA. The agency also expanded the labeling to provide for a wider variety of allowable statements in addition to the panel's lone choice of "reduces underarm perspiration."

The statement "apply to underarms only" replaces the phrase "not to be used generally over the body" in FDA's proposed labeling for antiperspirants. Aerosol products should be labeled with the warning "avoid excessive inhalation," the agency proposed.

In the matter of anthelmintic drug products, FDA disagreed with the view of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products that gentian violet is safe and effective for treating pinworms. This ingredient is a potential carcinogen, the agency said in its monograph. The agency did agree, however, that pyrantel pamoate should be moved from prescription to non-prescription status and that piperazine citrate should not be allowed in pinworm drugs.

Labeling for anthelmintic drugs should clearly state that the product is for the treatment of pinworms and should warn against use by those who have liver disease. Although the directions for use indicate that the entire household should be treated when one person in a family has pinworms, FDA included in its proposed monograph a warning that pregnant women should take the medicine only if they have pinworms themselves or are directed to



take it by a doctor.

Cholecystokinetic drugs are used to contract the gallbladder during diagnostic gallbladder studies. FDA and the Miscellaneous Internal Drug Panel agree that the only ingredient for this use is a 50 percent aqueous emulsion of corn oil. The agency also agrees with the panel that this product should be available as a non-prescription drug even though it is to be used under the direction of a doctor.

Publication of a proposed monograph is the next to last stage in FDA's massive review of ingredients in all non-prescription drugs. Final standards will be published after public comments on the proposed monographs have been evaluated. Final standards for antiperspirants and cholecystokinetic drugs will become effective 12 months after publication, while standards for anthelmintics will become effective six months after publication.

Whooping Cough Epidemic

Last September the British health department launched a publicity campaign to persuade parents to have children vaccinated for whooping cough. The move was in response to the worst epidemic of whooping cough to strike Britain in 25 years.

Government figures for the week ending Sept. 4, 1982, showed 2,267 new cases of whooping cough and reported the total for the year at 35,497. Four babies were reported to have died as a result of the highly contagious disease in the first seven months of the year.

In comparison, 58 cases of whooping cough (pertussis) were reported in the United States to the national Centers for Disease Control during the week ending Sept. 4, with 938 cases for the year.

The British health department attributed the epidemic to low vaccination levels that resulted from public fear about the safety of the pertussis vaccine in the mid-1970s. As a result of publicity about brain damage detected in a small number of vaccinated babies, vaccination levels in Britain plummeted from 80 percent of all babies to 31 percent in 1978. Levels gradually climbed to 45 percent in 1981.

In the United States, public concern over the risk of side effects from pertussis vaccine surfaced in April 1982, following a television documentary by the National Broadcasting Co.'s Washington, D.C., outlet and publicity on NBC's "Today Show." FDA Commissioner Arthur Hull Hayes Jr. was inter-

viewed in a follow-up news segment by the NBC Washington station. A transcript of that interview was published in the July-August 1982 *FDA Consumer*.

Arthritis Drug Withdrawn

Lilly Industries Ltd. surrendered its licenses to market the arthritis drug Opren (benoxaprofen) in the United Kingdom early in September. The drug, marketed as Oraflex in the United States, was suspended worldwide by Lilly on Aug. 4 after the United Kingdom halted its sale with a 90-day license suspension as a result of 61 deaths possibly associated with the product there.

Lilly was making arrangements to recall all existing supplies of the product and has advised pharmacists and doctors by letter to halt the drug's use. FDA announced Lilly's actions on Aug. 5. Earlier, Denmark's drug regulatory board had restricted use of the drug, primarily to hospitals.

Following U.S. approval of the drug in April, a number of deaths from liver and kidney failure were reported in the United Kingdom. All were among elderly persons who had received the highest dosage (600 milligrams). The British registry of adverse effects subsequently reported many more deaths of persons who had taken benoxaprofen, of which a substantial number were due to gastrointestinal hemorrhage or perforated ulcers. In the United States, 11 deaths associated with the drug were being investigated by the Food and Drug Administration.

In response to reports that mistakenly linked the controversy surrounding Oraflex with FDA's current efforts to improve the drug approval process, FDA noted that the approval time for this drug (28 months) was actually longer than the average approval time for most drugs (24 months). In addition, the agency classified Oraflex as a "C" type drug (having little or no therapeutic value over existing arthritis drugs) and did not target the chemical for priority review.

Under FDA's drug classification system, drugs designated "A" (offering important therapeutic gain) or "B" (offering modest therapeutic gain) take precedence over other drug applications not offering a therapeutic advance. In 1981 the average time for approval of "A" or "B" drugs was 10 months (see "Providing a Breakthrough for Drugs With Promise" in the July-August 1979 *FDA Consumer*).

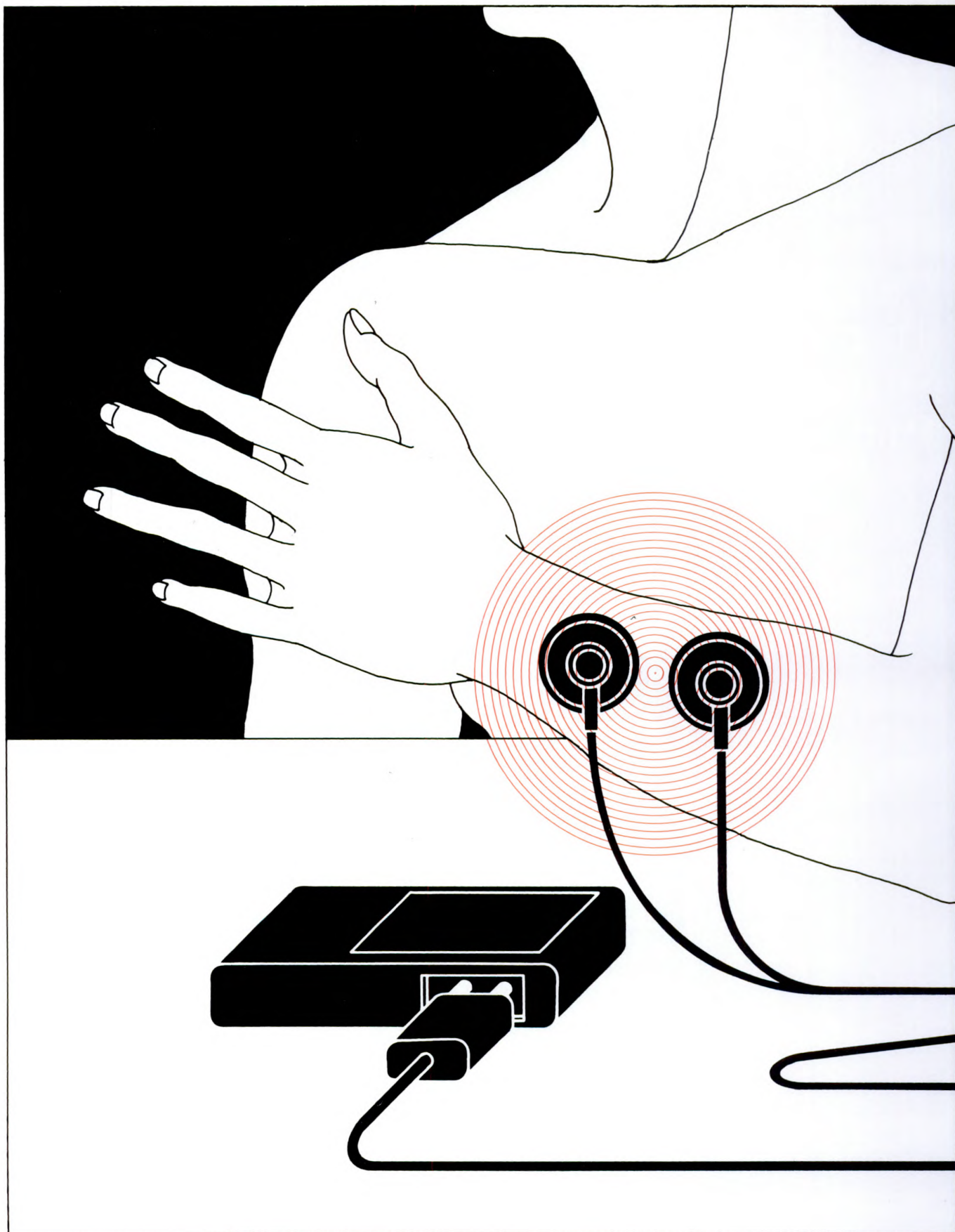
Current That Switches Off Pain

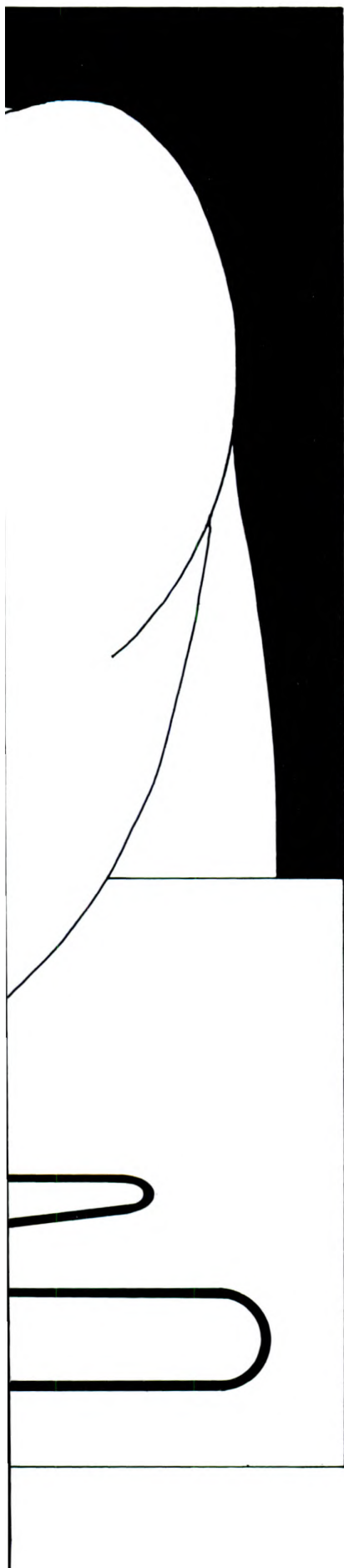
Thoreau's line about the mass of people leading "lives of quiet desperation" might best describe how it feels to live with chronic pain. Whether sharp, dull, aching or throbbing, chronic pain is still there.

This type of treatment is called transcutaneous electrical nerve stimulation or TENS. The nerve is stimulated transcutaneously (through the skin)—thus, the name.

The knowledge that an electrical charge can dull a nerve is not new. Aristotle noted the ray fish narcotizes its victims by overpowering them with shock. In the time of the Roman Empire, Scribonius Largus, court physician to the Emperor Claudius, experimented with the same fish to relieve headaches.

TENS works in some individuals and not others and why this is so is a mystery. Dr. Donlin Long, professor and chairman of the Department of Neurosurgery at Johns Hopkins University School of Medicine, studied 200 chronic pain patients who tried TENS. He reported that 78 of the patients said they experienced excellent relief three to six days after treatment, 54 said they had good relief, and 65 had little or no relief. Six months later, Long did follow-up interviews with the 78 people who had reported excellent relief, all of whom used TENS at home. Ten said they still had excellent relief from pain, 33 termed their





Long said that patients with chronic low back pain, phantom limb pain (an imagined sensation that an amputated limb is still there and hurts) and osteoarthritis (the "wear and tear" form of arthritis) experienced the best relief. TENS was adjudged less successful in treating cancer pain or pain caused by abnormalities of the nervous system.

In a 1981 survey done for FDA by physical therapists, 82.8 percent of the therapists said TENS was satisfactory in giving their patients relief from chronic pain, while 8.2 percent termed results partially satisfactory. Nine percent said the treatment was unsatisfactory.

Judging by these studies, measuring the effectiveness of TENS devices is not an easy task. One reason is that it is difficult to measure the intensity of pain. Pain is a subjective experience influenced by the psychological state of the patient. Environment also can influence a patient's perception of pain, including domestic and work pressures, cultural customs and economic values.

Also, the TENS effectiveness depends on such factors as the proximity of the pain site to the electrode, wave form, wave duration and current intensity, and therapy time. Often a physician or physical therapist tries a number of body locations and electric current settings before finding the best combination.

Although patient responses may vary, FDA's Advisory Panel on Review of Neurological Devices believes that TENS is "an effective method for the treatment of certain types of pain disorders." Said the panel: "Long-term trials in this coun-

try have documented a degree of efficacy which is reasonable and acceptable, particularly in view of the very low potential risk to the patient and the absence of alternate low-risk therapy." Low-risk uses for TENS include alleviating acute postoperative pain and often eliminating or reducing the need for narcotics.

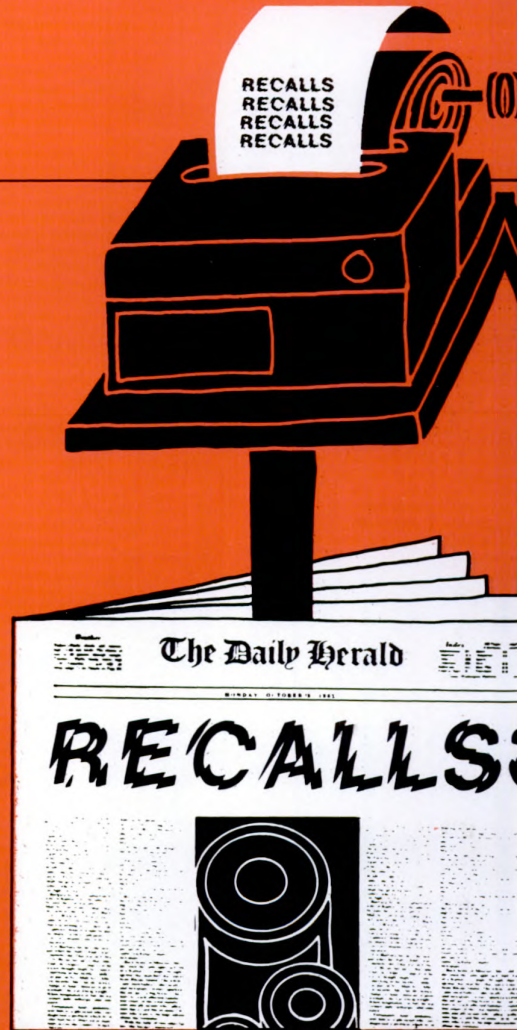
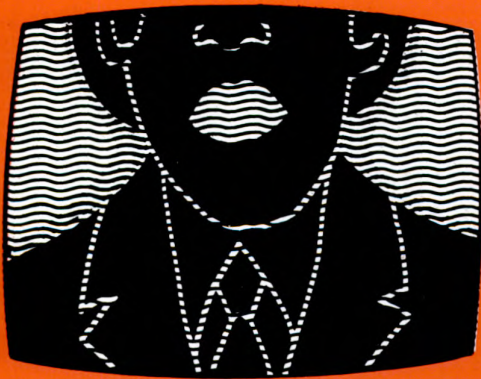
The most common risk to health in the use of TENS devices is the possibility of skin burns if the current is too high or the electrodes are too small. Some people may also experience skin reactions to the electrodes or the electrode gel.

FDA's Bureau of Medical Devices says that TENS devices should not be used by a patient wearing a demand-type cardiac pacemaker and should not be placed on the neck over the carotid sinuses, found on both sides of the neck near the collar bone. The flow of electrical current could interfere with the heart's natural rhythm and cause cardiac arrest. Likewise, pregnant women should shun the devices because safety during pregnancy or delivery has not been established. TENS devices should also be kept away from curious children.

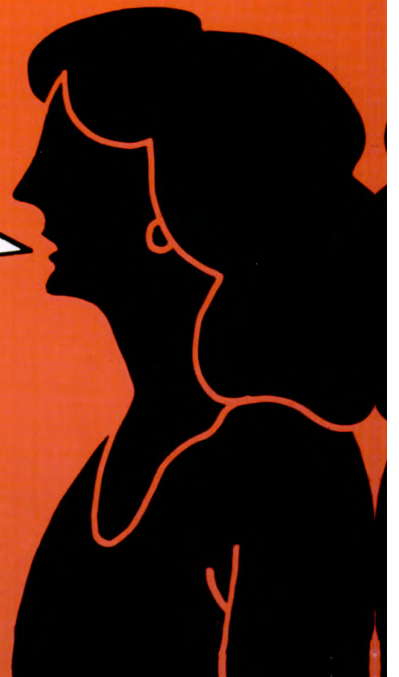
TENS products are Class II medical devices. This means that FDA believes that TENS devices' safety and effectiveness can be assured by a combination of general controls and, if necessary, a mandatory performance standard. A voluntary standard for TENS devices is presently being developed by the American Association for Medical Instrumentation.

Marti Asner is a member of FDA's public affairs staff.

RECALLS
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RECALLS



??? RECALLS!



