

FDA CONSUMER

March 1980

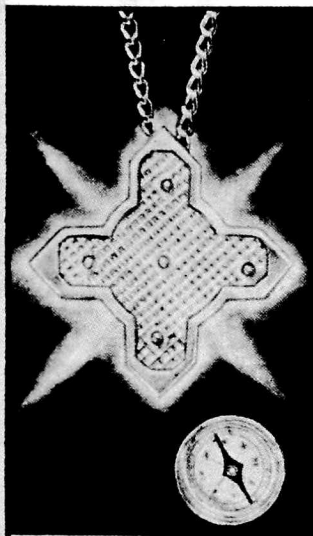
Time
Marches on
Despite
Serovital



Now, from France, home of Lourdes, come tales of new miracles!

Can This Amazing Cross Really Attract Life's Rewards To You?

From France, where the famed miracles of Lourdes took place, come stories of yet another remarkable series of events: stories of the lame discarding their crutches; the sickly becoming well; the troubled finding inner peace; failures achieving success.



THE STRANGE POWERS of the CROSS of MAGNATOR...

...can actually be measured. The needle of an ordinary compass will swing wildly when brought near the cross!

Heartwarming letters from grateful people describe miraculous changes in their lives. All these changes, they say, came soon after wearing an amazing Cross like the very one you see here. Some claim that they now can walk without crutches for the first time in years. Others swear that its powers ended long years of hopeless insomnia, relieved paralyzing anxieties and deep depression. Some claim it brought great physical and emotional energy. Others tell of greater success and satisfaction in business, love, and family relations. Incredible improvements in almost every aspect of their lives!

For example, consider the experience they tell of a 45-year-old woman of northern France. The reports say that she had problems with her ankles, knees, and legs until she was completely unable to walk. That doctors had no hope. That she was condemned to bed for life — until her son gave her a Cross like this as a gift. That thereupon her spirits lifted, her determination grew and her optimism returned. That movement stirred in her legs and a few days later she actually left her bed unaided. And that today, she functions normally and looks to the future with renewed strength and optimism.

Will this Cross bring you one of these 6 rewards?

The reward of health is what another woman joyously reports. After being bedridden for years, she says she wore such a Cross next to her body for 15 days. "My powers returned slowly to me and I succeeded in getting up," she says. "My joints obeyed me again. I feel like 20 again."

The reward of energy is the result reported by yet another woman who wore a Cross like this. She says, "... as soon as I put the Cross around my neck something happened within me. First, I felt full of energy. The next day a little nervous, and finally on the third day, a marvelous feeling of relaxation."

The reward of freedom from pain is what thrilled the next sufferer most after wearing a Cross such as this. "... After 5 years of suffering," she says, "I was ready to try anything to alleviate my pains. That's why I decided to order my Cross last summer. Today, as you can see, I no longer need my walking stick. I can walk normally. I can go up and down stairs and go around the town as I used to."

The reward of sound, natural sleep without drugs by wearers of such a Cross is reported in a famous French publication. "As soon as your head touches the pillow you

experience a delicious feeling of relaxation. Even if you try to keep your eyes open, you'll feel them close themselves." The report goes on to tell how you will wake refreshed, bursting with new-found energy.

The reward of success is reported by others who claim they can work harder and longer with less strain and fatigue than they ever imagined. And their enthusiasm, they say, seems limitless, so they accomplish more in less time. To them, nothing seems impossible!

The reward of love comes to men and women who are mentally and physically prepared to receive love, say people who've worn Crosses like this. Some say that worn next to their bodies, it has helped them attract the love of others. But, wear one on your own body for a short time, and judge for yourself.

How does it work?

Who can really say what causes such miracles as these? Our representative journeyed to France to learn the secrets and then arranged to produce a limited quantity of the magnetic Cross you see here for distribution in the United States. We call it the Cross of Magnator, and its magnetic field can actually be scientifically measured. Some believe the Cross regulates the bio-magnetic current flowing through your body to relax muscles and tissues so the body can start healing itself and so you can live more positively, joyously, and successfully.

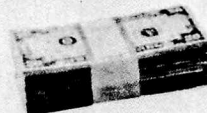
A magnificent object of beauty, too!

Of course, no one can promise that our exquisite Cross will produce miraculous results for you. It is something you must find out for yourself. We can, however, make this assurance: You will be completely delighted with the Cross as a magnificent object of the jewellers' craft and a superb personal adornment.

100% money-back guarantee
In any event, you risk absolutely

nothing when you order this magnificent Cross — because, if after 15 days, you are not absolutely delighted with it, and all the resulting benefits it may bring, simply return the Cross, and your money will be refunded in full. Promptly. With no questions asked.

Order today to qualify for a \$100.00 cash gift!



Once you have actually worn the Cross next to your skin, you may want to tell others about your experience. As an encouragement for you to do so, we will send you a unique honorarium of \$100.00 in cash — if your comment and experience is used to help us spread the word about the Cross. So, wear the Cross, and write us of your experiences. You must swear your statement is true and have it notarized by a notary public for it to be considered. When we receive your letter and decide it can be used, we will send you a certified check for \$100.00 cash.

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ORDER NOW AND SEE IF IT DOESN'T IMPROVE YOUR LIFE!

Cross of Magnator, Dept. MGC-54
416A Fox Pavilion, Jenkintown, PA 19046

Yes, I want to see if the Cross of Magnator can help me. Rush my order and I will wear it next to my skin for 15 days to judge the results. I must be completely satisfied or return it for a full refund (except postage and handling).

Please send me (MGC) Cross(es), gold-plated with 24" chain at only \$14.95 each. **SAVE \$3.00!** Order 2 for only \$26.90.

Please add 75¢ per cross to partially cover postage and handling.

Total amount enclosed \$_____ (Penn. residents add 6% sales tax).

Enclose check or money order. No CODs.

CHARGE IT! (check one) Exp. Date _____

☐ BankAmericard ☐ American Express

☐ MasterCard ☐ BANK NUMBER ☐ ☐ ☐ ☐

Credit Card # _____

Name _____

Address _____ Apt. # _____

City _____ State _____ Zip _____

Canadian customers please send orders to:
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Revelle, Ontario M9W 2K2

(Ontario and Quebec residents add sales tax)

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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.

Cover Design: Michael David Brown

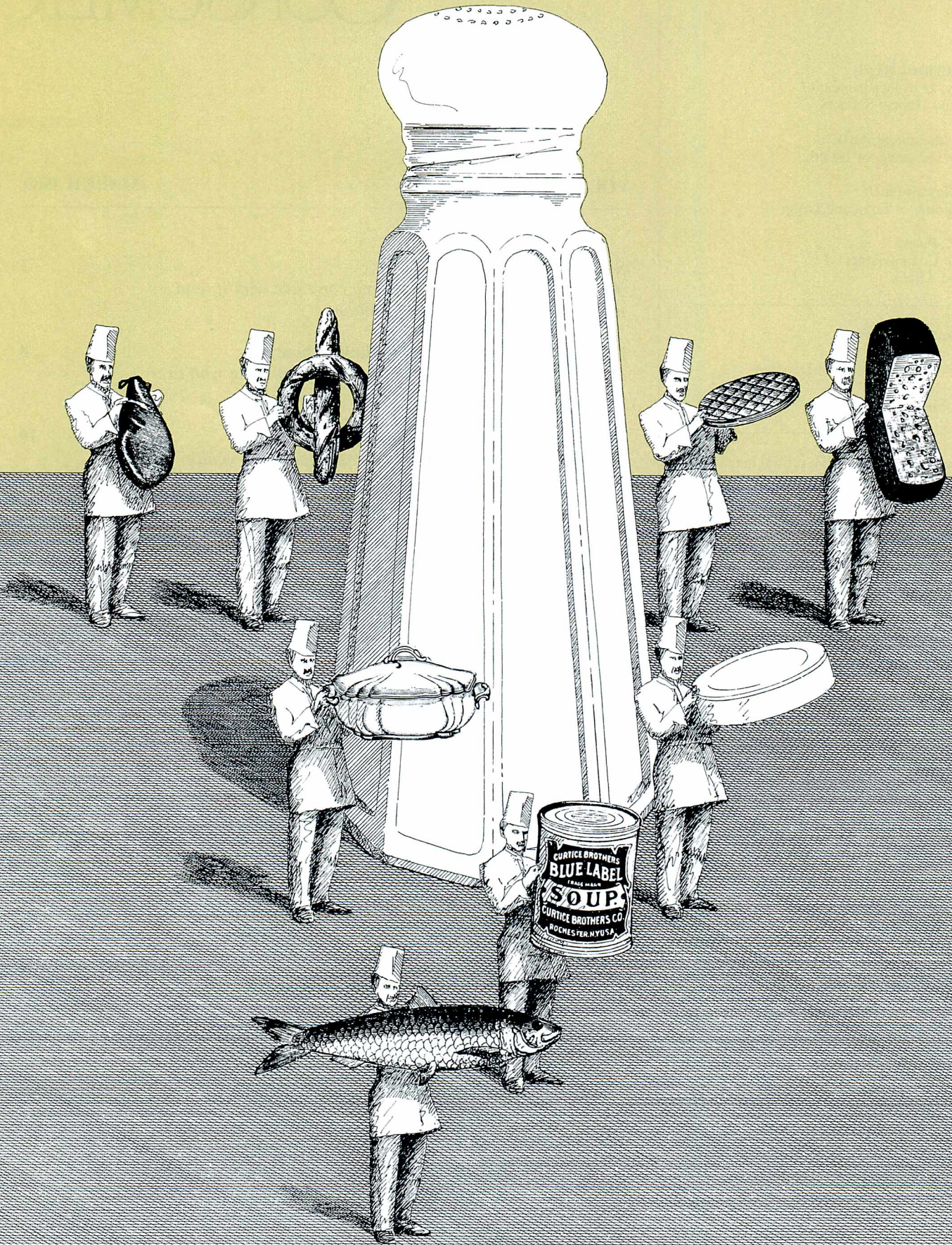
FDA CONSUMER

VOL. 14 NO. 2

MARCH 1980

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Inside Front Cover: This advertisement, which ran in the National Enquirer, was typical of the promotional efforts of American Consumer, Inc., a mail-order health and vanity firm. The company has since been placed under an unprecedented injunction, under which the firm must submit all labeling and promotional material to FDA before marketing food, cosmetic, or medical device products.



Salt Shakes Up Some Of Us

One thing that can't be taken with a grain of salt these days is salt. That's because salt contains sodium and sodium has been identified as a contributor to high blood pressure, a problem that millions of Americans have to contend with. Here's a roundup on the sodium problem.

by Louise Fenner

“**B**eing kissed by a man who didn't wax his mustache was—like eating an egg without salt,” said one of Rudyard Kipling's female characters. Although we may puzzle over the difference between mustaches with and without wax, we have no trouble visualizing the blandness of the saltless egg.

Salt—or sodium chloride—was probably the first food additive ever used when man discovered its ability to flavor and preserve meat and fish. Salt is certainly one of the most popular additives, second only to sugar in the total quantity added to food each year.

As with many other spices and flavorings, salt took on a special mystique in man's early days. Greeks and Romans included salt in their offerings to the gods. Covenants were sealed over sacrificial meals that included salt, and in parts of Africa and Tibet cakes of salt were once used as money. Even our word “salary” goes back to the days when the Roman army granted its officers an allowance of salt, called a “salarium.” That eventually was converted to an allowance of money the officers could use to buy salt and other necessary items.

Salt is a chemical compound of two substances that are unfriendly to man in their elemental states—sodium, a very reactive, soft, white, silvery metal; and chlorine, a toxic yellow-green gas. Salt is commercially mined from underground and surface deposits of rock salt, and is also obtained by evaporation and crystallization from seawater and other natural brines such as the Great Salt Lake in Utah. Since salt absorbs atmospheric moisture, it is usually combined with anticaking agents to prevent it from becoming a hard mass.

“It has been calculated that there are about 14,000 uses for salt,” reports the Salt Institute, a trade organization. Only 5 percent of all the salt used in the United States is food grade, but within the food-processing in-

dustry salt is essential to the production of many familiar products. It is a major flavoring ingredient, of course. Salt also helps cure meat and fish, forms the brine for pickles, olives, and sauerkraut, enhances the leavening of bread, and improves the taste of other ingredients. It makes cheeses turn out the way the cheesemaker wants by controlling fermentation. Salt also helps inhibit the growth of harmful bacteria in products such as bacon, sausage, and bread.

The addition of iodine to salt (in the form of cuprous iodide or potassium iodide) was instituted years ago as a public health measure to prevent goiter, an enlargement of the thyroid gland in the neck due to insufficient iodine. Salt manufacturers are not required to add iodine, so consumers should check labels to determine what type of salt they are buying. If the salt is iodized, the label must state: “This salt supplies iodide, a necessary nutrient.” Noniodized salt must indicate that no iodine has been added.

Americans like salt. Each of us eats an average of 2 to 2½ teaspoons of it a day—or about 8½ pounds a year. “Not me,” you say. “I don't put that much salt on *my* food!”

What comes pouring out of your salt shaker at dinner or during cooking tells only part of the story. It accounts for only about a third of all the salt in your diet. One-fourth to one-half comes from processed food, according to a panel of independent scientists who recently evaluated the use of sodium chloride as a food ingredient for the Food and Drug Administration. The remaining salt you eat occurs naturally in food and in some drinking water.

The panel's evaluation of sodium chloride was part of a continuing review of the safety of substances on FDA's “generally recognized as safe” (GRAS) list. The Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology (FASEB) is conducting the review for FDA.

In its final report on sodium chloride, published in August 1979, the FASEB committee estimated that Americans consume “not less than” 10 to 12 grams (equivalent to 2–2½ teaspoons) of sodium chloride a day. Since salt is about 40 percent sodium, a daily salt intake of 10 to 12

grams means that Americans are consuming at least 4 to 5 grams of sodium each day.

Many people are confused by the difference between sodium and salt. It is the *sodium* content of foods that is of health concern to some people. Sodium occurs naturally in many foods and is also added via salt and other sodium-containing ingredients.

To keep sodium in perspective, it's important to understand both its positive and negative aspects. Sodium is an essential nutrient—in fact, we could not survive without it. Sodium helps regulate body fluids (including blood) and maintain the balance of fluids and pressure inside and outside the cells. It also plays a major role in nerve impulse transmission, heart action, and the metabolism of carbohydrates and protein.

A daily human requirement for sodium is difficult to establish, because the need fluctuates depending on such conditions as excessive sweating and diarrhea (in which case additional sodium may be called for). Rather than recommending a specific daily amount, the National Research Council (of the National Academy of Sciences) last year issued an estimate of an “adequate and safe” sodium intake: 1,100 to 3,300 milligrams (mg) a day for adults.

Since 1,000 mg = 1 gram, the National Research Council's estimate of “adequate and safe intake” amounts to between 1.1 and 3.3 grams (compared with the 4 to 5 grams per day Americans now consume).

A healthy person's system can normally handle a wide range of sodium by conserving it when it is scarce and excreting any excess through the urine. However, in the past few years, the amount of sodium Americans consume has become a source of increasing concern to nutritionists, health professionals, and others who keep watch on the American diet. More and more evidence is linking excessive sodium intake with hypertension—high blood pressure—a disease that affects 10 to 20 percent of all Americans (estimates vary). Hypertension has been called a silent killer because it rarely produces warning

signals, yet it can lead to stroke, heart disease, and kidney failure.

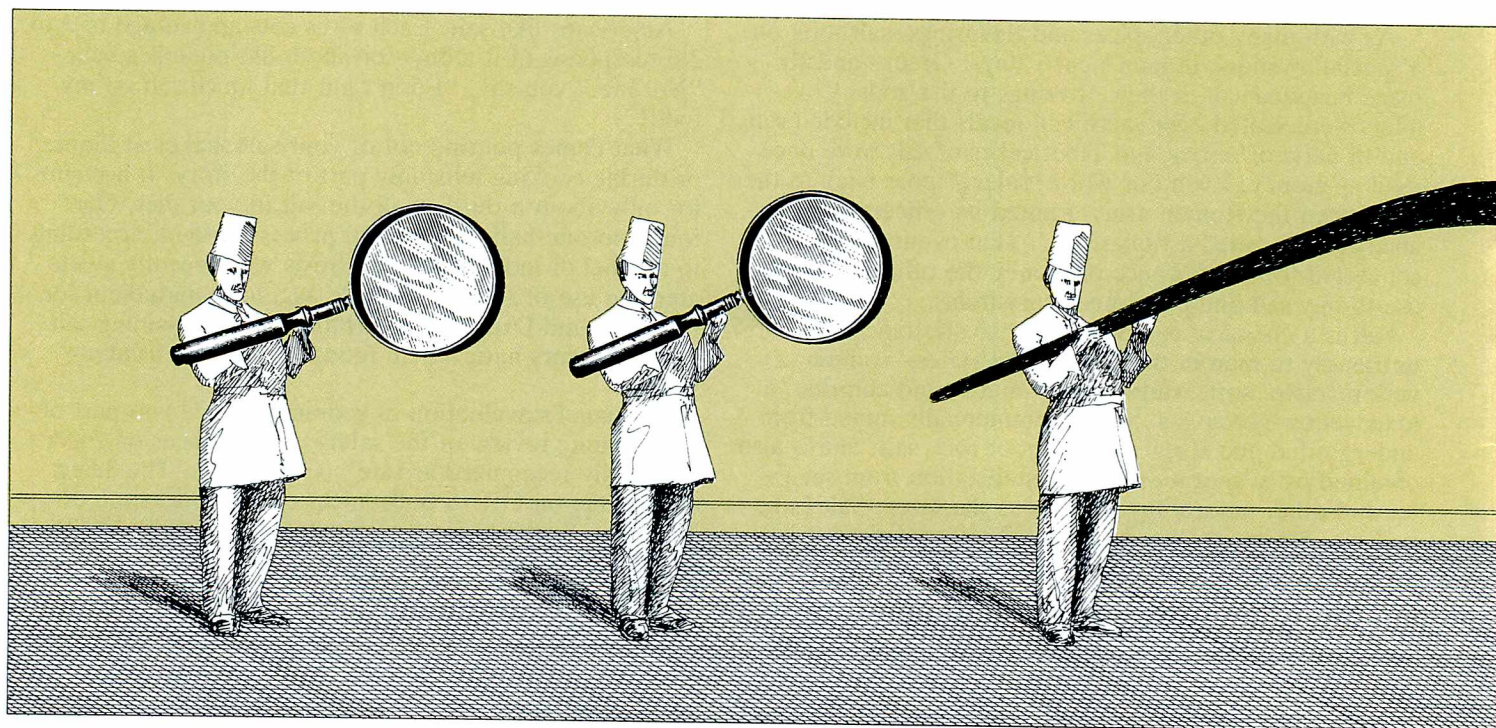
Although the body normally maintains a balance of sodium and other minerals at the proper level, evidence suggests that individuals who are genetically predisposed to hypertension may be increasing their risk by eating a diet high in sodium. Studies in animals and humans seem to support this theory.

As early as 1953, an experiment in which rats were fed various amounts of sodium chloride in their diets showed a positive correlation between the concentration of sodium chloride and the animals' blood pressure. In some well-known studies in the 1960's, a comparison was made between two strains of rats that were fed a diet high in sodium. One strain was genetically predisposed to hypertension and the other strain was resistant. The genetically sensitive group developed hypertension, while the resistant group remained normal. However, neither strain of rats developed high blood pressure on a normal diet.

In humans, it has long been established that a severe reduction in sodium intake will help lower the blood pressure of some individuals with hypertension. As early as 1920, one researcher reported successfully treating 20 patients with a low salt (sodium) diet, and many other reports have appeared in medical literature since then.

A substantial amount of evidence suggesting a relationship between sodium and hypertension comes from studies of populations that have different levels of sodium in their diets. Several geographically diverse populations, varying in size from a few hundred to a few thousand persons, do not exhibit essential hypertension (hypertension that cannot be traced to an underlying disorder). A low sodium intake is often cited as a characteristic of these groups, who range from South Sea Islanders to Brazilian Indians to Alaskan Eskimos. In contrast, some populations with a lot of sodium in their diets, such as the northern Japanese, have a very high incidence of hypertension and death from stroke.

Of course, sodium intake isn't the only difference be-



tween these populations. Many other factors are cited as possible contributors to their blood pressure patterns, including stress, age, body weight, genetic factors, chronic kidney infection, and potassium intake (the sodium/potassium balance in the body is very important for proper physiological function). Medical experts recognize hypertension as a complex disease in which a number of factors can operate—not only the foregoing, but also race (Blacks seem to be more susceptible than Whites), obesity, variations in kidney and endocrine function, congenital kidney abnormalities, and others.