Recalls, The Media And Motherhood

by William Grigg

Catching a moment's leisure over a cup of coffee, Mrs. Loving Motherwell glances over her newspaper. War . . . politics . . . taxes and. . .

What? Little Phil's fruit juice—the one she bought not more than an hour ago—is being recalled by the manufacturer?

Waving the newspaper, Mrs. Motherwell storms back to the grocery. She pokes the paper and the fruit juice in front of the grocer. "What are you trying to do?" she cries. "Kill my Phil?" The grocer bites his tongue. "Of course not," he says, "but I haven't had a recall notice for that product."

"Notice? Shnotice! Can't you read a newspaper?" Mrs. Motherwell snorts. "Idiot!"

Needless to say, neither she nor the grocer is pleased. The mother has been frightened and the grocer has been shouted at, and it wouldn't be human nature for either to think all is well.

Yet, this is the way the system is supposed to work. Indeed, if it's one of the three or four times a year when the Food and Drug Administration issues a press release announcing a food recall, FDA officials have already decided the urgency of the situation justifies scaring Mrs. Motherwell, and others.

There is no faster way to get notice of a recall to the public—and to food markets—than to distribute it to the nation's wire service and have it announced on the 6 p.m. TV news.

Although there are hundreds of recalls each year by drug manufacturers, food distributors and other firms regulated by FDA, there are only a few in which the agency actively seeks newspaper and radio and TV publicity.

FDA classifies these recalls as Class I because they involve a serious threat to life or health, such as a mix-up in a life-saving drug, a dangerous lack of an important nutrient in infant formula, or cans of mushrooms that contain deadly botulinum toxin.

For less serious situations there are

Class II and Class III recalls. Class II recalls involve products that may cause temporary or medically reversible adverse health consequences or involve situations where the probability of serious adverse health consequences are remote. In a Class III recall, the use of or exposure to the violative product is not likely to cause adverse health consequences.

By seeking publicity in a Class I recall, FDA not only can spread the word fast but can reach into homes and get consumers to avoid or return already purchased products. This may be inconvenient and even costly to the government and to manufacturers and distributors involved, but in the few cases such an announcement is used, FDA has judged the possible danger to life and health to be worth all the trouble.

Recalls are of two types: those begun by the company on its own and those requested by FDA. When a firm discovers that one of its products is in violation of FDA regulations, that firm may choose to recall the product. Most recalls are this type.

But when a firm fails to recall a defective product on its own, FDA may request it. Such requests are ordinarily made in urgent situations and, generally, FDA will have in hand enough evidence to back up its request with a threat of legal action, such as a seizure of products. This gives the agency's request some muscle, even though FDA has no specific legal authority to *require* a recall.

FDA may portray the alternatives via telephone calls or a visit by a representative from the nearest FDA district office, followed by an electronically delivered letter or telegram.

It remains the firm's responsibility to conduct the recall and to be financially and organizationally prepared to conduct one whenever necessary.

The firm is required to notify each of its affected direct national and foreign accounts promptly about the recall.

The firm should appoint a responsible individual as its recall monitor or

coordinator. It is this person's task to coordinate and direct the recall and to establish contact and keep in touch with FDA. The recall coordinator should have company authority to carry the recall to its conclusion.

The company should include in its recall plan a way to check the effectiveness or completeness of the recall, asking consignees if they have complied with the recall instructions. In recalls, it's important to quickly relay the recall message and then monitor it to completion. When there is a health hazard, FDA field offices audit the recalls by checking with a fair percentage of the consignees to be sure the product has been removed from the market. The consignees may include the nation's 52,000 drugstores or its 165,000 food retailers—or both.

In a recent infant formula recall, FDA decided to check every one of the consignees. Audit checks sometimes can be done by calling a retailer or wholesaler to be sure he received and acted on the recall notice. The infant formula recall check was so urgent that FDA employees were required to dogsled into remote Alaskan stores where there were no telephones.

When the audits show a product has been completely removed from the market, the recall is terminated.

Attention then can be given to any salvaging and reconditioning operations involving the violative product. A drug that has been improperly labeled can be dangerous but often it can be easily and safely reconditioned just by replacing the label. If a recall was made because a certain number of cans were malformed by a machine that started to function improperly, sometimes the faulty containers can be discovered by inspection and isolated. The others can then be returned to the market.

William Grigg is director of FDA's press relations staff.

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Blood: A Fluid You Can Bank On

by Louise Fenner

Blood. A powerful word. You can't say it without seeing the color. Blood is life itself and, despite experiments with liquids that perform some of blood's functions, there is still no substitute for the genuine article. The only source is the human body.

Blood performs a multitude of functions as it travels between the heart and the far-flung outposts of the body. It carries oxygen to the cells and removes carbon dioxide and other waste products. It transports food and water as well as hormones and other substances vital to maintaining health. It carries the cells and proteins that fight infections and protect the body from invaders. And the list could go on.

The fluid part of blood, which transports everything else, is called plasma. It is a solution of proteins and other substances in water and comprises about 55 percent of blood's volume. The other 45 percent consists of red cells, white cells and platelets. The red-colored hemoglobin in red cells enables them to carry oxygen and carbon dioxide. White cells are the body's guardians against invaders, and platelets are essential to clotting and to the repair of injured blood vessels.

The average man has 10 to 12 pints of blood and the average woman eight or nine pints. A healthy adult can easily spare a pint, the approximate amount of a blood donation. The body replaces the lost fluid within a few hours. Red cells are replaced more slowly, but well before a person is eligible to donate again, after a required eight-week wait.

A person may donate plasma much more frequently than whole blood, as often as twice a week. In a process called plasmapheresis, a pint of the donor's blood is removed, the red cells are separated from the plasma, and the cells are then returned to the donor along with enough added saline solution to make up for the lost fluid. The process is repeated to obtain the plasma from two pints of blood.

Since plasmapheresis takes about two hours, plasma centers usually pay their donors to compensate for the time

involved. In contrast, over 95 percent of whole blood is given voluntarily. Blood donation takes only about 30 to 40 minutes, including a brief medical examination, with less than 10 minutes spent actually drawing the blood.

The American Blood Commission estimates that approximately 40 percent of the American population is medically eligible to give blood. However, less than 10 percent of these people, or about 4 percent of the total population, actually donate. In 1980, the most recent year for which figures are available, nearly 11 million units (pints) of whole blood were donated.

Most blood is not transfused as whole blood but is divided into its components so that a single unit can benefit several patients. For example, one unit of whole blood might be divided into red cells for use in a patient with anemia, platelets for a leukemia victim undergoing chemotherapy, and plasma for a trauma patient who needs plasma volume restored. In this way, the nearly 11 million donated units of whole blood in 1980 were converted into more than 14.8 million transfused units. Nowadays, whole blood is used in less than one-sixth of all transfusions.

In addition to blood, Americans donate 10 to 11 million units of plasma each year at plasmapheresis centers. This plasma is not directly transfused; instead, it is sold to pharmaceutical manufacturers for processing into essential medical products. Because it is the source of many manufactured products, it is called "source" plasma to differentiate it from plasma that is transfused ("single donor" plasma). Source plasma is broken down by the manufacturers into various proteins, which are then concentrated into appropriate strengths for different uses. Some of the many products that result are serum albumin (used to treat shock and burns), immune globulins (which are rich in antibodies and can provide temporary immunity to various diseases), and protein clotting factors (used to treat hemophilia).

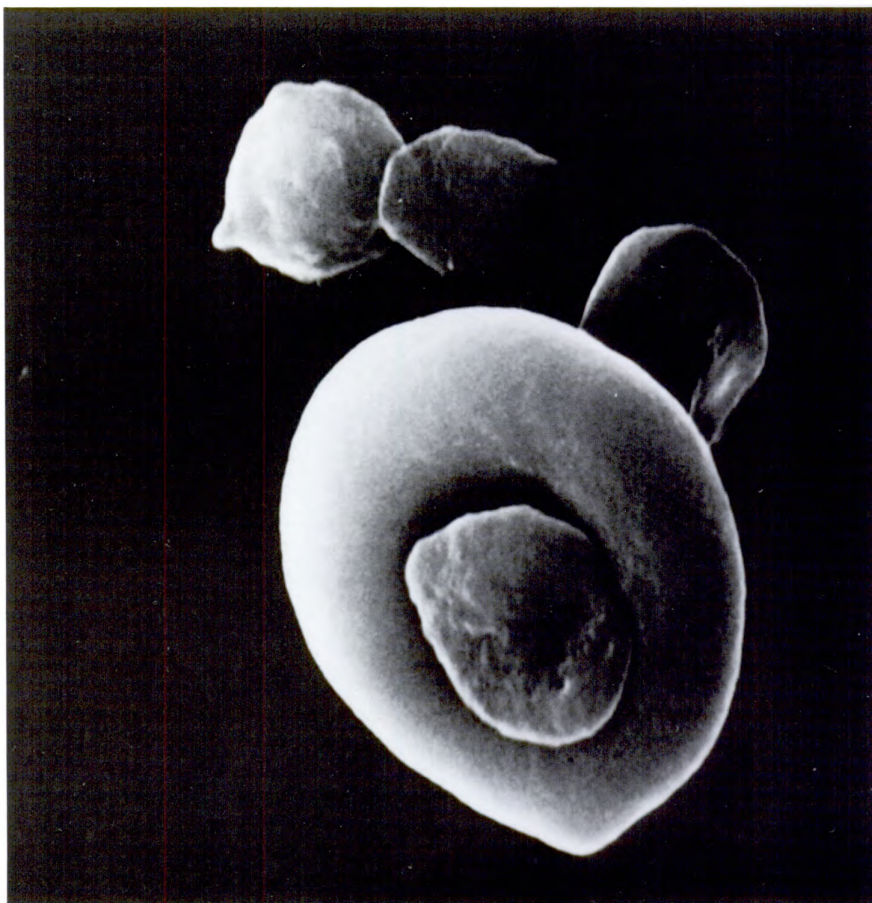
The transfusion of blood and its components now

The large doughnut-shaped structure in this scanning electron micrograph (right) is a normal red blood cell, highly magnified. In front of it is a platelet, and three platelets are seen above.

Less than 10 minutes is spent drawing approximately a pint of blood from Jean Fair, a regular donor at a suburban Washington, D.C., Blood Bank (page 13, top left).

The finger prick has been updated: now one quick punch and it's all over, and painless. A few drops of blood must be tested for red cell content and hemoglobin level before the donor can be accepted (page 13, top right).

This full blood collection bag contains anticoagulant solution and 475 grams of the donor's blood. The next step is determination of the blood group and type, which is done as soon as possible and the bag so marked (page 13, bottom).



happens some 37,000 times a day in the United States. However, until the beginning of this century transfusions were seldom performed because of the risk of unpredictable and often fatal reactions. In 1900, scientists discovered the existence of three blood groups among the population and learned that severe transfusion reactions could occur when patients received blood from groups other than their own. A fourth blood group was discovered two years later. Now all blood is classified into four major groups: A, B, O and AB.

When a person receives blood from the wrong group, naturally occurring antibodies in his or her plasma may attack the transfused blood. This can cause the transfused red cells to rupture and release their hemoglobin, with resulting shock, kidney failure and even death (although prompt treatment rescues most victims). While incompatibility between red cells causes some problems in about 1 in 6,000 transfusions of whole blood or red cells, life-threatening reactions are much less common. Every unit of donated blood is tested twice to determine its group, and the blood is again tested to assure that it is compatible with the recipient's before transfusion.

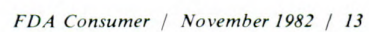
Two more major discoveries occurred before blood transfusions became safe and commonly accepted. In 1914, just in time for World War I, a non-toxic anticoagulant called sodium citrate came into use which prevented blood from clotting when removed from the body. Blood could be kept under refrigeration for three or four days before deteriorating. Storage time for whole blood and red cells is now

up to 35 days because of better anticoagulant-preservatives and plastic equipment that permits sterile preparation of individual blood components. Different storage techniques make the most of the various components. For instance, plasma and certain protein-clotting factors can be kept for years if frozen. Until recently, fragile platelets could be stored only three days; however, new plastic storage bags approved by the Food and Drug Administration in 1982 extended this time to five days.

In 1940 scientists discovered the Rh factor, named after the Rhesus monkeys that were used in experiments leading to its disclosure. In America, 85 percent of the population has blood that contains the Rh factor. Their blood type is Rh positive. Blood without the factor is called Rh negative.

The Rh factor is significant because the Rh types are not always compatible. People with Rh-negative blood can develop antibodies to the Rh factor if they receive a transfusion of Rh-positive blood. Once the antibodies develop, the Rh-negative individual can never again receive Rh-positive blood because the antibodies will destroy it.

This fact is especially important to a woman with Rh-negative blood who has an Rh-positive baby (which can happen if the father has Rh-positive blood). Since some of the baby's blood mixes with hers during pregnancy or delivery, she may develop anti-Rh antibodies. Then, if she has a second baby with Rh-positive blood, her antibodies could cross the placenta and attack the red cells of the child. The baby may be severely affected and may even die before birth. An affected newborn may require an



Blood Component Therapy

CELLULAR ELEMENTS		PLASMA	
Red Cells	Used for treatment of anemia. Also can serve for majority of blood transfusions.	Plasma	Historically, fresh frozen and single donor plasma have been used to restore plasma volume and to control bleeding.
White Cells	Used for combating infections. Clinical use experimental at present.	Cryoprecipitated Antihemophilic Factor	Prepared from fresh frozen plasma. Contains clotting factor (factor VIII) therapeutic for hemophilia A.
Platelets	Used in cancer patients, especially those with leukemia, to reverse low platelet count due to chemotherapy.	Plasma Proteins	
		Serum Albumin	Used to restore blood volume in case of trauma.
		Immune Globulins	Contain antibodies against diseases. Immune serum globulin is used for prevention of hepatitis A and measles and also for treatment of immunoglobulin deficiencies. Specific immune globulins are used for prevention of hepatitis B, rabies, tetanus and chicken pox in immunosuppressed patients. Also includes Rh immune globulin.
		Clotting Factor Concentrates	Used to control bleeding due to deficiencies of specific coagulation factors: antihemophilic factor (factor VIII) for hemophilia A; factor IX complex for hemophilia B; and anti-inhibitor coagulant complex (AICC) for hemophilia A patients with antibodies to factor VIII.

“exchange” transfusion shortly after birth to remove the Rh-positive blood which is being destroyed and replace it with fresh Rh-negative blood. Fortunately, it is possible to prevent a woman with Rh-negative blood from developing anti-Rh antibodies by giving her an injection of a substance called Rh immune globulin after the birth of each Rh-positive child.

One problem involving blood transfusion is not yet completely solved. A viral infection of the liver called hepatitis can be transmitted in whole blood, plasma and some plasma products. The infection can be mild and virtually without symptoms, but more serious infections can lead to chronic liver disease, including cirrhosis. There also has been evidence linking at least one type of the disease, hepa-

titis B, with an increased risk of liver cancer. Hepatitis B strikes an estimated 200,000 Americans, primarily young adults, each year—with about a tenth of the cases linked to transfusions. Of the unfortunate 1 percent of hepatitis B victims whose disease is extremely severe, about half die.

Since 1972 FDA has required all blood and blood products to be tested for hepatitis B. Labels of products for transfusion must indicate whether they come from paid or volunteer donors, since blood from paid donors carries a significantly higher risk of post-transfusion hepatitis.

On the average, about 10 percent of persons who receive transfusions will develop hepatitis. However, only 1 in 10 cases is hepatitis B. The other 90 percent are non-A, non-B hepatitis, so-called because symptoms exist that are not

Percentage of People in the United States With Different Blood Groups and Rh Types

ABO Group and Rh Type	How Many Have It	Frequency
O Positive	1 person in 3	37.4%
O Negative	1 person in 15	6.6%
A Positive	1 person in 3	35.7%
A Negative	1 person in 16	6.3%
B Positive	1 person in 12	8.5%
B Negative	1 person in 67	1.5%
AB Positive	1 person in 29	3.4%
AB Negative	1 person in 167	0.6%

caused by the hepatitis A or B viruses. (Hepatitis A is not carried by blood.) There is no specific test to detect whether blood is carrying non-A, non-B hepatitis. About 200,000 cases of post-transfusion hepatitis occur annually in the United States.

A vaccine to prevent hepatitis B was approved by FDA in 1981 and recommended for use in high-risk groups, but no such preventive exists for non-A, non-B hepatitis. Among the people at highest risk for hepatitis B are health-care workers, patients and staff at institutions for the mentally retarded, hemodialysis patients, homosexually active males, illicit injectable drug users, recipients of certain blood products (e.g., hemophiliacs), household and sexual contacts of hepatitis B carriers, immigrants from high-risk areas, and prison inmates.