From 10 to 30 percent of all Americans are born with a genetic predisposition to hypertension, the FASEB Select Committee on GRAS Substances estimated. Evidence suggests that when this genetic factor is present, a diet high in sodium will increase the risk of hypertension. It is not widely accepted that sodium actually *causes* hypertension. Many experts feel that if sodium consumption is high, the effects of other factors that are associated with high blood pressure might be intensified.

The Harvard Medical School Health Letter last year noted, "Few experts claim that salt [sodium chloride] is the sole cause of hypertension; rather, they describe salt as an important contributing factor in the 10 to 20 percent of Americans who are genetically susceptible to high blood pressure. And for such persons, the hidden salt in processed food of the typical American diet is a real hazard." (Note that this estimate of the percentage of genetically susceptible persons is somewhat lower than the FASEB committee's.)

Sodium restriction and weight loss (if appropriate) may control very mild elevations of blood pressure, the Medical School Health Letter also reported. However, most patients with blood pressure elevated to a certain level (above 160/100) will probably require antihypertensive medication. In these cases, sodium restriction may also be part of the treatment.

The growing evidence about sodium has prompted public health watchers, such as the Surgeon General and

the Senate Select Committee on Nutrition and Human Needs, to advise Americans to lower their consumption of salt. The 1979 document, "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention," maintained that Americans would "probably be healthier as a whole" if they made several dietary changes, including a reduction in salt.

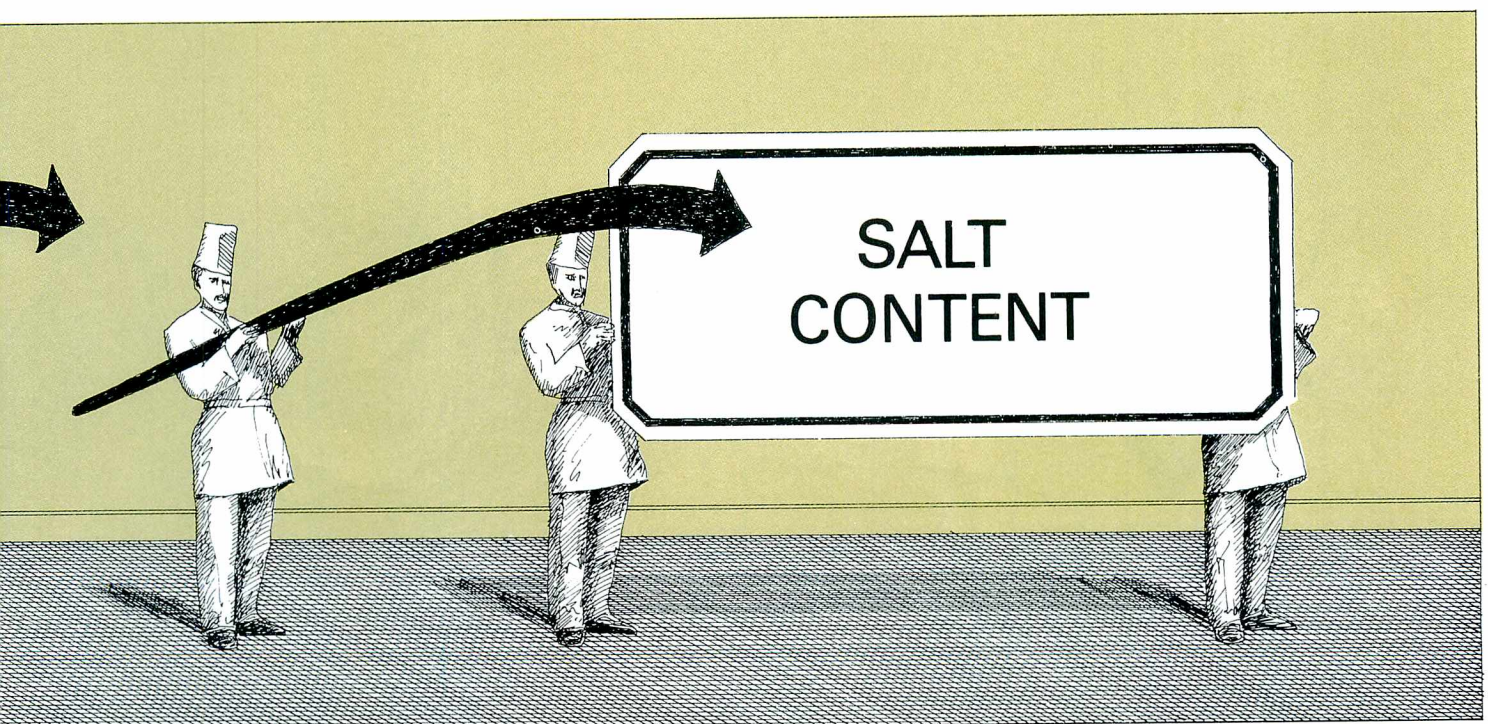
The Senate Select Committee's "Dietary Goals for the United States," published in 1977, suggested that Americans limit their intake of sodium chloride to about 5 grams a day. Senator George McGovern, chairman of the Senate Select Committee, later indicated in a letter to the Salt Institute that the 5-gram figure referred only to salt added to food commercially and by consumers. "This would be in addition to our nondiscretionary intake of approximately 3 grams of sodium chloride (sodium occurring naturally in foods expressed as sodium chloride)," McGovern stated. Thus, the committee's suggested limit for total salt intake would be about 8 grams a day for adults, or one-third less than current levels.

Echoing the same theme, the FASEB Select Committee on GRAS Substances last year told FDA: "It is the prevalent judgment of the scientific community that the consumption of sodium chloride in the aggregate should be lowered in the United States."

The committee's report on sodium chloride asserted: "The average daily intake of sodium expressed as sodium chloride from all sources . . . exceeds estimates of the amount that may elicit hypertension in susceptible individuals. A lower daily consumption of sodium chloride promises health benefits for the proportion of the population susceptible to hypertension."

To encourage Americans to use less sodium, the FASEB committee called for development of guidelines for restricting the amount of salt in processed foods, "a major contributor of dietary sodium," and for better labeling of how much sodium food contains.

Under current FDA regulations there are relatively few restrictions on the use of sodium chloride in food.



General regulations for GRAS substances state that such substances must be used in accordance with "good manufacturing practice." This means that the quantities of sodium chloride used must not "exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food."

The recommendation to restrict the amount of salt in processed foods is being evaluated by FDA. The Agency must consider whether such an action would involve a change in the GRAS status of sodium chloride and, if so, what type of change. FDA plans a tentative decision soon, but will make no final decision until industry and the public have the opportunity to express their views.

This year FDA intends to propose that sodium and potassium content be declared on nutrition labeling. Products that make nutritional claims or add nutrients are required to carry nutrition labeling, and many manufacturers provide it voluntarily. Potassium is included because some people, such as those with kidney disease, need to monitor both sodium and potassium in their diets. Regulations to define the terms "low sodium" and "reduced sodium" are also being considered so that label claims will have a standard meaning.

All these changes were described in a tentative policy statement issued by FDA in December 1979 as part of a joint effort between FDA, the U.S. Department of Agriculture, and the Federal Trade Commission to improve food labels.

What will knowing the amount of sodium in foods mean to consumers?

Substantial amounts of sodium are regularly added to processed foods, but not just in the form of salt. Some other common ingredients: sodium nitrite (a curing agent

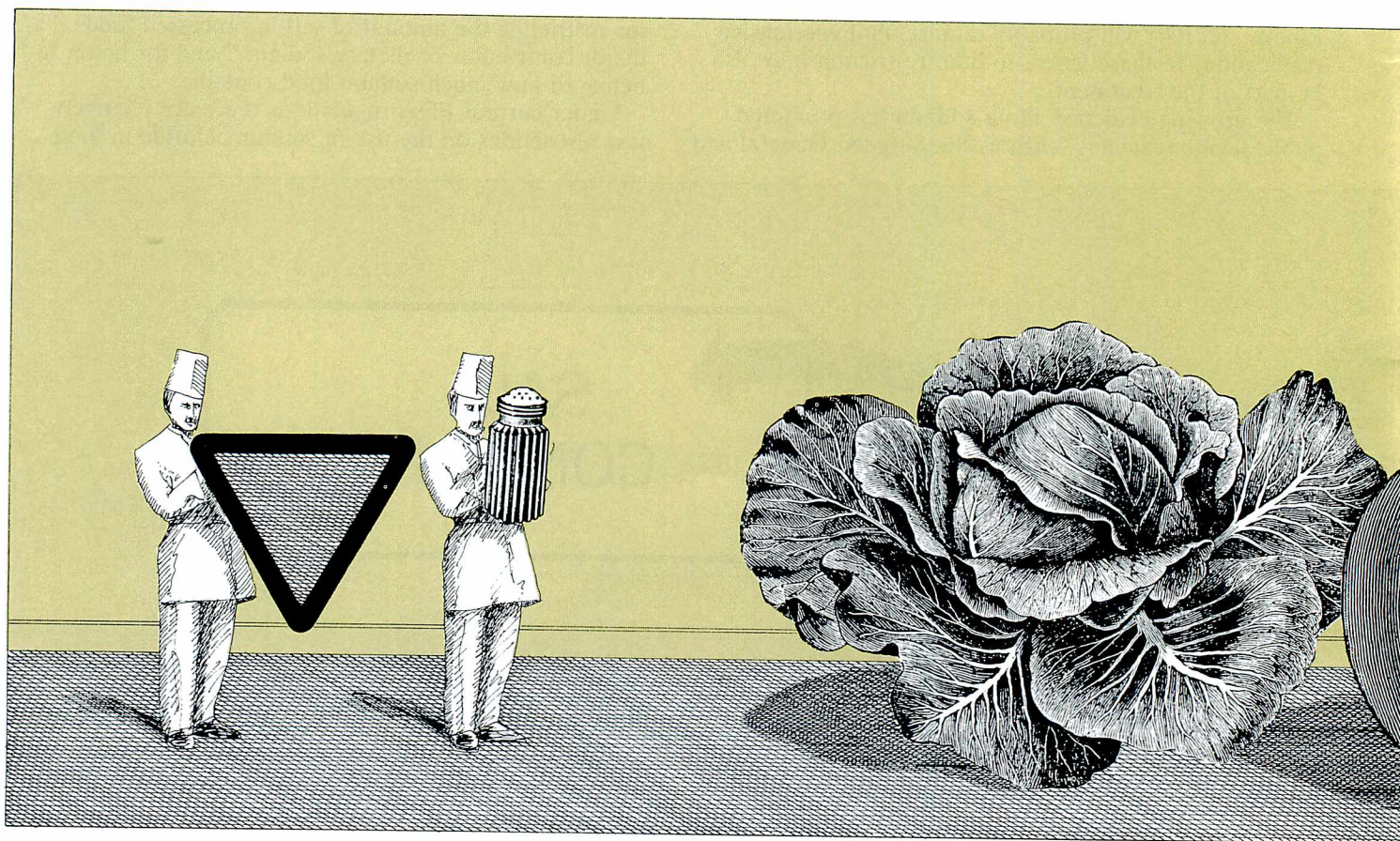
and preservative), sodium benzoate (a preservative), monosodium glutamate (MSG, a flavor enhancer), sodium bicarbonate (baking soda, a leavening agent), and sodium phosphate (a wetting agent for quick-cooking cereals).

For people who are trying to restrict their intake of sodium, eating is somewhat of a guessing game. There is no requirement that labels of food products state how much sodium they contain, except for foods claimed to be "low-sodium" or that are otherwise represented as being useful in sodium or salt-restricted diets.

The "hidden" sodium in processed foods can create difficulties for some people. Consider the predicament of a hypertensive patient who has been told by a physician to keep his or her sodium consumption down to 2,000 mg (2 grams) a day. A single serving of canned chicken noodle soup (about 1¼ cups) would use up over half the day's allowance of sodium. According to information furnished to FDA by one manufacturer, one serving of chicken or turkey noodle, tomato, chunky beef, vegetable beef, or cream of mushroom soup contains over 1,000 mg of sodium—but this fact is not stated on the label.

Besides canned and dried soups, some other processed foods that contain large amounts of sodium are canned vegetables, cheese, tomato juice, dill pickles, olives, canned tuna and crab, sauerkraut, frozen dinners, and condiments such as soy sauce, catsup, and salad dressing. Items such as instant pudding, breakfast cereals, ice cream, cookies, cakes, and bread also contain significant quantities of sodium.

Salt substitutes with little or no sodium are available, but these should be used only under advice of a doctor because they contain potassium or other substances that



should not be used by some individuals. Consumers can also buy low-sodium foods that offer enormous reductions in sodium content (for example, most low-sodium versions of the soups mentioned above contain less than 100 mg sodium.) These products are regulated as special dietary foods and must state their sodium content. Consumers should read the labels carefully, because some of these foods may contain more sodium than the purchaser realizes.

There is one drawback to low-sodium foods that most dieters will mention—the taste. There is just no denying it: To most people salt makes food more palatable.

“It took me a year to get used to the taste,” recalled Norma Chafe of Los Angeles. She has been restricting her intake of sodium for 7 years because of an intolerance to it. “Low sodium bread tastes like cardboard,” she said.

She avoids all processed foods except those labeled as low sodium or reduced sodium. Most of her experience with low-sodium food has been good, although she could recall at least two occasions when such products brought on nausea and swelling, indicating she had consumed a substantial amount of sodium.

Many more low-sodium products are available in America than in her native Canada, she found, but they are more expensive than regular products. Other than these special processed items, all her food has to be prepared from scratch.

“I can’t go to any fast-food place, although most other restaurants try their best if I ask them to leave out the salt when they cook,” she said. “I can’t have Chinese food because of the MSG and the soy sauce, or anything in a can or frozen. They don’t tell the amount of sodium,

and I’m afraid to try them.”

She was asked if food containing significant amounts of sodium now tastes unpleasant to her. “Oh no,” she said. “It tastes fantastic.”

For Norma and thousands of others on sodium-restricted diets, the addition of sodium content to nutrition labels will make it easier to find foods they can safely eat. And it should do a little to raise consumer consciousness about the amount of sodium in our diet.

“I think labeling and education will eventually act to restrict the amount of sodium that manufacturers put in foods,” a nutritionist with FDA commented. “If you want to watch your sodium intake, which product will you buy—the one with 1,000 milligrams of sodium or the one with 500 milligrams?”

Of course, after buying the low-sodium product, the consumer will need to resist the temptation to sprinkle the salt on at the table.

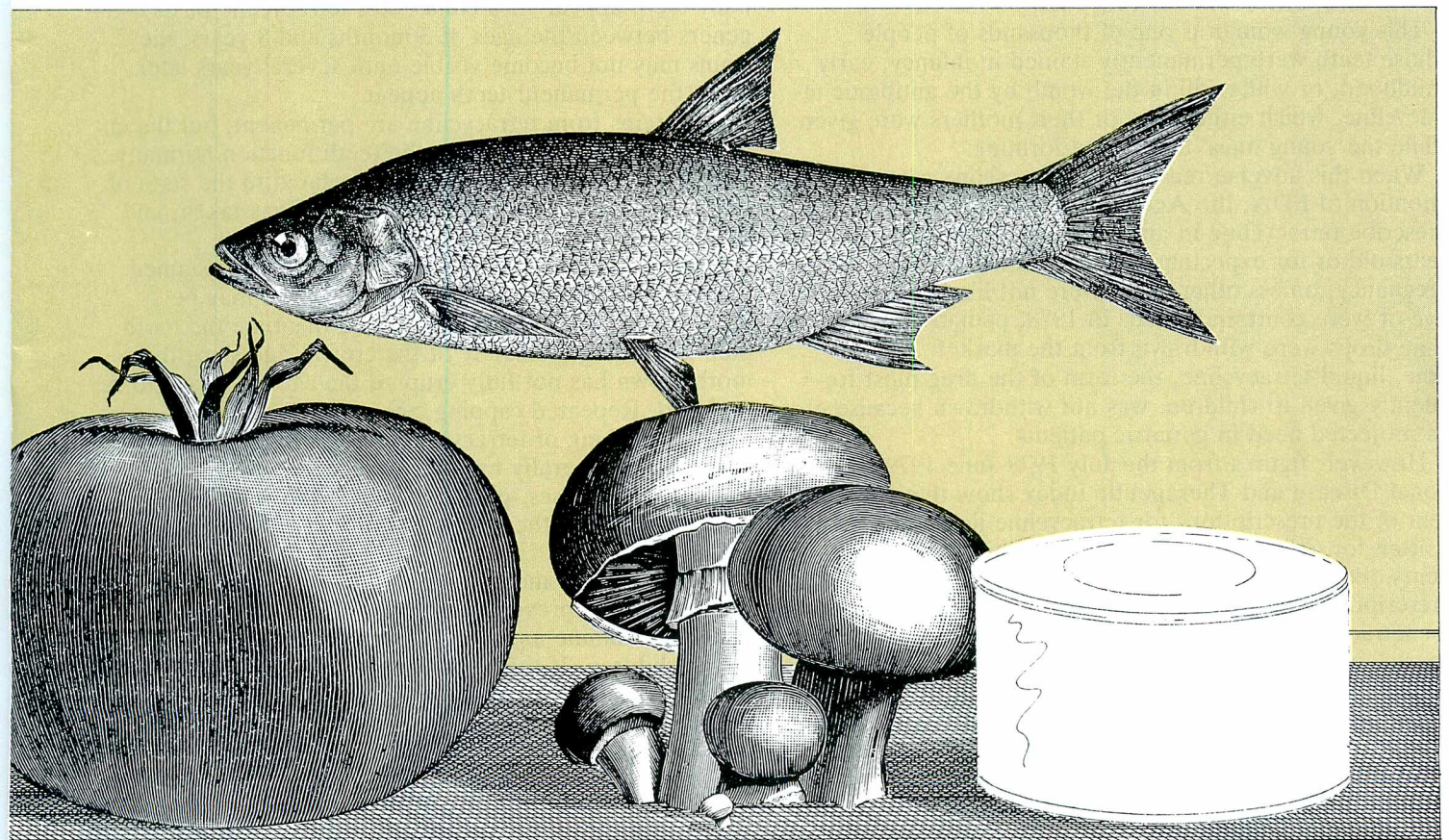
It does taste fantastic.

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

A copy of the final report of the FASEB Select Committee on GRAS Substances can be obtained from:

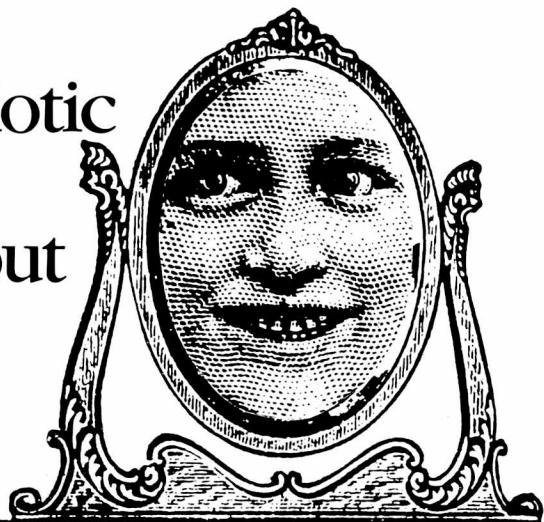
National Technical Information Service
U.S. Department of Commerce
P.O. Box 1553
Springfield, Va. 22161

The order number is PB298-139/AS. Current price is \$7.00.





Misused Antibiotic Nothing To Smile About



FDA has been unable, up to now, to make many physicians fully appreciate the unpleasant side effects—and social stigma—that can be imposed on some patients by prescribing the antibiotic tetracycline in inappropriate cases. It can cause newly forming teeth of young children and unborn babies to become a kind of tattletale gray as they grow up.

by Judith Willis

She gazes at herself in the mirror after putting on her first floor-length formal, a blue-green chiffon that brings out the color of her eyes. After one last brushing of her auburn hair and a dab of lipstick, her persimmon pink lips part in a smile revealing—gray teeth. She frowns and turns from her reflection.

This young woman is one of thousands of people whose teeth were permanently stained in infancy, early childhood, or while still in the womb by the antibiotic tetracycline, which either they or their mothers were given while the young ones' teeth were forming.

When this adverse reaction to tetracycline came to the attention of FDA, the Agency warned physicians not to prescribe tetracycline in any form for children under 8 years old or for expectant mothers during the last half of pregnancy, unless other drugs were not likely to be effective or were contraindicated. In 1978, pediatric tetracycline drops were withdrawn from the market. At that time, liquid tetracycline, the form of the drug most frequently given to children, was not withdrawn because of its projected need in geriatric patients.