In addition to hepatitis B testing, FDA has other requirements aimed at assuring the safety of blood and blood products and protecting consumers. Blood establishments are required to register with FDA, and those that ship products in interstate commerce must also be licensed. In 1975 FDA established Good Manufacturing Practice regulations for blood establishments. These regulations cover personnel, facilities and equipment, quality control, recordkeeping, and reporting of adverse reactions to FDA. Specific standards also exist for individual blood products.

A little over 2,000 blood establishments are registered with FDA. Licensed hospital and community blood banks, donor and distribution centers account for about 650 of this total. Approximately another 1,000 such firms operate only within their state borders. Also among the registered firms are some 350 licensed plasmapheresis centers, as well as about 50 diagnostic product manufacturers, laboratories, producers of plasma derivatives and other firms.

Each registered blood firm is inspected at least once every two years by FDA field investigators. The agency can suspend or revoke the license of a firm that does not fulfill its responsibility to protect donors and the blood supply. Other legal action, including prosecution, is also an option. However, such measures are seldom required.

One fairly recent medical innovation concerning blood has been the increasing focus on a blood treatment method called apheresis. It has been used experimentally to treat myasthenia gravis, systemic lupus erythematosus and other disorders that are linked to abnormalities in the immune system. During apheresis, blood flows from the patient to a machine where certain components thought to be connected with the disease are separated off. The remaining components are then returned to the patient.

An example is plasmapheresis for patients with myasthenia gravis. Since some of the patient's symptoms are related to antibodies in the plasma that attack the patient's own body, extracting the plasma and replacing it with plasma substitutes, such as serum albumin, may relieve symptoms until the antibody builds up again.

One type of apheresis device uses a centrifuge to separate the heavier parts of the blood from the lighter ones. In 1981 FDA approved a plasmapheresis device that employs a membrane filter to extract the plasma from the cellular elements of the blood. However, much research is still needed on the effectiveness of apheresis—sometimes called a modern version of bloodletting—in the treatment of various diseases.

Studies are also under way for testing a synthetic blood supplement made from oxygen-carrying compounds called perfluorocarbons. First suggested by American scientists in the mid-1960s, perfluorocarbons were produced in Japan in 1979. There they have been transfused into numerous patients at times when matching blood was not immediately available. In the United States the perfluorocarbon substance is an investigational drug being used by selected investigators under very carefully controlled conditions. Patients treated include those with severe anemia whose religion may forbid blood transfusions.

In cases of severe blood loss, perfluorocarbons can be temporarily used to transport oxygen through the body. They do not have to be matched with a patient's blood group or Rh type. However, perfluorocarbons cannot perform blood's other important functions, such as clotting, carrying nutrients and other substances, and fighting infection. Therefore, they should not be thought of as a blood substitute but rather as an alternate method of delivering oxygen to the body.

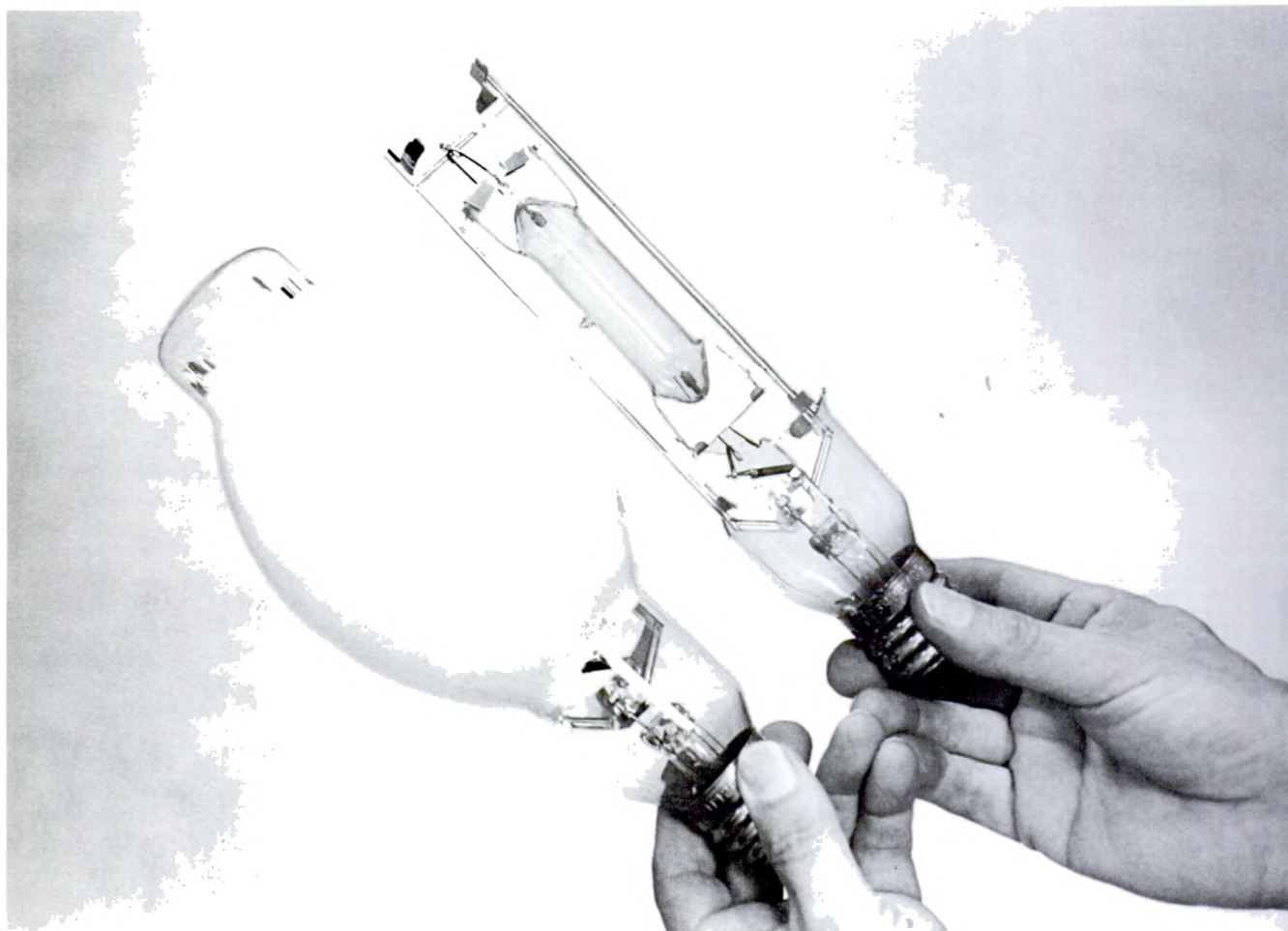
There is also intensive research on a chemically modified hemoglobin prepared from blood. It can be stored in freeze-dried form at room temperature, reconstituted and administered without concern for blood group and type. Someday such a product might be used when red cells are available, as during wartime combat or a mass emergency. Studies on humans are yet to be done with the substance.

As it stands, people who need blood still have to count on their friendly neighborhood blood bank.

Louise Fenner is a member of FDA's public affairs staff.

When A Broken Lamp Burns

by William B. Knight



A rough game of basketball is usually associated with a few bruises and some general aches and pains, but not with red eyes, swollen eyelids or sunburn-like symptoms. Yet those latter symptoms were suffered by 26 persons when the cover of a mercury vapor lamp broke but the lamp kept burning in a New Jersey community center gymnasium. When FDA scientists made measurements on a broken lamp identical to the one in New Jersey, they found ultraviolet radiation emissions over a hundred times in excess of recommended safe levels.

For reasons of economy, those bright bluish-white mercury vapor lights are being used more and more to

light large areas such as gyms, shopping centers, parking lots and streets. The lifetime of a mercury vapor lamp is many times longer than that of a conventional tungsten lamp and, for a given amount of electrical power, the mercury vapor lamp provides much more light than a tungsten lamp.

Mercury vapor lamps differ from tungsten filament lamps in that the mercury vapor lamp uses an electric arc produced within a quartz tube in the middle of the lamp instead of the heated metal filament of a tungsten lamp. High-intensity ultraviolet radiation, as well as visible light, is emitted by the mercury vapor in this tube. A borosilicate glass envelope surrounds

The mercury vapor lamp at top is the same kind as the one at bottom, but the coated glass envelope has been broken off. Even though the envelope is broken, the bulb can continue to operate, giving off harmful ultraviolet radiation.

the quartz tube. When intact, this envelope prevents the shortwave component of the ultraviolet radiation from leaving the lamp.

But if any or all of the envelope is broken off and the lamp continues to operate, the problems with ultraviolet radiation begin. Naturally occurring ultraviolet radiation produced by the

sun causes skin tanning and, if overexposure occurs, burning. The shortwave ultraviolet radiation that escapes from the broken lamps can cause sunburn and photokeratitis (an inflammation of part of the eye that causes a painful, gritty sensation). The severity of the effects depends on the distance from the lamp and on the length of exposure, as well as the individual's sensitivity to ultraviolet radiation. Very long exposures may result in permanent damage to the skin or eyes.

Broken mercury vapor lamps represent an insidious hazard for two reasons. First, a person may not be aware that he or she is being exposed to the invisible ultraviolet radiation, or know of the possible results of such exposure. And, to make matters worse, the symptoms in most cases will not appear until several hours after the exposure.

The New Jersey case described above was not an isolated one. Since 1969, 42 incidents of ultraviolet radiation injury involving about 700 persons have been reported to the Food and Drug Administration. Other incidents may have occurred that were either not reported or not diagnosed as related to ultraviolet radiation.

In an attempt to prevent future injuries, FDA's Bureau of Radiological Health has taken steps to make mercury vapor lamps safer for the consumer. With responsibility for the safety of light products, the bureau evaluates optical emissions and develops and enforces standards.

Standards for mercury vapor lamps went into effect in March 1980. Lamps designated as "self-extinguishing" (those that automatically go out when the glass envelope is broken) must be clearly marked with the letter "T," and the electric arc must extinguish within 15 minutes of breakage of the protective glass envelope. In addition, the standard specifies that those lamps that do not have the self-extinguishing feature must be clearly marked with the letter "R," and that packaging and advertisements for these lamps must display appropriate warnings relating to potential ultraviolet radiation hazards. For both lamp types, instructions for safe use must accompany each lamp.

The more expensive, self-extinguishing lamps were not made mandatory because in some situations the cheaper models do not pose a danger. In some parking lots, on roadways and in

remote locations such as ski slopes a person would be unlikely to remain exposed to a lamp long enough for it to constitute a hazard. Also, in many such instances the lamps are placed considerably farther from people than lamps used indoors.

Still another protective method is a protective shield made of a special glass or hard plastic and designed to fit over the lamp reflector. Such shields absorb ultraviolet radiation and help protect the lamp from flying objects.

Consumers can take some steps to reduce the possibility of ultraviolet exposure from a broken mercury

guidelines for use, check the lamp regularly for breakage when it is turned off, and replace broken lamps only when the current is turned off.

In recent years, orange-glowing sodium vapor lamps have appeared on roadways and in large buildings. These are another member of the family of high-intensity discharge lamps. However, sodium vapor lamps produce much less ultraviolet radiation, and the risk of acute eye or skin injury from intact or broken lamps is not significant.

Other high-intensity lamps include metal halide lamps (sometimes substituted for mercury vapor lamps) and



Some uses of mercury vapor lamps carry more potential risk to more people than the ordinary if a bulb should become defective and begin emitting harmful amounts of ultraviolet radiation. One such use is in gymnasiums, where both players and fans may receive harmful doses should the bulb defect go unnoticed.

vapor lamp. Areas with broken or suspected broken lamp envelopes should be avoided. Further, a responsible person should be alerted to the potential problem so that the lamp can be turned off and checked or replaced if needed.

Should skin burns and eye irritation develop following exposure to ultraviolet radiation from a broken mercury vapor lamp, a physician should be consulted and informed of the ultraviolet radiation exposure. Also, the incident should be reported to the state health department and FDA.

The person responsible for the lamp should follow the manufacturer's

sunlamps. Metal halide lamps are so close in nature to the mercury vapor lamps that the mercury vapor performance standard also is applicable to them. Sunlamps, which are purposely designed to emit ultraviolet radiation, have great potential for causing injury even when intact. FDA has a separate performance standard for sunlamps. Even so, it remains up to the user to exercise care and good judgment in using these lamps.

William B. Knight is an optical engineer with FDA's Bureau of Radiological Health.

About Body Wraps, Pills And Other Magic Wands For Losing Weight

by Judith Willis



Overweight and out of shape? Want to lose pounds without dieting and eliminate inches without exerting any effort?

So do millions of Americans who believe that somehow, as if by waving a magic wand, they will be thin and firm. Unwilling or unable to lose weight through diet and exercise, they turn to weight-loss gimmicks ranging from pills that supposedly let them eat unlimited pasta to rubber suits that make them sweat while they sleep.

Most current diet gimmicks seem to fall into two categories: (1) custom garments or body wraps that claim to "melt" fat away in a short time, and (2) pills that supposedly curb appetites without side effects, or allow dieters to eat as much as—or more than—normal and still lose weight. The pills are usually touted as the product of some previously undiscovered process.

Who can blame the fretfully flabby for being lured by the promise of losing inches without doing anything more strenuous than popping a pill or wrapping up the offending flesh? Who can resist ads for body wraps that promise "to burn away fat even while you sleep," to "lose 4-6 inches the first day"?

Some of the plastic or rubber garments are worn around the waist, some cover the waist, hips and thighs, and others cover nearly the entire body.

Some are to be worn while carrying out routine activities, others while exercising, and some while sleeping. One is inflated with air from a vacuum cleaner. Another uses an electric hair dryer to blow in warm air. Some are used after a cream, gel or lotion is applied or after the wrap is soaked in a solution.

The Food and Drug Administration has investigated a number of these products and has taken action against several promoters of wrapping devices and latex exercise or sweat suits for

making unsubstantiated medical or therapeutic claims.

The garments and wraps, with or without lotions and creams, reduce body dimensions by removing fluids. Most medical experts agree that such treatment will cause a loss of inches and perhaps pounds due to profuse perspiration, but the reductions are temporary. The fluid is soon replaced by drinking or eating. But rapid and excessive fluid loss is potentially dangerous because it can bring on severe dehydration and can upset the balance of important electrolytes in the body.

Wraps have no effect on fat deposits and will not dissolve fat, even temporarily. Fat is not broken down by perspiration. It is gotten rid of only when fewer calories are consumed than are needed to meet the body's energy requirements.

The latest twist in the body wrap bonanza is a product called La Creme, a cream to be applied to parts of the body where loss of inches is desired. La Creme differs from other wrap products in that the wrap is not sold along with it. Rather, consumers may choose their own wraps from among the plastic products normally used to wrap food. La Creme is applied and then six or seven layers of the plastic wrap are wound around the creamed area.

A leaflet for the product claims: "Lose up to two inches from those problem areas in just one hour." An advertisement adds, "Its gentle warmth penetrates into your skin and helps melt fatty deposits." But, as with other wraps, any weight or inches that disappear are lost from perspiration. (See "Fat Won't Melt," an Update in the November 1981 *FDA Consumer*.)

Promotional literature distributed to retail outlets, such as department stores and specialty salons, claimed that FDA had approved or classified La Creme as a skin toner, tightener and smoother. In truth, FDA had

never been given an opportunity to evaluate the product and had no idea what it contained.

FDA advised a distributor of La Creme that, based on the product's labeling, it should be regulated as a drug because it claimed to alter the size, shape or conformity of the body—a drug function as defined by the federal Food, Drug, and Cosmetic Act. When the distributor contended that La Creme was a cosmetic and therefore not subject to safety and efficacy requirements, FDA replied that claims of even temporary reduction of body measurements were not appropriate to a cosmetic.

The company has not replied to FDA's comments. In the meantime, many of the department stores that carried La Creme have stopped selling it.

In resorting to magical slimming items, the weight conscious are often either taking risks with untested products that may alter the body's functioning or being duped by products that have no more effect than a placebo. (Only two drugs—phenylpropanolamine and benzocaine, along with caffeine—should be used in non-prescription diet aids, according to an FDA advisory panel. Those recommendations have not been acted on by the agency.)

Yet, the marketing of untested diet aids persists. They appear on the market without FDA approval because manufacturers often contend that their product is a food and thus not subject to premarket approval from FDA as a drug would be.

Often a product does not come to FDA's attention until it has been used by a substantial number of persons, some of whom may be harmed by it.

Starch blockers are an example of a product sold as a food but considered by FDA to be a drug. Advertised and sold nationwide, starch blockers allegedly block or impede starch digestion and thus help in weight control

and weight reduction. One manufacturer touted the product as "a revolutionary new concept in natural weight control." Print and TV ads claimed people taking starch blocker pills could eat up to 600 calories a day of foods such as bread, potatoes and pasta without absorbing the calories.

Manufacturers did not seek FDA approval before putting starch blockers on the market. They claimed the product, prepared from raw beans, was a "special dietary food" instead of a drug.

FDA disagreed. The agency asked the manufacturers to discontinue marketing starch blockers until scientific testing could confirm their safety and efficacy as drugs.