However, figures from the July 1978-June 1979 National Disease and Therapeutic Index show that 60 percent of the prescriptions for tetracycline liquid are written for children 0 to 9 years old, while geriatric patients over the age of 65 account for only 6 percent of the prescriptions. Similarly, 80 percent of the prescriptions for tetracycline congener liquids (close pharmacological cousins of tetracycline with the same staining effect) are written for children under the age of 9.

The Agency is currently assessing this problem to see whether further regulatory action is necessary. In the meantime, consumers should be aware that tetracycline and its relatives may not be easily recognizable when prescribed by generic and commonly used brand names. The

generic names of tetracycline congeners are oxytetracycline, chlortetracycline, demeclocycline, doxycycline, methacycline, and minocycline. See the accompanying box for the many brand names of these generics.

When taken by the mother (usually in capsule form) during the last half of pregnancy or when the child is under the age of 8, tetracycline combines with calcium and becomes part of the dentin, the bone-like core of the tooth directly beneath the outside enamel. Although the enamel itself is rarely affected, the stained dentin shows through the enamel as a yellow-gray stain. (Oxytetracycline is thought to cause less discoloration, resulting in creamy white stains instead.)

If tetracycline has been taken during the last half of pregnancy, the resulting stains are visible as soon as the baby teeth appear. If a child takes tetracycline or its congeners between the ages of 3 months and 8 years, the stains may not become visible until several years later when the permanent teeth appear.

The stains from tetracycline are permanent, but the enamel is rarely weakened, so the teeth function normally. The severity of the stain is usually related to the state of tooth development at the time the drug was taken, and the amount and kind of tetracycline prescribed.

There is no simple treatment for tetracycline-stained teeth. After the age of 18, artificial crowns may be placed on the affected teeth. Before this time the tooth pulp is too large to safely fit the crown, and since the tooth crown has not fully erupted the cap may have to be replaced. Repeated capping can weaken the tooth.

The bleaching of tetracycline-stained teeth is time-consuming and generally has not produced satisfactory results. In some cases, plastic materials that coat the tooth surface can mask the stain. This type of veneer can be reapplied safely.

By far the best method of dealing with tetracycline stained teeth is preventing them. If you are a parent, carefully examine antibiotic prescriptions given to your young children. If the prescription is for tetracycline or one of its congeners, ask your physician if another drug would be just as effective. Remember, in the case of tetracycline-stained teeth, not only is an ounce of prevention worth a pound of cure—right now it's the only cure!

Judith Willis is on FDA's public affairs staff.

Brand Names for Tetracycline and Tetracycline Congeners

tetracycline HCl

Achromycin V
Bristacycline
Centet
Cyclopar
Fed-Mycin
G-Mycin
Kesso-Tetra
Lemtrex
Maytrex
Nor-Tet
Paltet
Panmycin
Piracaps
Retet
Robitet
Ro-Cycline 500
Sarocycline
SK-Tetracycline
Steclin
Sumycin
Tetrachel
Tetracyn
Tetramax
Tetrex-S
T-250 or T-125

chlortetracycline HCl

Aureomycin

demeclocycline HCl

Declomycin

doxycycline

Doxycycline Hyclate
Doxy-II
Doxychel
Vibramycin

methacycline HCl

Randomycin

minocycline

Minocin
Vectrin

oxytetracycline HCl

Oxypar
Oxybiotic
Oxy-Kesso-Tetra
Oxy-Tetrachel
Uri-Tet
Terramycin

Tetracycline Combinations

tetracycline-nystatin

Achrostatin V
Comycin
Declostatin
Terrastatin
Tetrastatin
Tetrex F

tetracycline-amphotericin B

Mysteclin F



Mail Order Miracles Face The Truth

When a major mail order firm specializing in health and vanity products writes off the efforts of enforcement agencies as minor annoyances that are the cost of doing business, it's time for the lawmen to come up with sterner stuff. Here's what happened to that repeat violator.

by Bill Rados

In his *THROUGH THE LOOKING GLASS*, Lewis Carroll tells of the unlikely adventures of young Alice on her journey through Wonderland. "One *can't* believe impossible things," Alice says of the bewildering events. "I daresay you haven't had much practice," retorts the White Queen. "When I was your age . . . [I] believed as many as six impossible things before breakfast."

Millions of Americans share the White Queen's willingness to believe the unbelievable. Proof lies in the huge financial success of mail-order campaigns for pills, potions, and contraptions with such promises as these:

- "Our incredible instant firm-up formula . . . reverses years of aging appearance in just minutes That perpetual youthful look finally can now be yours."

- "New Total Withdrawal Time-Release System automatically shuts off your body's taste—need—dependence on tobacco."

- "A remarkable weight loss discovery that helps turn ugly fat into harmless water and *flow* that fat right out of your body."

The promoters of such quack products are often compared to the medicine wagon pitchmen of old. But those snake-oil salesmen would drool over the size of the take from today's quack schemes. Government officials estimate that consumers spend hundreds of millions of dollars every year on mail-order health and vanity products that do not and cannot deliver on their promises to do the impossible. The most popular of these quack products are diet pills and plans, bust developers, wrinkle removers, and "effortless" exercisers.

The companies that engage in such quackery prey on the faith and hope of their unsuspecting victims. They also take advantage of the often cumbersome and time-consuming legal machinery that permits them to pocket substantial gains before government agencies can put a stop to their shady activities.

One of the giants of the mail-order health and vanity products industry is American Consumer, Inc., of Philadelphia. The company's nationwide newspaper and magazine ad campaigns and catalog mailings draw as many as 70,000 to 75,000 orders a day and ring up sales of more than \$30 million a year, according to U.S. Postal Service officials.

The company thrives despite numerous legal actions against it by FDA and other Federal and State agencies. American Consumer apparently has taken these actions in stride, as shown by this statement in the 1976 annual report of the firm's parent company, Panacolor, Inc.:

"Mail-order companies, such as American Consumer, Inc., on a continuing basis, receive inquiries and com-

plaints and are named in proceedings that are considered incidental and in the ordinary course of business The company is currently involved in several such inquiries and complaints covering several existing and prior promotions. Management believes that should modification or termination of these existing promotions occur, there would be no material financial effect on the company."

That attitude plus repeated legal actions against the company prompted the Federal Government in November 1978 to ask for an unprecedented injunction against the firm. FDA asked the court in effect to require that American Consumer submit to the Agency all labeling and promotional material for its health or vanity items and that it provide FDA with evidence to support any claims made for the products before they are marketed.

On September 6, 1979, the U.S. District Court for the Eastern District of Pennsylvania granted the injunction, the first of its kind regarding foods, cosmetics, and medical devices. The case also marked the first time—despite more than 20 suits by the U.S. Postal Service, suits by six States—and a previous FDA seizure, that an individual has been the subject of court-ordered relief regarding the quack practices of American Consumer. Martin Farber, chief executive officer of the company, will be held personally responsible for ensuring that the firm does not violate the injunction.

Specifically, the court order prohibits American Consumer from marketing *any* food, cosmetic, or medical device until it submits to FDA all labeling and promotional material and proof that any claims made for the product are not false or misleading.

In addition, American Consumer's medical devices must carry label warnings when use might be dangerous, particularly to children or those suffering from illnesses, where the product could do more harm than good. The court ordered these warnings because it found that several devices sold by American Consumer, including a so-called "Infralux Pain Reliever," could cause injury even when used according to directions.

FDA and other Government agencies hope that this extraordinary injunction will stem the tide of worthless—and sometimes even hazardous—products that for years have poured out of American Consumer. Until now, the best efforts of State and Federal law enforcement officials have not put a dent in the company's balance sheet.

The most frequently used legal weapon against the firm had been the threat of a mail stop order by the U.S. Postal Service. By showing at an administrative hearing that advertising for a product contains false representations, the U.S. Postal Service can stop all mail orders for that product, return them to the senders, and refuse to cash money orders payable to the promoter.

In October 1976, the Postal Service issued a mail stop order against American Consumer over a product called "Long 'N Strong," which the firm claimed would strengthen fingernails and help them grow. The advertising for "Long 'N Strong" used one of quackery's favorite ploys: the announcement of a "new wonder discovery."

Health and vanity quacks often tout their products as "important scientific breakthroughs" or "medical miracles."

In the case of "Long 'N Strong," however, the Postal Service did not agree that the "wonder formula" worked "like magic." FDA advised the Postal Service that fingerprints are dead tissue and cannot be nourished by the "natural protein" in "Long 'N Strong" or by any other substance. The Postal Service, therefore, refused to allow American Consumer to continue using the mails to profit from the misrepresentation.

The legal proceedings that lead up to a mail stop order are tedious and expensive—for both the Government and the company involved. Another handicap, from the Government's viewpoint, is that expert medical testimony against a product, such as that frequently provided by FDA scientists, can be countered by testimonials from a handful of supposedly satisfied customers. These witnesses may well believe that the product was responsible for their success in quitting smoking, losing weight, or being "cured" of a chronic disease such as arthritis. But medical experts do not put much stock in testimonials because they fail to show that the improvement was not due to factors other than the use of the product. Many ailments, for example, are self-limiting: the condition will eventually improve regardless of treatment. But a person who buys and uses a "miracle cure" is likely to believe that any improvement is a direct result of that "cure," even though time alone was the healer.

Testimonials also fail to take into account the placebo effect: When a person takes a remedy that he thinks will help him, he often will feel better, even if the remedy is fake. The placebo effect can be powerful. Dr. Stephen Barrett, in *THE HEALTH ROBBERS*, says "about 30 to 40 out of every 100 people will notice an improvement in their headache even if given a sugar pill."

For these reasons, it is usually easy for a promoter to produce "users" of a quack product who will literally swear by it in court or in an administrative hearing. Such nonexpert testimonials give a judge or hearing officer second thoughts about ordering a stop to sales of the product.

In many cases, therefore, the Postal Service will settle for a consent agreement, whereby the company, without admitting any wrongdoing, promises to delete the objectionable claims from its advertising so that it may continue to sell the product.