Users of these products have complained to FDA of nausea, vomiting, diarrhea and stomach pains. The pills are considered to be particularly hazardous to diabetics, who may rely on their purported carbohydrate-blocking effect to calculate their diets.

Although these products are made from a food substance, FDA considers them to be drugs because of the claim that they control or reduce weight by blocking or interfering with digestion. According to the starch blocker theory, the pills contain a substance that inhibits the activity of the enzyme amylase, which digests carbohydrates. This constitutes a drug action that may interfere with the body's normal metabolism. Under the FDC Act, a substance that is offered for a non-food purpose and that affects a function of the body is a drug, not a food, even if it is derived from a vegetable.

Another natural substance promoted as a weight-loss wonder is spirulina. It is sold as a food or food supplement in the form of a dark green powder or pill in many health food stores. Spirulina is one of about 1,500 known species of blue-green algae that grow in brackish ponds and lakes in mild and hot climates

throughout the world. Pure spirulina is a source of protein and contains a number of vitamins and minerals. However, in the amounts normally consumed when taken according to label directions, the nutrients derived are insignificant. As a food, spirulina can be legally marketed as long as it is labeled accurately and contains no contaminated or adulterated substances.

Claims have been made that phenylalanine, an amino acid found in spirulina (and in most other protein sources), "acts on the brain's appetite center to switch off your hunger pangs." However, an FDA advisory panel reviewing data on phenylalanine in 1979 found no reliable scientific data to demonstrate that it is safe and effective as an appetite suppressant.

Some nutritionists fear that consuming large amounts of spirulina might have an effect similar to that of the liquid protein diets which resulted in heart problems and even death for some dieters. Helene Swenerton, a nutritionist at the University of California's Davis Cooperative Extension, points out that because algae are single-celled organisms, they are rich in nucleic acids providing not only a lot of protein but also large amounts of uric acid, which could result in kidney stones or gout.

Another, more recently introduced "natural" pill is dubbed "Glucomannan." Advertised as the "Weight Loss Secret That's Been In The Orient For Over 500 Years," Glucomannan apparently is chemically processed from the konjac root, which has been used as a food in Japan and other Oriental countries for many years.

A search of both the Japanese and English language medical literature, however, shows no studies of this food as a weight-loss product. The manufacturer has not supplied FDA any

information to substantiate its claims. According to advertising, Glucomannan "helps transport food through your digestive system faster. . . . As a result, more of the calories you do take in (and you're likely to take in fewer, to begin with) can pass out of your system, still undigested, to help your weight loss along even further."

The manufacturer originally claimed that its pill was a food. When FDA wouldn't accept that claim, the firm maintained that its product was GRAS (generally recognized as safe) because it was commonly used in food prior to 1958.

FDA responded that although konjac tubers have been used as food in the United States since at least 1899, the substance in Glucomannan is a chemically processed extract from konjac tubers. This substance is not GRAS for food use and does not have a history of food use in this country before 1958. (Under the food additive law passed by Congress in 1958, any substance intended for food use has to be either GRAS or permitted under a food additive regulation. Substances commonly used as food prior to 1958 are generally recognized as safe.) FDA said that to be marketed as a food substance, Glucomannan would have to either be affirmed as GRAS or approved as a food additive. Both of these require submission of scientific data to FDA.

In addition to miracle pills with unproven claims, another type of dieter's delusion is still being perpetrated by some diet clinics years after both the FDA and the American Medical Association stated it was useless for weight loss.

This deceptive practice is injection with HCG (human chorionic gonadotropin). HCG is a hormone extracted from urine of pregnant women. It is approved by FDA for treatment of

certain problems of the male reproductive system and in stimulating ovulation in women who have had difficulty becoming pregnant. No evidence has been presented, however, to substantiate claims for HCG as a weight-loss aid.

An article in *JAMA (Journal of the American Medical Association)* in 1974 stated:

"No convincing scientific evidence exists that human chorionic gonadotropin has any pharmacologic effect in weight reduction. Hence, claims to the public that such effects do occur are a misrepresentation of the scientific facts."

FDA requires all labeling and advertising of HCG to state that it has not been demonstrated to be effective in the treatment of obesity. The ads must also state that HCG is not approved by FDA as safe and effective in treatment of obesity or weight control.

Yet the use of HCG for weight loss continues. For instance, advertisements for weight-loss clinics using HCG appeared in the Chicago area in the summer of 1982. The ads included the required disclaimer, but in type much smaller than that used to extol the virtues of the clinics' program.

The pill or shot to enable a person to lose weight without danger and without eating less has not been formulated. And the garment or other device to let one firm up or lose inches without moving a muscle has yet to be invented.

It looks like those who want to be slim will have to resort to those old, unglamorous standbys—eating less and exercising more—to shake those excess pounds.

At least until the next waving of the magic wand.

Judith Willis is editor of FDA's Drug Bulletin, a periodical for health professionals.

Diabetes Is A Controllable Disease With A Growth Factor

by John M. Couric

Diabetes mellitus—directly affecting more than 10 million Americans and growing at a rate of 6 percent a year—remains a major health problem even though the discovery of insulin 61 years ago enormously reduced its mortality rate.

Before insulin was discovered in 1921 and a way found to produce it from the pancreas of animals, diabetes mellitus—in its more severe form—meant almost certain, quick death.

Today, diabetes is one of the diseases in which accurate diagnosis and a proper medical regimen can make a real difference—in longevity and well being. There still is no cure, the cause is still unknown, the disease remains chronic, and children of diabetic parents are more likely to develop diabetes than those of non-diabetics. Nevertheless, the diabetic today can live a relatively normal, productive life. Early diagnosis and careful control of diabetes can reduce the severity of and delay, or possibly prevent, blindness, loss of limbs and other medical complications associated with the disease.

Exactly what is diabetes mellitus? Also known as sugar diabetes, the disease results from the body's failure to process food for energy. In the healthy person, sugar and starches (carbohydrates) in food are changed by digestive juices into a form of sugar called glucose and then used for heat or energy or stored in a slightly different form for later use.

In the diabetic, however, the body does not process glucose properly. This overloads the kidneys in disposing of the excess, forcing the body to use fats and proteins instead of glucose for energy. All of this is the result of a malfunctioning or non-functioning pancreas, the gland in the abdominal region that secretes hormones to aid in digestion. Insulin, one of these hormones, is necessary for the proper use of glucose. If the pancreas does not produce enough insulin or if other substances prevent insulin from performing its primary function, diabetes results. Injecting the right amount of insulin into the body can set the biological mechanism to working properly again and reduce the sugar in the blood.

There is a belief that diabetes is inherited by a child from a parent, sometimes skipping a generation. But not all cases can be attributed to hereditary factors. Other possible causes include previous severe virus infections, environmental factors and some form of autoimmunity—that is, a condition in which a person develops antibodies against constituents of his own tissues. But scientists have not been able to prove any of these theories. About all that can be said with certainty is that obesity worsens and may even precipitate diabetes.



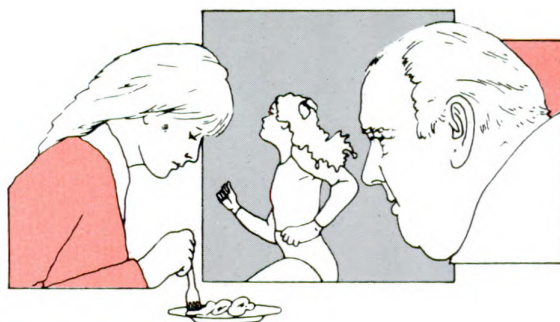
Not all diabetes mellitus cases are alike. There are two major types. Type I formerly was called juvenile-onset, and treatment is dependent upon insulin injections. Type II does not necessarily require insulin treatment and in the past was referred to as maturity-onset diabetes. Type I is more severe. Complications may develop more rapidly and life expectancy may be shortened. Only about 10 percent of diabetes cases are Type I. This form appears very quickly and progresses rapidly, usually in childhood or young adulthood. When it occurs, the patient's pancreas stops producing insulin or produces only a very small amount. Before the discovery of insulin, Type I patients lapsed into a coma and died after a short illness.

The American Diabetes Association, a voluntary, non-profit health organization, lists these Type I symptoms, which usually occur abruptly:

- Frequent urination accompanied by unusual thirst and excessive drinking of fluids
- Weight loss with easy tiring, weakness, irritability or nausea
- Uncontrollable craving for food, especially sweet foods and candy

Onset is sudden and the need for treatment is urgent or the patient will go into a coma. Insulin, in addition to proper diet, exercise and rest, is always required for treatment.

Type II diabetes is the more common form, usually less sudden and less severe. Generally, it is a disease of middle or old age in which the pancreas slows down, producing



less insulin and at a slower rate. Common Type II diabetes symptoms include:

- Any Type I symptom
- Frequent infections of the skin, gums or urinary system
- Unusual changed or blurred vision
- Pain or cramps in legs, feet and fingers
- Slow healing of cuts and bruises
- Intense itching
- Drowsiness

Only a physician can be sure that the patient has the disease, by using one or more laboratory procedures, including a urine test, a simple blood test and a blood glucose (sugar) tolerance test. A blood sugar test is useful for checking older people who do not have the classic symptoms but may just not feel well.

Although medical science does not know the basic cause of diabetes, one undisputed trigger for the onset of Type II is F-A-T. Weight loss through diet is mandatory for the overweight diabetic. If proper weight is maintained, many diabetics over 40 will not need additional treatment. If they do need it, the physician will combine medication—insulin injections or oral drugs—with diet. In a diabetic diet, the number of calories must be constant. Concentrated sugars such as those found in candies, baked goods and soft drinks are prohibited because the insulin in the diabetic cannot burn them fast enough.

Exercise and proper rest also are important for all diabetics. Exercise helps burn up food and takes some of the demand for insulin off the pancreas and also assists in maintaining proper weight. Necessary rest varies with the individual, but fatigue can affect body efficiency.

A diabetic's meals, exercise, medication and rest should follow a regular schedule. Insulin shock due to hypoglycemia (too little sugar in the blood) may result if the diet-exercise-insulin regimen is disrupted. Not eating enough, exercising too strenuously or taking too much insulin can upset the balance.

Wide swings in blood sugar levels may occur when the diet-exercise-insulin balance is disrupted. Among the symptoms of too little sugar in the blood are tremors, hunger, sweating, headache, nausea, blurred vision and—if untreated—loss of consciousness. The diabetic can get prompt relief by ingesting candy, orange juice or some other sugary food or beverage. In addition, the patient's physician should be contacted immediately.

Too much sugar in the blood (hyperglycemia) can result in diabetic coma. The sugar buildup can be attributed to insufficient insulin or failure to follow the proper diet. The patient's symptoms can include nausea, drowsiness, extreme thirst, headache, blurred vision, abdominal pains

and rapid breathing. If the condition is not treated by lowering the blood sugar level with insulin, loss of consciousness and coma will result.

Insulin cannot be taken orally but must be injected under the skin. The digestive juices apparently destroy the hormone. Other drugs, taken by mouth, have been available for the treatment of adult-onset diabetes since 1957. These drugs, which come in tablet or capsule form, are believed to lower the blood sugar level by stimulating the production of insulin in the pancreas.

The National Institute of Arthritis, Metabolism and Digestive Diseases says that, while these drugs have been widely used, a recent 10-year study of their effects in combating diabetes, conducted at 12 leading medical centers, "has raised doubts as to their value in controlling diabetes and its complications and, in fact, about their safety." The institute said studies indicate that use of the drugs brought on "a greater risk of death from coronary heart disease than use of diet plus insulin or diet alone." It was recommended that the drugs be used only in patients with maturity-onset diabetes in whom the disorder cannot be controlled by diet alone or by diet plus insulin.

There are other forms of diabetes mellitus in addition to the two major ones. Pregnant women sometimes are afflicted with gestational diabetes but return to normal after delivery. However, these women should continue to watch their weight and have frequent checkups because about 30 to 40 percent of them will develop diabetes again within 5 to 10 years. A condition formerly known as latent diabetes now is called impaired glucose tolerance. It should be treated by diet and weight loss, if necessary, to keep actual diabetes from developing. When certain conditions are induced by drugs, chemicals or diseases of the pancreas or endocrine glands, secondary diabetes results. Depending on the severity, this form of the disease is treated by diet or diet and insulin.

Since insulin must be injected under the skin, special care should be taken in its administration. Most diabetics, including children, are capable of administering the injections themselves. The skin of the arm, abdomen and thigh are considered the most convenient sites for injection. To prevent thickening of tissue at the site of injection, a plan should be developed to avoid using the same injection entry point. Authorities say the same puncture hole should not be used more than once every month or two.

Except for infants, the very young and the disabled, diabetic patients must take full responsibility for their own care. All Type I and some Type II diabetics must inject insulin daily for their bodies to use carbohydrates in a comparatively normal manner. The injections must be



given in precise doses at precise times and must be balanced with food consumption and physical activity. This requires measurements several times a day, either through a urine test that provides an indirect check on blood sugar levels or through a direct method of analyzing a single drop of blood in a home medical device. The single drop can be obtained by pricking the finger.

Some diabetics can get further help from a recently developed insulin pump. This device provides a predetermined, continuous dose of insulin throughout the 24 hours. Additional pre-meal doses of insulin can be given by pushing a button on the pump.

Sleep Sentry is a recently approved device that monitors insulin-dependent diabetics while they sleep and warns them of skin temperature drops and perspiration—two frequent symptoms of hypoglycemia. The device is worn on the wrist and is similar in appearance to a wristwatch.

Exercise is one way to avoid many of the complications associated with diabetes. If a diabetic is in otherwise good health, walking is recommended—provided warm-up routines are followed first. Prescribed sports activities also are recommended under the supervision of a physician or podiatrist.

Although diabetes is a complex disorder, its long-term complications chiefly affect blood vessels, nerves, kidneys and the eyes. Type I diabetics generally are more severely affected by complications.

Diabetic patients, particularly those with very high blood sugar, are more prone to infection because white blood cells that ordinarily fight infection do not work properly when sugar levels are too high. As a result, bacteria and other organisms may invade tissues rapidly and cause inflammation, abscesses and occasionally sepsis, a blood-borne infection. Women who have diabetes are more likely to give birth to babies with birth defects or who are stillborn; they are also somewhat more likely to die in childbirth.

Several years of poorly controlled diabetes can cause neuropathy, a complication arising when elevated blood sugars result in the deposit of glycoproteins (a sugar-protein complex) in the nerves. This is more likely to happen in the feet and legs. When it does occur in the feet there is a decrease in sensation because of the damaged nerves. A diabetic who is not watchful could be injuring his or her feet for days without being aware of it. For example, a patient who has difficulty telling the difference between hot and cold or sharp and dull could walk for days on a tack protruding through the shoe. A pebble lodged in the shoe could cause a similar injury that could lead to infection and gangrene. Similarly, many patients end up losing a leg because they fail to test bath water with a hand instead

of a foot or because they sleep with hot water bottles, electric blankets or heating pads set too high and burn themselves.

Diabetics should inspect their feet regularly for cuts, redness, swelling or sores. They also should have regular foot examinations by a physician or podiatrist.

Diabetes, hypertension, excessive cholesterol and cigarette smoking are believed to be major contributors to premature hardening of the arteries. Diabetics in particular are subject to narrowing of the arteries in the lower extremities. The most common symptom of poor circulation is pain in the calves while walking. Other indications are diseased and irregular toe nails and feet that turn bright red when sitting with feet hanging down. Circulation may improve dramatically if a person conquers addiction to cigarettes. Medication and exercise also can help, as can a surgical bypass of the narrow arteries of the leg.

Neuropathy or poor circulation or occasionally both can cause a diabetic foot ulcer, an opening in the skin forming a small crater. If bacteria are growing in the ulcer it is known as an infected ulcer. Persistent infection may involve bones in the feet and turn to osteomyelitis. Gangrene, one of the most feared complications of diabetes, occurs when overwhelming infection is present in a localized area of the foot and death of that tissue results.

Type II diabetes may be treated conservatively with bed rest and antibiotics. In addition, podiatrists frequently can improve ulcers by using foot supports to redistribute weight when the patient walks. Neglect of osteomyelitis or gangrene can result in amputation.

Diabetics also must be especially concerned about their eyes. A few diabetics may develop long-term retinopathy, a condition caused by hemorrhages, fat deposits and scar formation behind the eye. Once again, part of the circulatory system is involved, this time the capillaries (tiny blood vessels). A patient should see an ophthalmologist as soon as diabetes is diagnosed and have a visual check at least once a year or more often if the physician recommends. This way, patients can be considered for treatment while the therapy can do some good.

Diabetes is a misfortune, but with personal care and discipline and medical supervision, a victim can lead a nearly normal life. Medical research continues into factors that trigger diabetes, the development of new drugs to control the disease, and even an inoculation against juvenile-onset diabetes. Meanwhile, those who have it can learn to live with it.

John M. Couric is a writer-editor with FDA's National Center for Drugs and Biologics.

RDAs: Key To Nutrition

by Chris Lecos

How can a consumer make sensible food choices to provide nutritious meals for the family when bombarded daily with messages, claims and advice about which foods to buy and confronted with the bewildering stock of foods on supermarket shelves?

It isn't always easy. A conscientious food shopper must do some planning to choose foods with the nutrients essential to good health.

For most Americans, the most readily available source of nutrient information is the nutrition label that appears on many, but not all, food products. The Food and Drug Administration created the nutrition label to make it easier for shoppers to compare food brands and their nutrient content. Although FDA is at present studying various ideas for revising and simplifying the nutrition label (see October 1982 issue of *FDA Consumer*), until something better is devised, it is still one of the most reliable aids available to consumers.

Ten years ago FDA first presented proposals for nutrition labeling of foods, an effort that one writer described as "one of the most ambitious programs" the agency had ever undertaken, in which government, the food industry, nutrition experts and consumers all played an active role.

More than 3,000 responded to FDA's proposals in 1972, and final regulations published the following year spelled out federal requirements for nutrition labeling. The result has been a larger number of foods with useful nutrition information, partly because it was mandatory for some food producers to include labels on their products and partly because industry voluntarily made the information available.

Under FDA's regulations, any food to which a nutrient is added or for which a nutrition claim is made must have a nutrition label. Recent FDA studies show that about 44 percent of



The recommended allowances, in effect, represent the amounts of essential nutrients that are considered adequate to meet the known nutritional needs of most healthy persons in the United States.

packaged food sales in the United States involve products with nutrition labeling. About half of these bear the labeling because the producers are required to do so and about half because the manufacturers choose to include the information on their products.

The label includes two important areas of information for the consumer.

One discloses the number of calories in a specified serving of a food along with the amount—expressed in grams—of protein, carbohydrate and fat in a serving (there are approximately 28 grams in an ounce). The other, under the heading "Percentage of Recommended Daily Allowances (U.S. RDA)," tells the consumer the approximate amounts of certain essential vitamins and minerals contained in a serving. These amounts are expressed as percentages.

FDA established recommended daily allowances for protein and 19 vitamins and minerals in its 1973 regulations. However, under the regulations, percentages in a serving are required only for protein, five vitamins (vitamins A and C, thiamine, riboflavin and niacin) and two minerals (calcium and iron). A manufacturer has the option of listing the remaining 12 vitamins and minerals. Those that are optional are vitamin D, vitamin E, vitamin B₆, folic acid, vitamin B₁₂, phosphorus, iodine, magnesium, zinc, copper, biotin and pantothenic acid. If any of the 19 are added to a food or a claim is made about them, the label would have to include all the required nutrition information.

As discussed later in this article, the U.S. RDAs are based on reliable scientific information about human nutrient requirements. An explanation of why certain vitamins and minerals should be consumed is not necessary if the consumer can accept the fact that the levels recommended are those deemed best for a healthy diet.

What the consumer needs to understand are the percentages and how to use them. The shopper should know that 25 percent of the RDA of a particular vitamin or mineral means the serving is good for one-fourth of a person's recommended daily need.

The availability of this kind of information was an important advance for consumers. Until the U.S. RDAs were established by FDA, nutrition information on foods was quite limited. The agency's recommended allowances replaced what were known

as the "Minimum Daily Requirements." The latter, adopted by FDA in 1940, were specified in earlier FDA regulations for declaring the nutrient values in foods for special dietary use and for dietary supplements of vitamins and minerals.

The MDR system, however, produced confusion and widespread dissatisfaction. FDA summarized the problem in the *Federal Register* in January 1972: "The continued existence of the term 'Minimum Daily Requirements' has led to the production, promotion and sale of a variety of dietary supplements that contain large multiples of the minimum daily requirements for vitamins and minerals, and by far exceed the adequate human total daily dietary requirements."

FDA's recommended daily allowances were derived mainly from the extensive nutrition data published by the Food and Nutrition Board of the National Academy of Sciences-National Research Council. Using the expertise of nutrition specialists and scientists, the National Academy issues what is known as recommended dietary allowances for a wide variety of age and sex groups in the general population. Its recommendations are based on an extensive review of current research and knowledge in the nutrition field.

The publication of recommended dietary allowances by the National Academy began in 1943, primarily as a World War II planning guide for the general population and military services. Its early recommendations focused on calories and nine nutrients. The number of nutrients for which standards were proposed grew and the standards were revised, where necessary, as scientists learned more about human nutritional needs.

As indicated, the National Academy's recommendations are for general population groups, as are FDA's recommended daily allowances. The recommended allowances, in effect, represent the amounts of essential nutrients that are considered adequate to meet the known nutritional needs of



The availability of this kind of information was an important advance for consumers.

most healthy persons in the United States. They do not, however, take into account the special needs of people required to follow special diets because they are ill or suffering from other medical disorders that require professionally supervised diets. Those are special problems beyond the scope of the dietary recommendations made.

There is a further qualification. While they are presented as daily allowances, this does not necessarily mean the intake levels recommended need to be met religiously each day. Because the body is able to store some

nutrients for later use and can endure lower-than-required intakes for short periods without harm, the recommended dietary allowances can be met from diets that fulfill the nutrient requirements over a five- to eight-day period.

When FDA adopted its nutrition labeling regulations in 1973, it based its recommended daily allowances (or U.S. RDAs) in part on the nutrient values published by the National Academy in 1968. Although some changes have occurred in the academy's dietary allowances since then (the most recent were made public in 1980) the modifications were considered so minor that they did not warrant any changes in the U.S. RDAs.

FDA's recommended daily allowances apply to four general population groups (compared to 26 groups listed in the National Academy's 1968 report). This was done to make it simpler and easier for consumers to use the information on a label. The four population groups for which U.S. RDAs were established were for infants up to 1 year; for children (junior foods) under 4 years; for persons who are 4 years and older (most food products are based on these allowances); and for pregnant or lactating women.

The amounts of protein, vitamins and minerals shown as percentages on a food label simplify the consumer's task of comparing foods for their nutrient quality. Instead of having to refer to complex and technical tables, as published by the National Academy, to determine if they are obtaining enough of given nutrients, consumers can simply add the percentages for each nutrient. FDA's allowances are based generally on the highest values recommended in the National Academy's findings. For that reason, many normal, healthy people would not necessarily have to consume 100 percent of the U.S. RDA of a given nutrient each day.

Chris Lecos is a member of FDA's public affairs staff.

The Notebook

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

■ Labels on **non-prescription antacids** can now include the term "upset stomach" to describe symptoms associated with heartburn, sour stomach or acid indigestion. The effective date of the new FDA ruling was Sept. 30 (FR Aug. 31).

■ FDA is seeking information on the abuse potential, actual abuse and trafficking of four **sedative-hypnotic drugs** (chlorhydrate, paraldehyde, phenobarbital and potassium bromide) and five **analgesics** (buphrenorphine, butorphanol, cyclazocine, nalbuphine and pentazocine). The information will be submitted to the World Health Organization, which is considering whether to recommend international restrictions on these drugs (FR Aug. 31).

■ July 1, 1985, is the new uniform effective date by which food manufacturers must comply with **food labeling regulations** adopted by FDA after Aug. 13, 1982, and before July 1, 1984. Use of a uniform effective date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to develop new labeling materials (FR Aug. 13). Among the major proposals that could come under that 1985 date is the sodium labeling measure that would include sodium content listing on nutrition labels.

■ The standard of identity for **canned peas** may be amended to reinstate magnesium hydroxide, magnesium oxide and magnesium carbonate as optional ingredients. FDA deleted them from the standard, effective April 1981, because it was thought they were no longer used in the United States. A recent petition indicates a canner of peas is interested in using magnesium compounds in canned peas (FR Aug. 31).

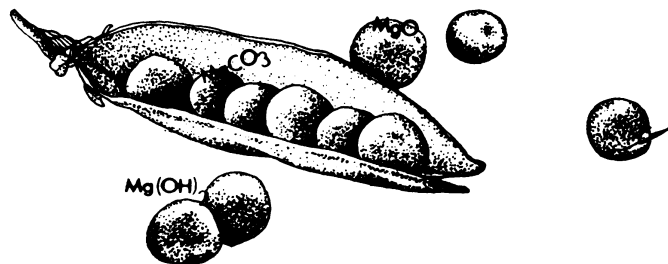
■ The U.S. Department of Agriculture has issued a final rule permitting the use of fresh, frozen or cured beef or veal or combinations, or pork or combinations with beef or veal, in **braunschweiger and liver sausage**, and beef fat in braunschweiger (FR Aug. 19).

■ Standards of identity for **cranberry juice cocktail, artificially sweetened cranberry juice cocktail, lemonade and colored lemonade**, originally established in April and May of 1968 and put on hold in July of 1968, have been revoked. This means that these products are non-standardized foods and are subject to FDA's ingredient labeling requirements (FR Aug. 6).

■ The Environmental Protection Agency has issued a final rule amending portions of its regulations on use of **PCBs in electrical equipment**. The amendments, which became effective on Sept. 24, prohibit use and storage for reuse of PCB transformers or electromagnets that pose an exposure risk to food or feed. The effective date is Oct. 1, 1985. PCB transformers are to be visually inspected once every three months (FR Aug. 25).

■ FDA is proposing to amend its biologics regulations to reduce the number of samples of **hepatitis diagnostic test kits** manufacturers must submit for testing prior to marketing. The proposed rule will eliminate unnecessary burdens on both manufacturers and the agency (FR Aug. 17).

■ **RIMSO-100**, a DMSO product manufactured by Research Industries Corp., Salt Lake City, Utah, is not available over the counter for reagent and drug use, no matter what was said in the February 1982 edition of the *DMSO Report*, an Oregon newsletter. FDA says the product does have a legitimate use as a cryopreservative (freezing solution) for certain blood components, but distribution for drug use would violate new drug provisions of the Food, Drug, and Cosmetic Act. The agency has advised the manufacturer of its responsibility to sell RIMSO-100 only to firms known to have the capability to freeze blood components, such as blood centers and large hospital blood banks.





Dalton's Deception

A clinical investigator tests new drugs. He is required to monitor the health of the patients and keep accurate records. If all goes well, and the drug is proven safe and effective based on these trials, the product can then be sold. But all didn't go well in the case of Dr. Fred C. Dalton, a psychiatrist and clinical investigator in Mineola, N.Y. On May 11, 1982, he was charged with two counts of falsifying data, convicted, fined \$1,000 and disqualified from participating in future new drug studies.

Dalton's troubles stemmed from his clinical research on the drug Dothiepin, a tranquilizer used for treating depression. Marion Laboratories Inc., Kansas City, Mo., sponsored the new drug and hired Dalton from 1972 to 1975 to conduct the patient tests. The written protocol (a plan setting forth how clinical trials will be conducted) required all 30 patients to have electrocardiograms (EKGs), ophthalmological exams and blood and urine tests, as well as personality tests.

When representatives from Marion visited Dalton's office in July 1977 to review patient records and compare his results with those of other clinical investigators participating in the study, Marion noticed that Dalton's results were oddly uniform. Patients receiving Dothiepin showed immediate and sharp improvement; patients given a comparison drug showed much less improvement; and patients in the placebo group showed no improvement.

Three months later Marion Laboratories tried talking to Dalton to find out if he had broken the patient code, a means of concealing from the investigator which patient receives the placebo and which the real product. Dalton said that he didn't know the code and that his results were accurate. Dissatisfied, Marion Laboratories ended Dalton's participation in the study and in November 1977 submitted Dalton's records to FDA, as required by law.

FDA reviewed Dalton's records and

those of two other physicians and one laboratory, the Center for Laboratory Medicine in Mineola, all of whom had done tests for the psychiatrist. The discrepancies were apparent.

Forty-eight of the 51 eye examination reports submitted by Dalton contained false information; dates and signatures were also suspect. Only 3 of the 52 EKGs submitted by Dalton to Marion Laboratories corresponded completely with the records kept by the physician who performed the tests. In about 20 cases, results from the EKGs were completely false.

Blood and urine tests were no different. Dalton produced such records for 26 of the patients in the study, yet the Center for Laboratory Medicine, where the tests were conducted, had records for only 16 individuals.

FDA filed charges in the U.S. District Court for the Eastern District of New York, in Brooklyn, N.Y., and Dalton pleaded guilty to creating false, fictitious and fraudulent records of ophthalmologic tests and laboratory test results.

FDA Seizure Upheld

April 1980 was more than just income tax time for Goshen Labs, Goshen, N.Y. U.S. marshals seized \$71,000 worth of finished animal drugs and raw materials from the veterinary drug firm for two types of violations. The company protested the seizure, claiming their products were "grandfathered" and thus were exempt from FDA's new animal drug regulations. FDA took a different view. Two years later the U.S. District Court for the Southern District of New York upheld the agency's charge that Goshen was selling unapproved new animal drugs.

Goshen's problems involved more than unapproved drugs. For several years the firm had failed to comply with FDA's Good Manufacturing Practices, including quality control, sanitation, packaging and labeling requirements. In October 1979 FDA sent Goshen a regulatory letter outlining the violations of the GMPs and

new animal drug regulations. Agency representatives even sat down with the company management and explained the regulations and how to comply with them.

Reinspection of the firm by the Buffalo district office showed no improvement, and in April 1980 U.S. marshals seized all finished products manufactured by the firm, including several new animal drugs distributed by the firm without New Animal Drug Applications and 200 kinds of raw materials (totaling 3,100 pounds and packaged in more than 230 various containers). Some of the containers appeared very old and bore illegible labeling. Some contained toxic substances such as arsenic trioxide and xylene.

Goshen Labs not only claimed its products were "grandfathered" but rebutted the charge of GMP violations by arguing it had never had a problem with any of its drugs.

Cracked Necks

No imperfection is too slight to overlook when it comes to ensuring drug purity. Last June, a total of 711,184 vials of an anti-infection drug were destroyed because of hairline cracks in the necks of some of the vials.

The drug, lyophilized flagyl I.V., sold by Searle Pharmaceuticals Inc., Skokie, Ill., is prescribed for trichomonas infections. Originally in a liquid state, the drug is dried and packaged in vials. When ready to be used, it is reconstituted with sterile water and injected intravenously into the patient.

Problems with the product were reported to Searle between December 1980 and May 1981. Some reports said the vials exploded after water was added for dilution. Others said the powder could be seen outside the rim of the seal. FDA's Chicago district office learned of the problems through drug product defect reports.

The drug was made for Searle by Elkins-Sinn Inc. of Cherry Hill, N.J. It is believed that the cracked necks

resulted from excessive pressure placed on the seals during the assembly process.

Elkins-Sinn Inc. has since increased its inspections and improved its quality control procedures. Searle initiated a Class II recall of all lots of flagyl I.V. by sending letters and Mailgrams to hospital pharmacists and administrators nationwide.

The condemned vials were returned to Searle's warehouse in Elk Grove Village, Ill., where they were crushed by four compacted garbage trucks, hauled to a landfill in Glenview, Ill., and buried on June 8, 1982.

A Tale of Two Warehouses

Two Seattle Oriental food warehouses, beset by insect and rodent infestation, have solved their problems and are back in the business of providing clean and orderly food storage.

Mekong Market, the first, held many kinds of rice products. When **Seattle district** office inspectors visited the firm in April 1982 they found mice on the floor, rodent-defiled food products and Indian meal moths in one lot of rice. The mouse and insect infestation was serious enough for FDA to initiate a seizure in May 1982.

The firm reconditioned the rodent-contaminated food, destroying about 6,000 pounds at a landfill in Seattle. The firm also segregated the insect-infested lot of rice, pending a decision as to its disposition. However, when FDA investigators returned to the firm they found that the insect infestation had spread to 60,000 pounds of rice which had already been reconditioned. The firm then fumigated the rice and shipped it to a California



company for cleaning under FDA's supervision. FDA re-inspected the warehouse and found it free of vermin.

The second Seattle warehouse had similar problems. The Yick Fung Co. housed dried fish, salted plums, rice and noodles, among other Oriental foods. Scattered among the crowded cases of food products were thousands of beetles. FDA attributed the firm's insect problems to crowding, poor stock rotation and inadequate cleaning. The building was also old and in disrepair, so much so that fumigation would have been extremely difficult.

U.S. marshals seized all affected items, and the owner chose to destroy, rather than try to recondition, the contaminated foods. About 6,000 pounds of food was hauled to a local landfill and buried. Yick Fung hired a pest control consultant, corrected storage and operating conditions, and brought the warehouse into compliance with agency standards.

Mora Trouble?

Although it was called a biofeedback instrument, a "Mora Therapy" unit offered for import from Germany looked more like an acupuncture device to inspectors at FDA's **St. Louis station** in Missouri. And that is what it turned out to be: an electro-acupuncture unit that uses an unproved method of diagnosis and treatment (Mora Therapie) for various ills and conditions.