American Consumer, Inc., has entered into a number of such agreements. In 1977, the firm advertised in a number of popular magazines and newspapers, as well as through its own catalog, a weight loss product alluringly called the "Total Contentment Pill." The advertising was a textbook example of the fine points of quackery: "You are about to become immune to fat for the rest of your life," it promised. Revealing a "brilliant new development" that was the "secret behind this miracle program," the ads cited unnamed "medical experts" who claimed the Total Contentment Pill was "so effective, just one pill has the same hunger-satisfying potential as a serving of bread, mashed potatoes, or any of these filling foods you would normally heap on your plate. Lose as much as 12 pounds in just 14 days without a moment of ravenous hunger."

Dr. Vincent Cordaro, an FDA medical officer who reviewed the product, took exception to such claims.

"None of the ingredients can depress hunger feelings," he advised the Postal Service. "Immunity to fat buildup is a futile dream." Based on this advice, the Postal Service in November 1977, reached an agreement with American Consumer whereby the company agreed to abandon its promotion for the pill, to return any orders still arriving in the mail, and to honor any requests for refunds.

This was not the first time American Consumer was called on the administrative carpet for a quack diet scheme. The company had signed earlier consent agreements for such deceptively promoted products as the "Permanent Reducing Plan" that promised to "liquify fat right out of your life forever"; a "Health Watcher Diet," with similar fat-melting claims; and a booklet called "Fat Free Forever," that claimed to offer a method of weight loss that would cause the average obese person to lose 14 pounds the first 2 weeks and continue at that rate without the need for a diet! ("Eat virtually anything," the ads urged. "Fats, fried foods, six hamburgers in a row.")

FDA found that none of these diet plans could deliver on the promise of such spectacular weight loss.

But quackery promoters know there is more than one way to skin a cat—or fleece a sucker. A consent agreement can take the hot air out of a promoter only temporarily. A new ad campaign and a new name for the product may be the next ploy. Or a company, forced to stop a deceptive promotion for a quack item, may sell its remaining stock to another firm, which will continue to tap the seemingly inexhaustible market for such goods.

Thus, the case in 1976 involving an American Consumer product called "Loofah Pads," said to contain "the amazing oriental plant that helps wipe away ugly cellulite (fat) in just minutes a day." Ads promised that "Loofah Pads . . . must make your body supple as a teenager in days or pay nothing."

FDA, after reviewing the sponge-like pad and its claims, found that it could in no way help remove cellulite. The Agency sent a Regulatory Letter to the firm saying that the product was misbranded, a violation of the Federal Food, Drug, and Cosmetic Act. The Postal Service also advised the firm that its claims for "Loofah Pads" violated Postal false representation statutes.

After reaching a consent agreement to stop the misleading campaign, American Consumer cut its losses by selling its remaining unlabeled stock of the ersatz fat erasers to a New York firm.

Regulatory Letters from FDA point out to a firm that certain of its practices violate the law or the Agency's regulations. In sending the letter, FDA hopes that the firm will voluntarily make whatever changes are needed to bring its products into compliance. But it isn't always that easy.

In 1976, FDA sent a Regulatory Letter to American Consumer telling the firm that its rope-and-pulley "Body Exerciser" contraption and its Scandia Bust Developer (a plastic gadget with a booklet for "self development of bustline shape and contour") were misbranded; that is, the claims for the products were unfounded. The firm relabeled the "Body Exerciser" but FDA was not satisfied with the changes. The firm refused to relabel the bust developer.

So in June 1977, the Agency seized more than 1,000 of the bust developers, more than 80,000 of the exercisers, and more than 11,000 of something called the "Cross of

Magnator.” This metal cross was accompanied by a pamphlet titled “The Mystery of Magnetism” that told of the “essence of life . . . Biomagnetism . . . Life Force and Improved Health.”

The pamphlet suggested that the cross was effective for treating neuritis, high blood pressure, leg aches, shortness of breath, respiratory and nervous disorders, heart trouble, rheumatic fever, allergies, Plantar warts, sneezing, and itchy eyes, ears, and throat; that it would facilitate good sleep and family happiness and relaxation. This was supposed to be possible because the cross was said to regulate biomagnetic currents flowing through the body. FDA scientists viewed the claims as patently false. They also warned that the directions for use of the body exerciser while lying on one’s stomach could result in injury to persons with back or spinal problems.

A U.S. district court judge in October 1977 ordered the products condemned. American Consumer was not to be permitted to promote them again until it dropped the false claims.

But consent agreements, mail stop orders, and even seizures and condemnations merely slow down a quack. These remedies may have too little clout to seriously hamper him because, under such civil actions, the quack is not convicted, imprisoned, or even fined. These more severe penalties can come only from a criminal prosecution for fraud.

But fraud as a felony is difficult to prove. Not only must the Government show that the product will not do what it says, but it must also show that the promoter knew the claims were false and that he intended to deceive the public.

Some quacks actually do believe that their products can do the impossible; the rest are good at pretending they do. But proving intent to deceive involves testimony of expert medical witnesses, whose learned opinions of the worthlessness of a product can be offset by one well-meaning defense witness who swears by it. Furthermore, testimony from victims of the scheme is often hard to come by. Many people either will not let themselves believe that they have been bilked or they may not want to admit it—particularly at a public trial. Others, because they do not consider the placebo effect or the self-limiting nature of many ailments, believe the questionable product was responsible for their improvement. Still others prefer to deceive themselves, especially about diet plans and exercise devices that promise to whisk away fat. They believe that any failure was due not to the product but to their own laziness or lack of willpower to follow the suggested regimen.

For these reasons, the chief investigator of the Postal Service’s health fraud unit estimates that less than 1 percent of those who buy quack health and vanity products ever complain to the promoter that the items don’t work. This puts the Government at a disadvantage in fraud cases, since the number and patterns of complaints have a direct bearing on successful prosecution.

A fraud conviction proved costly last year to American Consumer, Inc. The firm was indicted on September 7 on 1,000 counts of mail fraud for selling a “Cross of Lourdes.” The item, a piece of costume jewelry priced at \$15.95, was promoted in various national publications, such as NATIONAL ENQUIRER, MIDNIGHT, NATIONAL STAR, and GRIT. The indictment charged that the com-

pany claimed its “Cross of Lourdes” actually had been dipped in the fabled waters of Lourdes “. . . from the same miraculous spring divined by Bernadette . . . our international representatives made a special pilgrimage to Rome to have each Cross of Lourdes blessed by His Holiness Pope Paul VI in a mass blessing at the Vatican.”

To the contrary, charged the Postal Inspection Service, the crosses came from a costume jewelry company and never reached Rome, the late Pope, or Lourdes. But some 5,500 believers paid \$103,000 to American Consumer for more than 6,400 crosses.

On September 29, 1978, American Consumer, Inc., pleaded guilty to all 1,000 counts of mail fraud. Under a plea bargaining agreement, a \$25,000 fine and restitution of \$15.95 to each person who bought the cross was ordered.

But even these stiff penalties could not put the lid on American Consumer’s schemes.

Less than 2 months after that guilty plea, the Justice Department seized quantities of American Consumer products and asked for the unprecedented injunction to require premarket labeling submission and supporting evidence for labeling claims to FDA for all of the firm’s health and vanity products. The devices and foods seized included the “Infralux Pain Reliever”; a urine testing device for use by diabetics; “Tummy Trimmers”; “Slimcycles”; “Thera-Slim 100,” which the company calls a food supplement; and “Calmeze” tablets.

Ordinarily, FDA has authority to require premarket labeling submissions (as part of its premarket review for safety and effectiveness) only for drugs and certain medical devices that are implanted in the body or are life-supporting. But few mail order devices fall into either of those categories and mail-order pills for dieting, nerves, and so on are seldom sold as drugs, but as nutritional supplements. Under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, however, FDA can ban administratively—without going to court—devices that are deceptive, as well as those that present a risk to health. And FDA can ban a product if the promoter fails to back up claims about what it will do.

In making the request to the Justice Department for the injunction action, FDA stated: “In spite of regulatory letters, seizure and court litigations, American Consumer, Inc., continues to cause products to be misbranded . . . We strongly believe that broad injunctive relief is necessary in this case because they consider the *ad hoc* approach taken thus far by agencies in efforts to stop these deceptive and irresponsible practices as simply the cost of doing business. Not only are the defendants involved in economic cheats but, much more importantly, practices which may be harmful to the consumer.” The injunction helps FDA uncover any quack promotions by American Consumer before they start. But legal actions are only one way to protect the American public against mail-order quackery. The public has to do some of the protecting itself, those in the quackery battle say. The experts agree that one of the most effective weapons against quackery would be a public better educated in matters of health, a public with some idea of what a product reasonably can and cannot be expected to do.

Bill Rados is a member of FDA’s public affairs staff.

How To Recognize Quack Bait

Quacks play on human emotions and weaknesses to ensnare their victims. They sell hope. They appeal to an individual's vanity, misfortune, or fear—fear of illness, of death, or of rejection for not measuring up to the popular image of beauty: a slim figure; a youthful, wrinkle-free face; for women, a bountiful bustline; for men, bulging muscles and a full head of hair.

The quacks also rely on the still widespread belief in magic and miracles. Otherwise rational men and women fall victims to obviously absurd, quack schemes simply because they want to believe. Others defend their gullibility with the belief that “anything is worth a try.”

With quacks so skilled in manipulating emotions, it's easy to be conned. How can you protect yourself? First, when you see an advertisement for a sensational new health or vanity product, remember the quack artist's favorite ploys:

- **Is the product touted as a “new scientific breakthrough” (or words to that effect)?** Many quack promotions refer to medical studies or “reports in leading medical journals” without mentioning the journals, authors, or institutions by name. Such claims, especially when promoted in sensational popular magazines and newspapers, are generally shams.

- **Does the promoter call his product a “secret” cure?** Some quacks even claim they are being persecuted by the Government or the medical establishment for seeking to inform the public about their product's value. These appeals are often successful in evoking sympathy—as well as money—from those who tend to cheer for the underdog.

- **Does the advertising recite testimonials from satisfied users?** Scientists generally view such testimonials with skepticism. They may be outright lies or they may be honest statements from people who do not realize that the product they used had nothing to do with their improved condition.

- **Does the ad refer to ill-defined pains and feelings?** A person who diagnoses himself and believes that the product will help relieve those vague symptoms may well be doing himself harm by delaying proper treatment. Avoid promotions that involve self-diagnosis.

- **Does the product claim to be effective for a wide variety of ailments?** All such cure-alls are pure quackery.