The equipment resembled an FM radio tuner, and included cables, hand electrodes and other attachments. It was intended for a St. Louis clinic, but U.S. Customs there would not release it from storage at the airport until

FDA had determined that it could be legally imported.

FDA found that it could not. The Bureau of Medical Devices at FDA headquarters told the St. Louis station that the unit was a Class III medical device, meaning that the manufacturer was required to show that it was safe and effective for its intended uses. This had not been done. Also, the unit had been made by a foreign manufacturer not registered with FDA, and the unit did not include adequate instructions for safe use.

Because of these several violations, the unit (with a declared value of \$4,862) was refused entry and was returned by Customs officials to the manufacturer.

Grain Is Salvaged

Grain elevator explosions are not uncommon in the Plains States and upper midwest sections of the United States. Fine dust from the stored grain floats through the huge concrete structures and, despite strict safety precautions, can be ignited by a chance spark or even an electric switch. Then the towers explode and collapse on themselves, reduced to piles of rubble. When this happens, FDA investigators must check through the damaged grain to see what can be salvaged.

A dust explosion earlier this year destroyed a 200-foot elevator in Council Bluffs, Iowa, killing five workers and injuring many others. When firemen arrived, they discovered that fire hydrants had been broken or were buried under tons of concrete and grain and that no water was available to fight the fire. Two railroad tank cars were quickly filled with water a



few blocks away, and a Union Pacific railroad engine pushed them onto a siding near the elevator site. The firemen used that water to bring the fire under control.

When an FDA investigator from the Kansas City district arrived to oversee the grain salvage work, he learned that one tank car had contained sludge, a byproduct of railcar cleaning. The grain to be salvaged may have been wetted down with water from that car.

The investigator sent a sample of the water still in the car and several samples of the grain to the FDA laboratory in Kansas City. The laboratory found polychlorinated biphenyls in the water sample, but no detectable PCBs in the grain. With that assurance, the investigator allowed the salvage operation to continue. When salvage was completed, more than 1.5 million bushels of corn and soybeans had been reconditioned and converted into animal feed.

Correction: On Report of Oyster Seizure

A shipment of oysters seized by FDA in Baltimore did not come from "contaminated Virginia waters" as stated in the May 1982 Investigators' Reports. They were uncertified and subject to seizure because they were shipped by an unlicensed Virginia packer. Cloyde W. Wiley, director of the Bureau of Shellfish Sanitation, Virginia Department of Health, supplied this clarification.

— This small sample of reports from the field was compiled and written by Marti Asner, Louise Fenner 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 7 actions to remove from the consumer market products charged to be violative was reported in August. These actions included 3 seizures of foods with charges concerning contamination and insanitary handling. Others included 4 of drugs.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Contamination, Spoilage, Insanitary Handling		
Flour, beans, whole wheat meal, and other food stocks/ U.S. District Court for the Southern District of West Virginia 7/14/82	Crook Product Co./ Beckley, W. Va.	Certain of the foods contain rodent and bird filth, and all of the foods have been held under insanitary conditions.
Fruit cocktail, canned/ U.S. District Court for the Eastern District of Arkansas 6/29/82	Shipped from Tipton, Ind.	Product was held in swollen cans.
Peanuts/ U.S. District Court for the Eastern District of Virginia 7/22/82	Hancock Peanut Co. Inc./ Courtland, Va.	Products have been held under insanitary conditions.
DRUGS/Human Use		
A-Van pentylenetetrazol capsules/ U.S. District Court for the Western District of Tennessee 8/12/82	D. M. Graham Laboratories Inc./ Hobart, N.Y.	Product is a new drug without an effective approved New Drug Application.
Cough syrups/ U.S. District Court for the District of New Jersey 7/13/82	Anything & Everything/ Brooklyn, N.Y.	Products are new drugs without effective approved New Drug Applications and are misbranded in that the products' labeling falsely and misleadingly represents and suggests that the drugs contain specific amounts of chloroform, which representation and suggestion are contrary to fact because chloroform is not present in the labeled amounts.
Myco Triacet Cream/ U.S. District Court for the Western District of New York 6/17/82	Lemmon Co./ South Hackensack, N.J.	Circumstances of the product's manufacture, processing, packing and holding failed to conform with current Good Manufacturing Practice.
Nicozol pentylenetetrazol capsules and pentylenetetrazol elixir/ U.S. District Court for the Western District of Tennessee 8/12/82	Vale Chemical Co. Inc./ Allentown, Pa. Pharmaceutical Associates Inc./ Greenville, S.C.	Products are new drugs without effective approved New Drug Applications.

Complaints Filed by Law Department Under 39 U.S.C. (False Representation)

May 21, 1982: **Body Science**, 20 Medford Ave., Patchogue, N.Y. Advertising and sale through the mail of the product "SEA-10," representing the ability to "help thicken the synovial fluid that lubricates the joints so it doesn't become watery and leak through tiny holes in the membrane."
June 4, 1982: **Bee Pollen From England**, P.O. Box 636, Newton Lower Falls, Mass. Advertising and sale through the mail of the product "Bee

Pollen From England." The ad states, in part, "the energy pill is here. A patented natural food supplement can be the answer for housewives, dieters, joggers, business people—anyone who wants more energy. Athletes training on English bee pollen daily recover energy faster after exercise and fatigue. It's amazing how this natural product improves recovery power."

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

March 19, 1982: Against **Bob's Sundries Inc.**, P.O. Box 7908, Pittsburgh, Pa. Satisfactory evidence was presented to the Postal Service that Bob's Sundries Inc. and its representatives 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.
April 5, 1982: Against **Speciality Sales Co.**, 130 Buena Vista Ave., Yonkers, N.Y. Satisfactory evidence was presented to the Postal Service that Speciality Sales Co. and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Sauna-Slimmer." The ad states, in part, "reduce waist and stomach bulges in 3 days . . . lose unwanted inches, tighten sagging muscles—without diets or exercise. Now you can quickly trim embarrassing bulges the safe effortless way."
April 23, 1982: Against **Formula Four Inc.**, P.O. Box 81262, Chamblee, Ga. Satisfactory evidence was presented to the Postal Service that Formula Four Inc. and its representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Jennifer Lord Formula #714." The ad states, in part, "is the first natural, nonsurgical way to enlarge your breasts that makes sense. It utilizes the body's own breast development mechanism to improve your natural appearance and self-confidence . . . best of all, it works!"
April 23, 1982: Against **Formula Four Inc.**, P.O. Box 81262, Chamblee, Ga. Satisfactory evidence was presented to the Postal Service that Formula Four Inc. and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Total Control." The ad states, in part, "cellulite! You can do more than be self conscious about it. Total Control

starts getting rid of cellulite immediately."
May 27, 1982: Against **Leucadia Pharmaceuticals**, 103 N. Highway 101, Leucadia, Calif. Satisfactory evidence was presented to the Postal Service that Leucadia Pharmaceuticals and its representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Prost-Rite Tablets." The ad states, in part, "relief of the most common prostate trouble—benign prostatic hypertrophy . . . all natural ingredients—proven effective in 2 separate clinical tests published in leading medical journals."
June 11, 1982: Against **Slim Suit**, 175 Fifth Ave., New York, N.Y. Satisfactory evidence was presented to the Postal Service that Slim Suit and its agents are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Slim Suit," representing the ability to "lose weight while you sleep! Slimsuit, the sensational body trimmer, no exercise, no dieting, no drugs . . . quickly melts away excess weight and fluid without any effort on your part."
June 21, 1982: Against **Athena Products Ltd.**, P.O. Box 81112, Chamblee, Ga. Satisfactory evidence was presented to the Postal Service that Athena Products Ltd. and its representatives are engaged in conducting a scheme or device to obtain money by means of false representation. The firm was advertising the product "Pollen-Ade - Bees Pollen." The ad states, in part, "pollen-ade gives you the energy and vitality to go further than you've ever gone before. The bee pollen used in pollen-ade has been shown to greatly increase vitality and physical endurance by stimulating the production of more energy. Pollen-Ade can also improve circulation and even alleviate many allergic symptoms including hay fever."

Notices of Judgment



NOTICES OF JUDGMENT on Seizure Actions

FOOD/Contamination, Spoilage, Insanitary Handling

Aniseed, rosemary leaves, chanadal beans, and marjoram leaves, at Brooklyn, E. Dist. N.Y.

Charged 8-21-80: while held by Purity Millers Inc., Brooklyn, N.Y., one lot of aniseed and one lot of marjoram leaves contained rodent and/or insect filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4).

The various owners of the articles claimed the articles and subsequently authorized the dealer to file and maintain their respective claims on their behalf. Ultimately, a consent decree authorized release of the articles to the dealer for salvaging. (F.D.C. No. 63133; S. No. 80-194-017 et al.; N.J. No. 1)

Black-eyed peas, dried, at Wasco, E. Dist. Calif.

Charged 9-29-81: when returned to Berger & Co./San Joaquin Crops Co. Inc., Wasco, Calif., the article contained rodent and insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Berger & Co. for salvaging. (F.D.C. No. 63549; S. No. 81-265-787; N.J. No. 2)

Cheese, low-moisture, part-skim mozzarella, frozen, at Portsmouth, E. Dist. Va.

Charged 8-28-79: while held for sale, the article was unfit for food due to the presence of plastic-like particles and metal fragments; 402(a)(3).

The Massachusetts counsel for Cheese Corp. of America Inc., of Lawrence, Mass., and Amsterdam, N.Y., discussed the filing of a claim and answer in this action, but no person intervened in this action as required by the rules of the court. The purported owner of the article (Cheese Corp. of America Inc.) had submitted the requisite papers to the clerk of the court but had failed to obtain local counsel. On numerous occasions, the government advised of the need to obtain local counsel.

The clerk of Cheese Corp. of America Inc. advised that the corporation would appeal the denial of the corporation's right to appear and defend itself "per se," since the necessary papers were on file with the court and there was no reason why the action could not be transferred as was done with companion cases in other jurisdictions. Ten months after the action had been filed, a default decree of condemnation ordered the article destroyed.

The article was destroyed pursuant to the default decree. The purported owner of the cheese filed a notice of appeal, but the court refused to accept an appeal because the corporation had never become a party to the proceeding. (F.D.C. No. 62406; S. No. 79-151-598; N.J. No. 3)

Garbanzo beans, white beans, farina, chocolate-flavored drink mix, and cornmeal, at Mayaguez, Dist. Puerto Rico.

Charged 12-3-81: while held by Sucesores de Esmous & Co. Inc., Mayaguez, Puerto Rico, the articles had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63590; S. No. 81-281-761; N.J. No. 4)

Peppers, jalapeno, pickled, canned, at El Paso, W. Dist. Texas.

Charged 4-12-82: while held for sale, the article was held in swollen cans; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 63697; S. No. 82-266-692; N.J. No. 5)

Pinto beans, dried, at Portales, Dist. N.M.

Charged 3-1-82: while held by Portales Valley Mills Inc., Portales, N.M., the article contained rodent urine and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 63640; S. No. 82-266-854; N.J. No. 6)

Rice, at Mineola, E. Dist. Texas.

Charged 5-20-81: when shipped by Western Rice Mills Inc., McGehee, Ark., the article contained insect filth and had been prepared, packed and held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 63273; S. Nos. 81-210-591/2; N.J. No. 7)

Rice, candy, and dried codfish, at Bronx, S. Dist. N.Y.

Charged 2-19-82: while held by 37 & 38 Bronx Terminal Produce Inc. (Las Villas), and 37 & 38 Bronx Terminal Market, Bronx, N.Y., one lot of rice and the lot of dried codfish contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 63639; S. No. 82-138-324 et al.; N.J. No. 8)

FOOD/Economic and Labeling Violations

"Flounder" fillet-portions, at Windsor Locks, Dist. Conn.

Charged 12-12-79: when shipped from Watertown, Mass., the article, labeled in part "High Liner North Atlantic Flounder . . . Flounder Coated with 'Flavor-Tex' . . . National Sea Products (U.S.) Corp., Tampa, Florida," had had Greenland turbot substituted for flounder—402(b)(2); the article's labeling was false and misleading in claiming that the only fish in the article was flounder—403(a)(1); Greenland turbot was offered for sale under the name of another food—403(b); and the article's label lacked the common or usual name for Greenland turbot and of each ingredient, because "flounder" was not the common or usual name for Greenland turbot—403(i)(1), 403(i)(2). Before allowing the entry of a default decree, the court ordered FDA to enter the custodian's warehouse for inspecting and testing of the article to determine its fitness for human consumption and for the appropriateness (due to time in storage, the article might no longer be fit for human consumption) of delivering the article for charitable distribution. Due to the delay, the article was destroyed by the custodian. (F.D.C. No. 62695; S. No. 80-160-603; N.J. No. 9)

"Honey," at Ponchatoula, E. Dist. La.

Charged 12-10-81: when shipped by Anthony Syrup Co. (Oliver Anthony), Philadelphia, Miss., the article, labeled in part (38-oz. and 20-oz. jars) "Anthon's Wild Flower Brand Honey Packed by Anthony Syrup Co. . . . Philadelphia, Miss. . . . [and 20-oz. jars only: 'Ingredients: Honey, corn sweetener [sic] and citric acid']," had had glucose syrup (in the 38-oz. jars) and corn syrup (in the 20-oz. jars) substituted wholly or in part for honey—402(b)(2); the article's labeling was false and misleading in claiming the article to be honey—402(a)(1); and the article was also in violation of the Fair Packaging and Labeling Act, since the net quantity of contents statements were not expressed in fluid ounces followed in parentheses by a declaration of the largest whole unit—15 U.S.C. 1453(a)(3)(A)(i). Default decree ordered destruction. (F.D.C. No. 63599; S. Nos. 82-281-395/6; N.J. No. 10)



FOOD ADDITIVE

Beverage mixes, Sun-Ripe Diet Lem and Sun-Ripe Lem-Or, at Cedar Grove, Dist. N.J.

Charged 4-29-81: while held by Concentrates Co. Inc., Cedar Grove, N.J., after manufacture locally from interstate sugar, the articles contained the non-conforming food additive saccharin, since the articles (which contained sugar and which were intended for use as mixes for alcoholic beverages) were not for a valid special dietary use; 402(a)(2)(C). The articles were claimed by the dealer. The claimant agreed to reformulate and relabel its food products purporting to be diet or reduced calorie mixes and to consent to a decree of destruction, without any admission concerning the issue of violations. (F.D.C. No. 62318; S. No. 81-274-386; N.J. No. 11)

DRUGS/Human Use

Allopurinol tablets, and other specified drugs, at Hollywood, S. Dist. Fla.

Charged 2-12-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). The shipper intervened, denied the charge, claimed the articles, and demanded a jury trial. Thereafter, pursuant to stipulation of the parties, the action was consolidated for trial with a similar action in the District of New Jersey. Ultimately, a consent decree ordered the articles destroyed. (F.D.C. No. 62771; S. No. 80-193-371 et al.; N.J. No. 12)

Diethylpropion HCl tablets, at Valley Stream, E. Dist. N.Y.

Charged 12-12-78: when shipped by Pharmadyne Laboratories Inc., Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). The shipper intervened and claimed the article. The action was consolidated for trial in the District of New Jersey, with similar actions. Ultimately, a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 61980; S. No. 79-139-805; N.J. No. 13)

Furosemide tablets, furosemide, and in-process furosemide powder, at Hackensack, Dist. N.J.; furosemide tablets (a lot returned from Hialeah, Fla.), at Hackensack, Dist. N.J.; triamterene with hydrochlorothiazide capsules, at Elmwood Park, Dist. N.J.; and triamterene with hydrochlorothiazide capsules, and other specified drugs, at Elmwood Park, Dist. N.J.; four seizure actions.

Charged on or about 3-28-79, 1-22-80, 3-18-80, and 3-13-80: while held by Pharmadyne Laboratories Inc., of Hackensack, N.J. (and subsequently of Elmwood Park, N.J.), which was using interstate furosemide, triamterene with hydrochlorothiazide, and other interstate components in manufacturing finished drugs, the articles were new drugs without effective approved New Drug Applications—505(a); and (all actions except the returned lot of furosemide tablets) the articles' labeling lacked adequate directions for use, and the articles were not exempted due to their New Drug Status—502(f)(1).

The articles were claimed by the dealer, who denied the charges, who asserted, as affirmative defenses, that the articles were not "new drugs" because they were generally recognized as safe and effective among qualified experts, and that the government was estopped because of the claimant's reliance upon the Lannett case (585 F.2d 575). The government served written interrogatories on the claimant.

The government moved that this action be consolidated for purposes of discovery and trial. The actions were consolidated. Ultimately, a consent decree ordered the articles destroyed. (F.D.C. Nos. 62369, 62809, 62907 and 62911; S. Nos. 79-193-425, 80-208-590, 80-208-597, et al.; N.J. No. 14)

K. H. 3 procaine HCl & hematoporphyrine capsules, at Laredo, S. Dist. Texas.

Charged 5-5-80: when imported from England by Premier Inc., Laredo, Texas, the article, labeled in part "K.H. 3 Geriatricum Schwarzhaupt Oral Procaine Geriatric . . . Manufactured by Schwarzhaupt Ltd., Cork, Republic of Ireland," was a new drug without a New Drug Application; 505(a).

The article was claimed by Premier Inc., Laredo, Texas, who denied the charge and who moved to dismiss the action on the grounds that the court lacked jurisdiction, since the article was never in interstate commerce but was brought into the United States "in bond" and placed in an import and export warehouse.

The court denied the claimant's motion to dismiss, saying:

"Pending for consideration is a Motion to Dismiss filed by Premier, Inc. ('Premier'), the party in interest. The motion seeks dismissal on the grounds that the complaint fails to state a claim upon which relief can be granted. Rule 12(b)(6), *Fed. R. Civ. P.* The filing of such a motion has the legal effect of admitting all facts alleged in the complaint, and in deciding such a motion the Court must view the allegations of the complaint in the light most favorable to the Plaintiff. *Ward v. Hudnell*, 366 F.2d 247 (5th Cir. 1966). A motion to dismiss for failure to state a claim should not be granted unless it appears to a certainty that the plaintiff would not be entitled to recover under any state of facts which could be proved. *Cook & Nichol, Inc. v. Plimsoll Club*, 451 F.2d 505 (5th Cir. 1971).

"The fundamental deficiency in the motion to dismiss is reflected in paragraph 2 therein, where it is alleged that 'it appears on the face of the complaint . . . that said goods and items are not and never were in interstate commerce within the United States, but were brought into the United States "in bond" . . . ' Nothing of the sort appears on the face of the complaint. Instead, the complaint simply alleges that the articles in question are presently in Laredo, Texas, having been imported into the United States via steamship from England. It is true that Premier's unverified answer alleges that the items were never in interstate commerce because they were brought into the United States 'in bond.' The court also realizes from reading Plaintiff's opposition to the motion that this unverified allegation by Premier may well be true. Nevertheless, the state of the record is such that a motion to dismiss could not be granted. Even if the Court were inclined to go outside the pleadings at this time, Rule 12(b)(6) would require that the pending motion be converted into one for summary judgment and disposed of accordingly. See *Underwood v. Hunter*, 604 F.2d 367 (5th Cir. 1979).

"The Court declines to convert the present motion into a motion for summary judgment. Even if proper documentation would be presented to establish that the items in question were actually shipped 'in bond,' other issues would remain for determination. Plaintiff has furnished the Court a copy of Findings of Fact and Conclusions of Law entered in *Laboratorios Kem, S. A. v. Fink*, Civil Action No.



76-804-N (S.D. Cal.). While that opinion is clearly in point, nevertheless the court there considered many factors which do not seem clearly established at this time in the present record. For example, the California court apparently had evidence that the Food and Drug Administration compiled an administrative record in a rule-making proceeding designed to determine whether the item in question was a 'new drug' and whether or not it was exempt under either of the so-called 'grand father issues' of 1938 and 1962. There was also evidence as to whether the item in question was intended for use in the treatment of man and whether any new drug applications or requests for exemptions were on file. No similar record is before the Court in the present case. There is an affidavit from Jerome A. Halperin expressing certain 'opinions' of the FDA as to the item in question but the Court is not satisfied at this point that such an affidavit would have the same import as a formal decision by the Commissioner of the FDA. Premier had indicated as early as June 24, 1978, that it was in the process of furnishing to the Court a brief on the issues presented, but no such brief has been discovered.

"For all of the foregoing reasons, Premier's Motion to Dismiss is hereby Denied. The Court hereby directs the attorneys for both parties to meet and confer forthwith toward the end of deciding how this case can be expeditiously concluded. The Court is prepared to give a trial setting as soon as the parties are ready. It may be possible for the parties to stipulate most if not all of the facts in the case, which would also expedite a final ruling, and they are encouraged to explore this possibility. The parties are further directed to correspond with the Court, and by copy to each other, no later than Dec. 5, 1980, advising the Court of the status of this case at that time, including whether or not the case is ready for trial and whether the parties feel that a formal pre-trial conference with the Court would be helpful."

The action was consolidated with three other seizure actions involving the identical law question based on virtually identical facts. The parties filed motions for summary judgment and agreed that the disposition of the motion for summary judgment would effectively terminate the actions. In ruling in favor of the government, the court said:

"The United States seeks condemnation of the boxes of K.H.3 on the grounds that they were brought into the United States in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq.* (hereinafter 'the Act'). All facts necessary to disposition of this case have been stipulated to by the parties or are conclusively established by uncontested affidavits.

"Section 505(a) of the Act provides that 'No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.' 21 U.S.C. §355(a). . . . The Act provides that any new drug introduced into interstate commerce in violation of section 505(a) 'shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned . . . ' 21 U.S.C. §334(a)(1). Any new drug so condemned 'shall be disposed of by destruction.' *Id.* (d)(1).

"The parties have stipulated that the drug under seizure, K.H.3, is a 'new drug' within the meaning of 21 U.S.C. §321(p)(1), and that it is

labeled for use in the treatment of disease in man. Further, that there is neither an approved 'New Drug Application' nor an 'Investigational Drug Exemption' in effect for K.H.3 and therefore the drug cannot come within the exemption of 21 U.S.C. §355. The only issues to be decided, then, are (1) whether the K.H.3 under seizure was introduced 'into interstate commerce' within the meaning of 21 U.S.C. §321(p); and (2) if so, whether the United States is equitably estopped from destroying the seized drugs because of the Government's alleged prior conduct in approving the entry of the drug into the United States for export as in-bond merchandise.

"The Court concludes that the K.H.3 under seizure was unquestionably 'introduced into interstate commerce,' and therefore is liable to be proceeded against by the United States. It is fundamental that Congress has the constitutional power 'to regulate Commerce with Foreign Nations, and among the several States. . . . ' *U.S. Const. Art. I §8, Cl.3*. Such power is not confined to commercial or business transactions. Indeed, '[f]rom an early date such commerce has been held to include the transportation of persons and property no less than the purchase, sale, and exchange of commodities, *United States v. Hill*, 248 U.S. 420, 423, and goods may move in commerce though they never enter the field of commercial competition. . . . '

"Claimants urge, however, that the drugs were never introduced into interstate commerce because the drugs were transported 'in bond' from the United Kingdom and the Republic of Germany to the state of Texas, solely for the purpose of being exported to foreign countries. See Tariff Act of 1930, 19 U.S.C. §1553. While this argument undoubtedly has a certain surface appeal, it ultimately fails. Congress has explicitly precluded the bonding of 'merchandise the importation of which is prohibited.' K.H.3 cannot qualify for protection under the bonding statute since it clearly cannot legally be imported under 21 U.S.C. §355(a). *United States v. 300 Oz. Gerovital Lotion*, 492 F. Supp. 114 (C.D. Cal. 1980); *Laboratories Kem, S.A., Inc.*, Civil No. 76-804-N (S.D. Cal. 1979). Therefore, as improperly bonded merchandise introduced into interstate commerce, the drugs are subject to destruction under 21 U.S.C. §344. *U.S. v. Gerovital, supra*; see *United States v. 76,532 Pounds of Frog Legs*, 423 F. Supp. 329, 337 (S.D. Tex. 1976).

"The Claimants here argue that since the final destination of the drug is not within the United States, the drugs have not been introduced 'into' commerce. In support of this contention, they cite several cases which draw distinctions between the word 'into' as opposed to the words 'in,' 'from,' and 'through.' The word 'into,' however, must be read in light of the modifying words that follow. Thus, those authorities dealing with what is meant by 'into a state' or 'into a country' are inapposite. The pertinent language of the Act does not simply prohibit introduction of certain drugs 'into the United States' but rather 'into interstate commerce.' 21 U.S.C. §355(a). The Act then defines interstate commerce as 'commerce between any state or territory and any place outside thereof. . . . ' 21 U.S.C. §321(b)(1). As mentioned above, 'commerce' includes interstate shipments or transportation *as such*. *Powell v. U.S. Cartridge Co.*, 339 U.S. 512. Therefore, the meaning of the term 'into interstate commerce' necessarily encompasses the introduction of items into the flow of shipments and transportation within the United States.



"Claimants also contend that the United States is equitably estopped from proceeding against the drugs because Claimants and others have been purchasing K.H.3 and bringing it in-bond from Europe through Texas for export for at least six years. Since the United States never proceeded against the prior shipments, Claimants claim that the United States is now estopped from proceeding against them.

"The general rule that the government is immune from the defense of equitable estoppel has, in recent years, been severely criticized and limited. See *United States v. Georgia Pacific Co.*, 421 F.2d 92, 99 (9th Cir. 1970). The Fifth Circuit takes the position that equitable estoppel is a proper defense against the United States only in certain situations, *United States v. State of Florida*, 482 F.2d 205, 209 (5th Cir. 1973), stating the test to be: 'Whether the defense of equitable estoppel may be asserted against the United States in actions instituted by it depends upon whether such actions arise out of transactions entered into in its proprietary capacity or contract relationships, or whether the actions arise out of the exercise of its power to government. The United States is not subject to an estoppel which impedes the exercise of the powers of government, and is not estopped to deny the validity of a transaction or agreement which the law does not sanction. *Sanitary Dist. v. The United States*, 266 U.S. 405 (1925); *Utah Power & Light Co. v. United States*, 243 U.S. 389 (1916). (emphasis added).' While the distinction between proprietary (private) and governmental (sovereign) function is not always an easy one to make, the Court is convinced that where as here the United States is suing to prevent violations of its laws, the United States is clearly exercising its powers of government and cannot be estopped from proceeding against the seized K.H.3.

"For the above reasons, it is therefore Ordered that the Motion for Summary Judgment by the United States be Granted and the cross-motions for summary judgment by the Claimants be Denied."

For the reasons explained in the above opinion, the court granted summary judgment to the government and ordered the article destroyed. (F.D.C. No. 62934; S. No. 80-122-315; N.J. No. 15)

Metronidazole tablets, and other specified drugs, at Brooklyn, E. Dist. N.Y. Charged 12-12-80: when shipped by Pharmadyne Laboratories Inc., Elmwood Park, N.J., the articles were new drugs without effective approved New Drug Applications; 505(a). Default decree ordered destruction. (F.D.C. No. 63203; S. No. 80-194-186; N.J. No. 16)

MEDICAL DEVICES

X-ray control panel, Traceray III, at Louisville, W. Dist. Ky.

Charged 10-15-79: the article, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed because the device would emit radiation beyond the pre-set exposure time—502(j); the accompanying labeling was 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).

The article was claimed by Anthony Selton (Community Medicine Foundation Inc.), Tarboro, N.C. A consent decree authorized release

to the claimant for bringing into compliance. Pursuant to the conditions of the decree, the claimant obtained and filed a bond. However, the claimant was unable to bring the article into compliance within 30 days (as required by the decree) and the claimant advised FDA that it had abandoned its efforts to bring the article into compliance. Upon motion of the claimant, the bond was cancelled, the claimant was relieved of its responsibilities for compliance operations, and a U.S. marshal was ordered to retain custody of the condemned article pending issuance of an order of disposition. The government moved for an order of destruction. The court found that the claimant had failed to bring the article into compliance and accordingly ordered the article destroyed. (F.D.C. No. 62625; S. No. 79-229-221; N.J. No. 17)

X-ray control panel, Traceray III, at Miami, S. Dist. Fla.

Charged 10-10-79: the article, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed because the article would emit radiation beyond the pre-set exposure time—502(j); the accompanying labeling was 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 the possessor for reconditioning. However, the article was subsequently destroyed. (F.D.C. No. 62517; S. No. 79-166-427; N.J. No. 18)

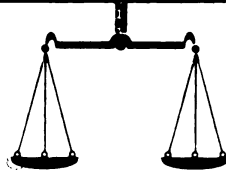
X-ray system, Traceray IV, at Pueblo, Dist. Colo.

Charged 10-2-79: the article, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed because the device would emit radiation beyond the pre-set exposure time; 502(j). Default decree ordered destruction. (F.D.C. No. 62533; S. No. 79-195-670; N.J. No. 19)

X-ray system, Traceray III, at Landover, Dist. Md.

Charged 12-17-79: the article, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., was dangerous to health when used as directed because the device would emit radiation beyond the pre-set exposure time—502(j); the accompanying labeling was 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). Default decree ordered destruction. (F.D.C. No. 62502; S. No. 79-207-186; N.J. No. 20)

X-ray systems, Traceray III, 14 seizure actions, at Dayton, S. Dist. Ohio; Greenville, S. Dist. Ohio; Dayton, S. Dist. Ohio; Mansfield, N. Dist. Ohio; Chalmette, E. Dist. La.; Rockville, S. Dist. Ind.; Muncie, S. Dist. Ind.; Washington, S. Dist. Ind.; Mt. Vernon, S. Dist. Ind.; Knightstown, S. Dist. Ind.; Bedford, S. Dist. Ind.; Wausau, W. Dist. Wis.; Spokane, E. Dist. Wash.; and Los Angeles, C. Dist. Calif. Charged 10-23-79, 10-23-79, 10-23-79, 10-19-79, 10-1-79, 10-9-79, 10-9-79, 10-9-79, 10-9-79, 10-9-79, 10-9-79, 10-19-79, and 10-9-79 (amended 10-29-79): the articles, which had been manufactured by Western States Supply Ltd., Pueblo, Colo., were dangerous to health when used as directed because the devices would emit radiation beyond the pre-set exposure time—502(j); the accompany-



ing labeling was false and misleading in claiming compliance with the regulation's standards, and in claiming that the devices would deliver the radiation exposure stated in the instruction manual—502(a); and the articles' quality fell below their purported quality—501(c). Consent decrees authorized release to owners/possessors for reconditioning. (F.D.C. Nos. 62481, 62482, 62483, 62500, 62503, 62508, 62509, 62510, 62511, 62512, 62513, 62515, 62534, 62587; S. Nos. 79-216-127, 79-216-128, 79-216-130, 79-186-073, 79-171-864, 79-186-855, 79-192-008, 79-199-595, 79-199-594, 79-187-362, 79-199-596, 79-201-993, 79-152-919, 79-214-645; N. J. No. 21)

NOTICE OF JUDGMENT on Civil Penalty Action

Bucky X-ray International Inc., and Peter A. Bucky, New York, S. Dist. N.Y.

Charged 10-16-79 in a complaint for injunction and civil penalties: that the defendants designed, commercially promoted, sold and assembled cabinet X-ray systems used in interstate commerce for mail and package inspection and which X-ray systems are defined as "electronic products"; that when a partially assembled cabinet X-ray system identified as "Buckysearch X-ray Unit (Unit 1)" was shipped to Chicago, Ill., the X-ray system did not comply with the federal standards for X-ray systems and electronic products, since it lacked a key-actuated control, since it lacked (1) an indicator (other than milliammeters) to indicate when, and only when, X-rays were being generated and (2) an indicator (visible from each door, access panel, and port) which was legibly labeled "X-Ray ON," and since it lacked the date of manufacture permanently affixed or inscribed by means of tag or label; and proper certification that the units conformed to all applicable standards was lacking, initial reports to FDA prior to the shipment of the units were lacking, and FDA employees were not permitted to inspect documents concerning the defendants' cabinet X-ray systems; when a cabinet X-ray system identified as "Unit 2" was shipped to Hartford, Conn., the X-ray system did not comply with the same federal standards as charged against Unit 1 above and also lacked a label stating "Caution: X-Rays Produced When Energized near the x-ray controls"—42 U.S.C. 363j(a)(1) and (5), 42 U.S.C. 363j(a)(3) and (4); that the defendants had been notified they were in violation because they had not submitted specified reports; that the defendants had not notified the purchasers of the defects in the systems and had not corrected the defects; and that the defendants had failed and had refused to comply with the law.

In answering the government's complaint, the defendants demanded trial by jury; the defendants admitted the distribution of two portable, collapsible type of X-ray units to only two customers; and the defendants asserted that the distribution of such units had been discontinued, asserted that the X-ray units had been built according to federal and local standards with all protective and safety devices, with caution signs and with a warning red light when the machine was in operation; that a misunderstanding resulted when FDA investigators came unannounced to the defendants' business office; that the defendant firm had always tried to live within the regulations but that the government's maze of regulations was so vague as to be impossible to comply with, understand and interpret; that the government's cause of action was barred by the statute of limitations and, in any event, the government was guilty of laches; and that this enforcement would

abridge the defendants' privileges and immunities, deprive them of property without due process of law, and deny them the equal protection of law.

The government served written interrogatories on the defendants and requested them to produce certain documents. The defendants responded to the government's written interrogatories and requests to produce documents, and also contended they were being forced to prepare the government's case by the proposed interrogatories which were overly broad and lacked specificity. The defendants contended that the action should never have been brought, and contended the action was instituted wholly and solely as a punitive measure against the individual defendant.