Consumers should be particularly suspicious of promotions for certain types of products. The favorite quack items are:

- **Effortless exercise and dietless reducing plans:** No exercise is any good unless you exert yourself. The only proven way to lose weight is to eat less. While many quack promotions advertise a pill that guarantees incredible weight loss, the fine print usu-

ally mentions that a diet plan accompanying the pills must be followed. Even then, don't expect to lose any more weight than you would by dieting alone, because such pills generally are worthless. Beware of any product that promises amazing results in a very short time.

- **Vitamins and other dietary supplements:** An FDA survey has shown that three out of four Americans mistakenly believe that no matter how adequate their diets, taking extra vitamins automati-





cally provides more energy and pep. The food quack can usually be spotted taking full advantage of this myth to support his product's claims. He also may claim that his diet supplement will cure or prevent any number of illnesses. Ordinarily, how-

ever, very few cases of those illnesses are due to a diet deficiency.

- **Hair growers and baldness preventers:** 85 to 95 percent of all cases of baldness are of the male pattern type for which there is no known cure.

- **Alcoholism cures:** Such concoctions are worthless and may be harmful because they delay effective medical treatment.

- **Bust developers:** These are usually the so-called hormone creams or exercise devices. Despite testimonials and alluring before-and-after photographs, none of these products builds buxom bosoms.

- **Quit-smoking products:** There is no known drug or combination of drugs that can, in itself, cure or permanently eliminate the desire for tobacco. They all lack the most important ingredient: will power.

A great many people believe that advertisements for health and vanity products must be true or magazines and newspapers wouldn't be allowed to print them. On the contrary, few publications screen ads for accuracy. And legal actions against a quack promotion can drag on for months or even years, during which time the ads continue, raking in profits for the promoter. In short, there is no guarantee that what you see is what you get.

While these suggestions will help you judge promotions for health and beauty products more realistically, the best cure for quackery is education, for quackery plays not only on emotions but on lack of knowledge as well.

If you believe a product you've seen advertised may help you, talk to your family doctor. He or she is in the best position to know if the product is worthwhile for you. You can also check on the product and its promoter with consumer protection agencies or the local Better Business Bureau.

If you think you've been swindled, notify the appropriate Government agency. The Food and Drug Administration deals with cases of mislabeled or harmful food, drugs, cosmetics, and health devices. See your local phone directory for the FDA office nearest you, or write: Food and Drug Administration, Rockville, Md. 20857.

The U.S. Postal Service handles complaints of fraudulent or misleading promotions involving use of the mails (either to advertise or to receive orders for products). Contact your local postmaster, postal inspector, or write to, Inspector in Charge, Special Investigation Division, U.S. Postal Service, Washington, D.C. 20260.

The Federal Trade Commission is concerned with cases of suspected false advertising. Write to: Federal Trade Commission, Sixth Street and Pennsylvania Avenue, NW., Washington, D.C. 20580.

Local consumer agencies, State attorney general offices, and local offices of the Better Business Bureau also may be able to help.

Time Marches on Despite Gerovital

Ponce de Leon never found the Fountain of Youth in Florida, but many modern-day senior citizens thought they had in the form of a drug promoted to wipe away the cares of senescence. A U.S. district court stopped sales of the product when FDA found its claims for treating the ills of age were not supported by scientific fact.

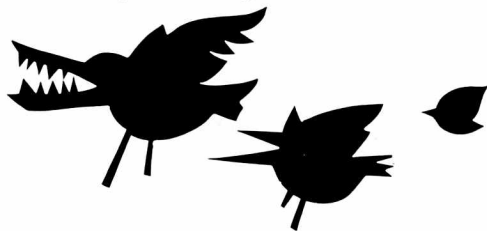
by Annabel Hecht

Despite the assurance of Robert Browning that "the best is yet to be," a good many people look on the prospect of growing old with abhorrence. Or as Jonathan Swift put it, "Every man desires to live long, but no man would be old."

The search for the Fountain of Youth has been going on for centuries, pre-dating even the venerable Ponce de Leon. The conquistador never did find the fountain which legend had placed somewhere in Florida. Modern seekers after continuing youth have gone to greater extremes, subjecting themselves to injections of various ani-

mal glands or suffering the surgery of facelifts, among other things. Cosmetic measures may make a person appear younger, but no drug has yet been developed that will halt the march of time—for, as the poet Swinburne said, "Time stoops to no man's lure." Some have been promoted with that claim, however, and one recently made the headlines in Florida when a U.S. district court judge put at least a temporary halt to its illegal distribution.

Championed as the "wonder substance" of the 20th century, the drug in the Florida case, called GH 3, was said to have a "favorable effect" on such diseases as arthritis, diabetes, hypertension, and heart disease. People of any age could get GH 3 by becoming members of

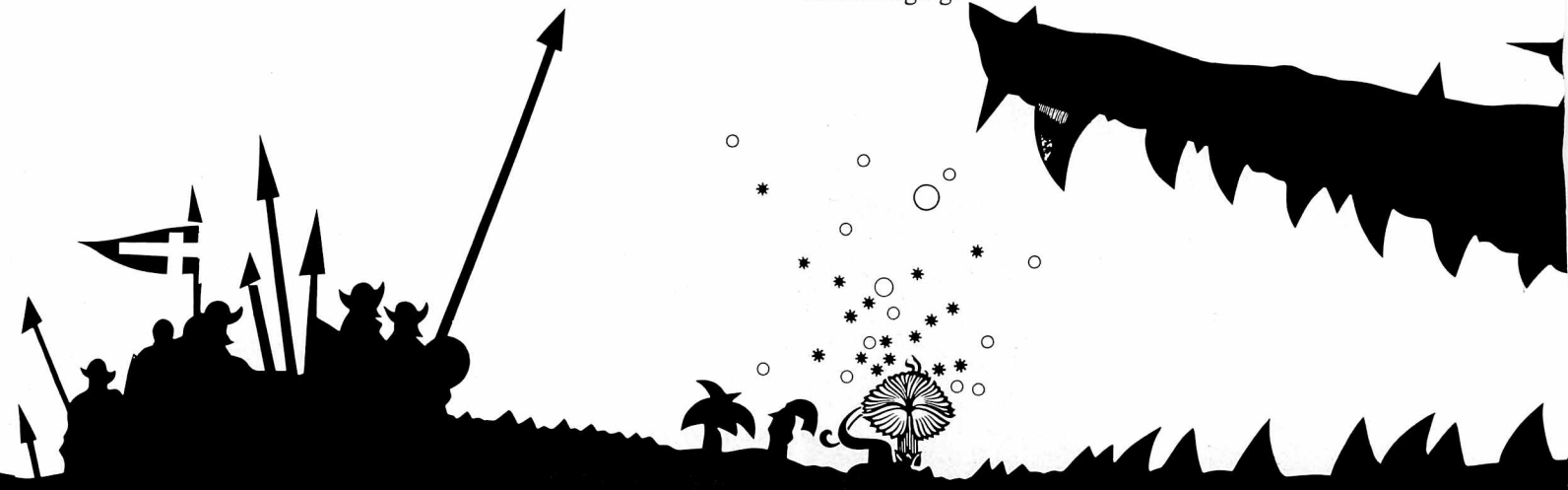


Club SeneX, a subsidiary of the SeneX Eleemosynary Foundation, located in Miami. Membership fees of \$130 for 6 months (\$240 for a year) entitled Club members to supplies of GH 3 and a variety of printed materials.

GH 3 is not a drug, according to the Club's elaborate promotion materials. It is an "effective anti-aging nutritional factor that is beneficial in almost every disease associated with premature aging." GH 3, says FDA, is an unapproved new drug that is misbranded.

What Club SeneX was promoting is not new and hardly a wonder substance. Maybe best known as Gerovital, it has also been called H 3 and GH 3. Whatever the name, it has been around some 30 years. It is nothing more than a buffered and stabilized solution of procaine hydrochloride, better known as Novocain, used by dentists to deaden the mouth before drilling.

Procaine was introduced to medicine in 1905. From 1930 to 1950 there was considerable enthusiasm about its use in the treatment of a variety of conditions, including arthritis, peptic ulcer, asthma, and hypertension. Researchers, however, found it had no curative effect. It was Dr. Anna Aslan of the C.I. Parhon Institute of Geriatrics in Bucharest, Rumania, who first used procaine to combat aging.



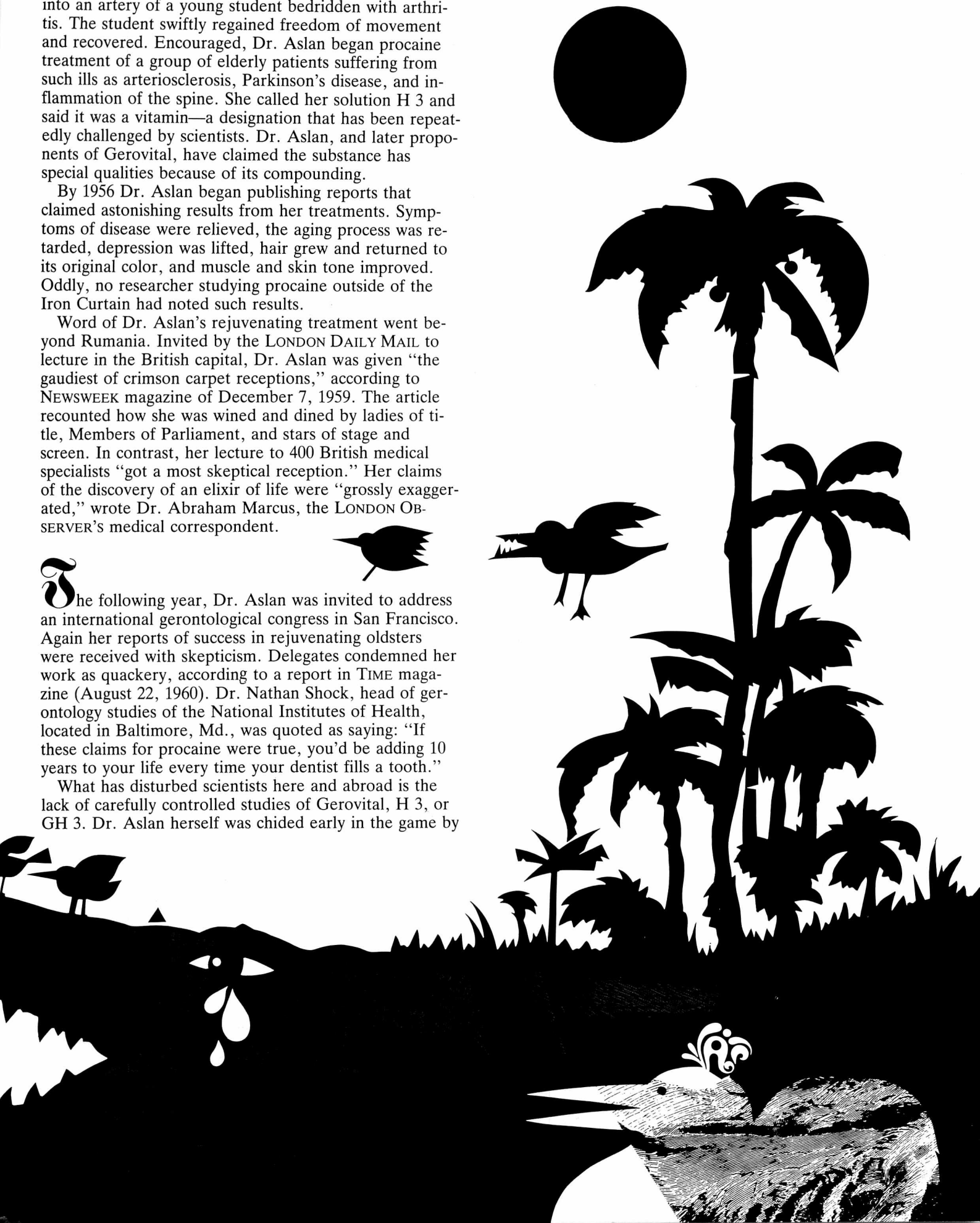
In 1949, the story goes, Dr. Aslan injected procaine into an artery of a young student bedridden with arthritis. The student swiftly regained freedom of movement and recovered. Encouraged, Dr. Aslan began procaine treatment of a group of elderly patients suffering from such ills as arteriosclerosis, Parkinson's disease, and inflammation of the spine. She called her solution H 3 and said it was a vitamin—a designation that has been repeatedly challenged by scientists. Dr. Aslan, and later proponents of Gerovital, have claimed the substance has special qualities because of its compounding.