Ultimately, pursuant to stipulation of the parties, the defendants were ordered to make repairs and ordered to pay \$1,500 in civil penalties. (Inj. No. 895; S. No. 78-104-990 et al.; N.J. No. 22)

NOTICES OF JUDGMENT on Criminal Actions

Carr Brothers Institutional Foods & Paper Co. Inc., and Kenneth R. Carr, president, and James K. Carr, general manager, Plant City, M. Dist. Fla.

Charged 4-26-82: breakfast cereal and lentil beans were held under insanitary conditions in a building accessible to rodents and were exposed to contamination by rodents; 402(a)(4). Guilty plea by corporation; \$2,000 fine. Guilty pleas by individuals; \$1,000 fines and 6-month probations. (F.D.C. No. 63554; S. No. 79-166-061 et al.; N.J. No. 23)

Massachusetts Coastal Seafoods Inc., Lewis Lee Harrington, president, and Michael E. Mineo, vice president, Magnolia, Dist. Mass.

Charged 9-16-81 by the grand jury, and superseded 10-29-81: (Count 1) while held for sale, Greenland turbot (*Reinhardtius hippoglossoides*) was repacked and relabeled in April 1977 by the placement and display of words (which were contrary to fact) consisting in part of "Carnation North Atlantic Flounder Net Wt. 16 ozs. (1 lb.) Distributed By Seabrook Foods, Inc., Great Neck, N.Y., Oceans of the World, Inc., Los Angeles, Calif." and resulting in: the indicating (by false and misleading labeling) that the Greenland turbot was flounder; the offering for sale of Greenland turbot under the name of another food, flounder; and the placing of a label which did not bear the common or usual name of the food; and (Count 2) while held for sale, Greenland turbot (*Reinhardtius hippoglossoides*) was repacked and relabeled in March 1977 by the placement and display of words (which were contrary to fact) consisting in part of "Carnation Quick Frozen Breaded Natural Fillets Flounder, Ingredients: Selected Flounder Fillets, Net Wt. 5 lbs., Seabrook Foods, Inc., Seafood Division, Great Neck, N.Y., Oceans of the World, Inc., Los Angeles, Calif.," and resulting in: the indicating (by false and misleading labeling) that Greenland turbot was flounder; the offering for sale of Greenland turbot under the name of another food, flounder; the placing of a label which did not bear the common or usual name of the food; and when shipped, with intent to defraud and mislead, to (Count 3) Seabrook, N.J., and (Count 4) Englewood, N.J., shipments of Greenland turbot, labeled in part "Carnation North Atlantic Flounder Fillets" or "Carnation Brand Flounder Fillets," were in violation of the law as above;



403(a)(1), 403(b), 403(a)(1).

The defendants pleaded not guilty and made a number of motions for discovery and inspection. With respect to such motions by each of the three defendants, request No. 1 asked the government for any and all oral, written or transcribed statements made by the defendants or of any person whose statements might legally bind the defendants, in respect to conduct constituting the offense alleged; request No. 2 asked the government for a copy of the defendants' criminal record, if any; request No. 3 asked for reports of physical or mental examinations and of scientific tests or experiments, or copies; request No. 4 asked for copies of photographs, papers, documents, photograph books, and tangible objects, within the possession, custody and control of the government, which were intended for use as evidence in chief at the trial, or were obtained from or belonged to the defendants or any co-defendants; request No. 5 asked for an inventory of all property seized by the government during the arrest of the defendants; request No. 6 asked for all available statements made by co-defendants or any alleged participants not named in the indictment which the government intended to introduce at trial and which might tend to implicate the defendants; request No. 7 asked for an inventory of all seized property which: (a) had been seized from the defendants or defendants' premises; and/or (b) had been seized from other persons or premises and which tended to implicate defendants; request No. 8 asked for copies of all government surveillance photographs taken during the investigation leading to the indictment; request No. 9 asked for the names and addresses of all government informants furnishing information either knowingly or unknowingly either before, during or after the commission of the alleged crimes; request No. 10 asked for the names and addresses of all government agents gathering information relative to the investigation of the alleged offenses; request No. 11 asked for the names, addresses, field of expertise and the substance of the testimony of any of the government's intended expert witnesses; request No. 12 asked for all criminal records, if any, of the government's trial witnesses; request No. 13 asked for the names and addresses of all witnesses who testified before the grand jury pertaining to the present indictment; and request No. 14 asked for the names and addresses of all witnesses having personal knowledge of matters alleged in the indictment and/or intended by the government to be called at the trial.

On Nov. 2, 1981, the court ruled on the motions, saying:

"Pursuant to Rule 12(d) of the Local Rules of this Court, this court takes the following action on the pretrial motions filed by the defendants:

A. Motions Filed by Defendant Harrington

"1. *Motion for Discovery and Inspection:* With respect to Request No. 1, motion allowed to the extent of any relevant written or recorded statements made by the defendant, or copies thereof, within the possession, custody, or control of the government, the existence of which is known, or by the exercise of due diligence may become known, to the attorney for the government; the substance of any oral statement the government intends to offer in evidence at trial made by the defendant whether before or after arrest in response to interrogation by any person then known to the defendant to be a government agent; and recorded testimony of the defendant before a grand jury

which relates to the offense charged. In all other respects, Request No. 1 is denied.

"Request No. 2 is allowed.

"Request No. 3 is allowed.

"With respect to Request No. 4, motion allowed to the extent that the defendant may inspect, copy or photograph such exhibits and documents as the government intends to offer in its case-in-chief, or which were obtained from or belong to the defendant.

"Request No. 5 is allowed to the extent that inventories which have already been prepared and attached to a return on a search warrant shall be produced. In all other respects, Request No. 5 is denied.

"With respect to Request No. 6, to the extent that defendant seeks discovery of statements of co-defendants or co-conspirators who will be government witnesses at trial, discovery of those statements are prohibited under the express terms of the Jencks Act (18 U.S.C. 3500). . . . To the extent that defendant seeks the statements of co-conspirators and co-defendants who will not be called as government witnesses, those statements are likewise not discoverable under controlling authority. . . . Request No. 6 is accordingly denied.

"Request No. 7 is allowed to the same extent as set forth with respect to Request No. 5 above.

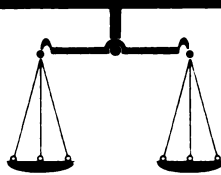
"Request No. 8 is allowed.

"With respect to Request No. 9, as drafted, the motion is denied. To the extent, however, that the United States is under an obligation to disclose the identity of an informant under the rationale of *United States v. Roviato*, 353 U.S. 53 (1957), *United States v. Picard*, 464 F.2d 215 (1st Cir. 1972), and *United States v. Estrella*, 567 F.2d 1151 (1st Cir. 1977), the United States is hereby ordered to take all reasonable steps necessary to ensure that the informant will be available for a pre-trial interview (should defense counsel desire to interview him, and should the informant desire to be interviewed) and/or for trial (should defense counsel choose to call the informant as a defense witness). Cf. *United States v. Nutile*, 550 F.2d 701 (1st Cir. 1977).

"In the event that the attorney for the government cannot determine whether or not the identity of the informant must be disclosed under the circumstances of the particular case, he or she may apply to this court for an *in camera* hearing and ruling thereon.

"Requests Nos. 10 and 11 are denied.

"With respect to Request No. 12, as drafted, the motion is denied. If the United States, however, knows, or has reason to know, that any of its witnesses has a prior conviction(s), then it is incumbent upon the attorney for the government to take whatever steps that are reasonable in the circumstances in order to obtain properly authenticated copies of such convictions for use by defense counsel at trial. Such authenticated copies, however, need not be tendered to defense counsel until, and unless, the witness actually testifies at trial. Alternatively, the attorney for the government—in lieu of obtaining properly authenticated records—may stipulate at trial as to the convictions of its witnesses, if such convictions are otherwise admissible for impeachment pursuant to the provisions of Rule 609, *Federal Rules of Evidence*, or other applicable rule of law. Nothing contained herein shall be construed as requiring the Chief Probation Officer for this District to search for such records, or to make available probation records maintained by his office.



"Request No. 13 is denied.

"With respect to Request No. 14, to the extent that the motion relates to persons who will not be called as trial witnesses, motion denied. To the extent that the request relates to trial witnesses, motion denied. Even if it is proper to assume that this court has the authority to order the government to disclose the names and addresses of its witnesses (compare Conference Committee Notes, House Report No. 94-414, *United States v. Brown*, 535 F.2d 424, 429 (8th Cir. 1976); *United States v. Pelton*, 578 F.2d 701, 708 (8th Cir. 1978); *United States v. Krohn*, 558 F.2d 390, 394 (8th Cir.), certiorari denied, 434 U.S. 868 (1977); *United States v. Rogers*, 549 F.2d 490, 494 (8th Cir. 1976), certiorari denied, 431 U.S. 918 (1977); and *United States v. Mitchell*, 540 F.2d 1163, 1166 (3d Cir. 1976), with *United States v. Cannone*, 528 F.2d 296 (2d Cir. 1975)), the motion—in its present form—does not even warrant the exercise of that discretion, since defendant has only made a generalized request without any showing of need in the circumstances of this case. . . .

"2. *Motion for Disclosure of Prior Misconduct, Crimes or 'Bad Acts'*: To the extent that the government intends to offer evidence of other crimes or wrongs otherwise admissible under the provisions of Rule 404(b), *Federal Rules of Evidence*, in its case-in-chief, the government shall provide the defendant, to the extent known by the government, with a generic description of the other crime or wrong, its date, and its place.

"To the extent that the government intends to offer a prior conviction under the provisions of Rule 404(b) and 803(22), *Federal Rules of Evidence*, in its case-in-chief, the government shall provide defendant with a copy of that conviction.

"In all other respects, the motion is denied.

"3. *Motion to Enlarge Time for Filing of Motion to Suppress*: Motion allowed.

"4. *Other Motions*: To the extent that this motion seeks leave to file other pretrial motions (other than a motion to suppress as set forth immediately above), motion denied without prejudice to defendant filing a motion for leave to file a specific motion(s), provided that counsel for defendant make a good and sufficient showing as to why the motions could not have been otherwise timely filed.

"To the extent that defendant seeks to join other unspecified motions (including so-called 'omnibus motions') filed by other defendants, motion denied. . . . [On motions filed by other defendants, like rulings were made]."

Subsequently, the defendants changed their pleas. Guilty plea by corporation to Counts 3 and 4; \$20,000 fine. Guilty pleas by Harrington to Counts 1 and 2 and by Mineo to Counts 3 and 4; \$2,000 fine each, imprisonment for one year, suspended, and probation for one year. (F.D.C. No. 61516; S. No. 77-91-535 et al.; N.J. No. 24)

NOTICES OF JUDGMENT on Injunction Actions

American Bakery & Pastry Inc., John F. Lalka, president, John R. Lalka, vice president, and Ronald J. Lalka, assistant treasurer, Detroit, E. Dist. Mich.

Charged 10-25-79 in a complaint for injunction: that the defendants at this bakery held for sale, after interstate shipment, various bakery ingredients (e.g., flour, sugar, donut mix and modified whey solids)

and prepared, packed and held for sale various bakery products (e.g., cakes, bread and donuts) after interstate shipment of their components; that such bakery ingredients and products were held, prepared or packed under insanitary conditions; that some of such bakery ingredients and products contained insect filth; that FDA inspections of the defendants' bakery revealed a number of specified insanitary conditions; and that the defendants had been warned repeatedly of the insanitary conditions in their bakery; 402(a)(3), 402(a)(4).

A consent decree of permanent injunction enjoined the complained of violations, and enjoined continued operations involving interstate foods unless and until a number of specified conditions were met and unless and until all the food on hand at the defendants' bakery had been examined for filth, necessary analyses had been made, and all food shown to be contaminated was either destroyed or otherwise brought into compliance with the law. (Inj. No. 922; S. No. 79-185-482 et al.; N.J. No. 25)

Samuel Damato, t/a D'Amico's Bread Co., Worcester, Dist. Mass.

Charged 10-18-79 in a complaint for injunction: that the defendant, at his Worcester, Mass., plant, manufactured, processed and held for sale breads, rolls and pastries after interstate shipment of their components; that the defendant's flour contained insect filth; that the defendant's breads, rolls and pastries had been prepared, packed and held under insanitary conditions; that FDA inspections disclosed a number of specified insanitary conditions; that FDA analyses confirmed the insanitary conditions; and that the defendant had been warned of the insanitary conditions in his plant; 402(a)(3), 402(a)(4).

A consent decree of permanent injunction enjoined the complained of violations and enjoined manufacturing, packing, holding and distributing food which contained interstate components and which had been prepared, packed or held in the defendant's plant unless and until a number of specified methods, facilities and controls were established, operated and administered to assure that food was not contaminated and unless and until all articles of food on hand at the defendant's plant were examined for filth, necessary analyses were made by FDA, and all foods shown to be contaminated were destroyed or otherwise brought into compliance with the law. (Inj. No. 924; S. No. 78-105-644 et al.; N.J. No. 26)

Patricia A. Purcell, t/a Mid-Michigan Laboratories, Boon, W. Dist. Mich.

Charged 6-2-80 in a complaint for injunction: that the defendant manufactured, processed, packed, labeled and distributed in interstate commerce *in vitro* diagnostic products (microbiological culture media); that such products, which were devices within the meaning of 21 U.S.C. 321(h), contained microbial filth; that such products had been prepared, packed or held under insanitary conditions; that the methods used in, and the facilities and controls used for, their manufacture, packing and storage were not in conformity with good manufacturing practice; that FDA inspections revealed a number of specified deviations from good manufacturing practice regulations; and that the defendant was well aware that her activities were in violation of the law and had been warned of the deficiencies in her facility at Boon, Mich.; 501(a)(1), 501(a)(2)(A), 501(h).

A consent decree of permanent injunction enjoined the complained of violations and enjoined the production, packing, labeling or holding on the premises, and the interstate shipment of any devices (includ-



ing *in vitro* diagnostics, such as microbiological cultures media), unless and until specified methods, facilities and controls had been established, operated and administered in conformity with good manufacturing practice and all devices on hand were examined, necessary FDA tests were made, and all examined and tested devices were destroyed or otherwise brought into compliance with the law. (Inj. No. 935; S. No. 80-191-682 et al.; N.J. No. 27)

NOTICE OF JUDGMENT on Miscellaneous Action

PROven snake venom therapy and FDA regulatory letter requesting cessation of its manufacture and distribution, Miami, S. Dist. Fla.

Charged 9-26-80 by Joan F. Ripps, Faye Browning, James Yingst, Heddy Recht, Suzanne Toney (by her father James L. Toney), and Miami Serpentarium Laboratories Inc. (in an amended complaint), against the United States of America (through Department of HEW and FDA) in a complaint for injunction and declaratory judgment: that the individual plaintiffs suffered from various diseases (Joan Ripps—multiple sclerosis; Faye Browning—multiple sclerosis; James Yingst—multiple sclerosis and loss of eyesight; Heddy Recht—crippling arthritis; and Suzanne Toney—the eye disease Pars Planitis); that the treatment of multiple sclerosis, arthritis, inflammation, eye and other neurological disease with a snake venom preparation emanated from Miami Serpentarium Laboratories Inc. in 1954 to the time of this action; that it had been suggested that the venom therapy also might be effective in relieving symptoms of amyotropic, lateral sclerosis, muscular dystrophy and Parkinson's disease; that the individual plaintiffs had obtained positive results from the use of PROven (e.g., Joan Ripps—improved overall condition, remarkable transformation, immediate relief at the onset of any painful episode, improved and retained balance and coordination and restoration of hope; Faye Browning—benefits and freedom from pain and other symptoms, and partial restoration of sight; Heddy Recht—pain sub-

sided progressively and completely; Suzanne Toney—restoration of eyesight and disappearance of cloudiness symptoms); that the Miami Serpentarium Laboratories Inc., Miami, Fla., had received a regulatory letter from FDA requesting that the firm "cease all manufacturing and distribution of PROven (or any other similar product) for use in humans"; that the government action was arbitrary, unjustified and unreasonable, and that the government action deprived them of life, liberty and pursuit of happiness as well as due process of law and equal protection under the law.

The government moved to dismiss the action or, in the alternative, for summary judgment. In response to the government's motion, the plaintiffs (assenting to the government's motion for dismissal) moved for a voluntary dismissal of the complaint because they desired to file an amended complaint so as to cure any and all defects found. (Misc. No. 619; N.J. No. 28)

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

Notices of Judgment are prepared by Food and Drug Division, Office of the General Counsel, HHS.

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

Arthur Hull Hayes Jr., M.D., *Commissioner of Food and Drugs*
Washington, D.C., Nov. 1, 1982

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Section 705[375] of the Food, Drug, and Cosmetic Act: (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

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Read the Label, Set a Better Table. Dick Van Dyke explains how reading labels can help consumers both nutritionally and economically. 14 minutes. *Also in Spanish.*

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