By 1956 Dr. Aslan began publishing reports that claimed astonishing results from her treatments. Symptoms of disease were relieved, the aging process was retarded, depression was lifted, hair grew and returned to its original color, and muscle and skin tone improved. Oddly, no researcher studying procaine outside of the Iron Curtain had noted such results.

Word of Dr. Aslan's rejuvenating treatment went beyond Rumania. Invited by the LONDON DAILY MAIL to lecture in the British capital, Dr. Aslan was given "the gaudiest of crimson carpet receptions," according to NEWSWEEK magazine of December 7, 1959. The article recounted how she was wined and dined by ladies of title, Members of Parliament, and stars of stage and screen. In contrast, her lecture to 400 British medical specialists "got a most skeptical reception." Her claims of the discovery of an elixir of life were "grossly exaggerated," wrote Dr. Abraham Marcus, the LONDON OBSERVER's medical correspondent.

The following year, Dr. Aslan was invited to address an international gerontological congress in San Francisco. Again her reports of success in rejuvenating oldsters were received with skepticism. Delegates condemned her work as quackery, according to a report in TIME magazine (August 22, 1960). Dr. Nathan Shock, head of gerontology studies of the National Institutes of Health, located in Baltimore, Md., was quoted as saying: "If these claims for procaine were true, you'd be adding 10 years to your life every time your dentist fills a tooth."

What has disturbed scientists here and abroad is the lack of carefully controlled studies of Gerovital, H 3, or GH 3. Dr. Aslan herself was chided early in the game by



the *BRITISH MEDICAL JOURNAL*, which editorialized at the time of her London visit: "A study of the clinical reports of the Parhon group makes sad reading for the clinician trained in modern scientific method. There is almost complete absence of controls, and blind trials were never made."

But the same charge can be made of other research on procaine and the aged. A review and evaluation of 285 papers in the field, commissioned by the National Institute on Aging, cited numerous studies that were flawed in design and statistical analysis. Published in the January 1977 *JOURNAL OF THE AMERICAN GERIATRICS SOCIETY*, the review concluded that "clinical trials of new agents in the treatment of the elderly may be very poor."

Even studies that were well designed and conducted failed to substantiate the claims of the Rumanian scientists. The authors' summary: "There is little reason to doubt that many patients have been treated at the Geriatric Institute in Bucharest and have felt and looked better. However, there is no compelling reason to believe that procaine, aside from a possible antidepressant effect, contributed to this improvement. The evidence that procaine has a prophylactic or therapeutic effect in aging or the diseases of later life is unconvincing."

According to the *MEDICAL LETTER* of January 12, 1979: "Gerovital H 3 has not been shown to be of value in retarding the aging process, or for the treatment or prevention of any disorder in the elderly."

Despite such scientific judgments, Gerovital is readily available in many European countries where it often can be purchased without a prescription. Dr. Aslan, still vigorous at 83, continues her work as head of the Institute of Gerontology and Geriatrics in Bucharest. Each year, some 20,000 people, including some Americans, flock to the health-spa-like atmosphere of her clinic.



Gerovital came to this country some 15 years ago. In 1965, Dr. Alfred Sapse, one of Dr. Aslan's disciples, came to the United States convinced of Gerovital's merits. He believed that the drug affected the level of monoamine oxidase, an enzyme linked with depression in persons over 45. In 1971, he and Manfred Mosk formed Rom-Amer Pharmaceuticals, Ltd., with a small amount of capital and an exclusive 10-year contract with the Rumanian government to sell Gerovital in the United States if FDA approved it.

In 1972, Rom-Amer submitted to FDA a Notice of Claimed Investigational Exemption for a New Drug (IND) to investigate the use of Gerovital for the treatment of depression in the elderly. While these studies were going on, stories appeared in the popular press about the "rejuvenating" qualities of the drug. FDA was afraid the public and physicians might link these anti-aging claims with the drug then being studied as an antidepressant. Rom-Amer's use of the name Gerovital in its investigations also implied an effect on aging. When FDA learned of plans to dispense Gerovital in the United States through a network of health resorts, the Agency called a meeting with Rom-Amer representatives. If it was going to be sold to combat aging, Gerovital would have to be tested for that use, said FDA. In August 1976, Rom-Amer was told clinical studies of Gerovital as an antidepressant could be resumed if they were extended to include younger patients—since depression is not exclusive to the aged—and if the drug was called by its established name, procaine hydrochloride, instead of Gerovital.

But by 1977, Rom-Amer had run into financial difficulties and had been sold to Marvin Kratter, a California real estate promoter. Kratter, learning that the Nevada legislature was considering a bill to legalize Laetrile, managed to have a measure legalizing the sale of Gerovital in that State included in the bill. Kratter has since withdrawn the FDA IND for Gerovital and no further clinical tests are being done by Rom-Amer.

Kratter has been producing Gerovital for use in Nevada since January 1979. Only in the last few months has FDA inspected the plant. In the meantime, a German firm, Schwarzhaupt, has been licensed by the State to manufacture the drug. The firm has registered with FDA.

What has been happening in Florida is a story with some different twists. Club SeneX is not connected in any way with Rom-Amer. The principals in this case are

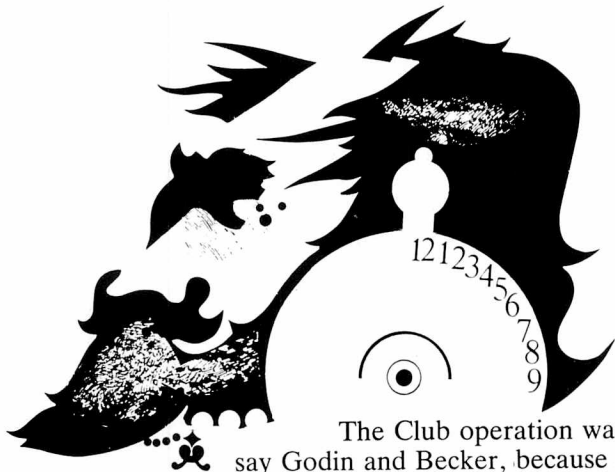


Dr. Alan Kratz and Harry Emerson, president and vice president, respectively, of the SeneX Foundation, and Roger Sabastier, president of the Seven Freedom Pharmacy.

The Club and the Foundation are the brainchild of Dr. Kratz. The Foundation purported to be a nonprofit, tax exempt research and educational organization. The Club was intended to spread the word about aging, GH 3, and holistic health, as well as to make it possible for members to get GH 3 "legally." Club dues were payable to the Foundation, which made them tax deductible.

The method of operation was simple. Members were to have a medical evaluation by their own physician, or one recommended by the Club, who then prescribed GH 3. What they got for their dues was a half gallon of the product in liquid form—6 months' supply—compounded exclusively by Seven Freedom Pharmacy. Literature describing the Foundation, instructions on how to take and store GH 3, reprints on nutrition and exercise, and suggested reading lists were also provided. Prescriptions were refilled for an additional fee, and membership and prescriptions were renewable annually.

Club SeneX wooed members with ads that hit home. GH 3, the ads said, could safely relieve the effects of degenerative diseases of premature aging, including stress, impotence, frigidity, graying hair and baldness, and "ugly wrinkling skin." The Club's most enthusiastic supporters were Jerome Godin and Samuel Becker, authors of "GH 3 Your Prescription for a Healthier Happier Life" and "GH 3 Discovery." Although they claimed not to be connected with the SeneX Foundation except through membership in the Club, their books are lavish in praise of Kratz's work and the virtues of GH 3.



The Club operation was legal, say Godin and Becker, because a doctor can prescribe any official substance, such as procaine, for his patient, and the pharmacy that services Club members has the knowledge and the right to compound and dispense this solution just as the prescription is written. The Federal District Court in Florida took a different view, indicating that the Club's operation was not the usual way in which drugs are prescribed and prescriptions filled.

Procaine itself is a well known and approved drug in the United States. The formulation called GH 3, however, is considered a "new" drug by FDA because it is not generally recognized by qualified experts to be safe and effective in treating all conditions that it is claimed



to treat. The labeling is false and misleading because claims that it is of proven value in the treatment of disease associated with aging are not supported by adequate, well-controlled scientific studies. Since some of the materials used in GH 3 came from other States, the drug was considered to be in interstate commerce and thus within FDA's regulatory authority.

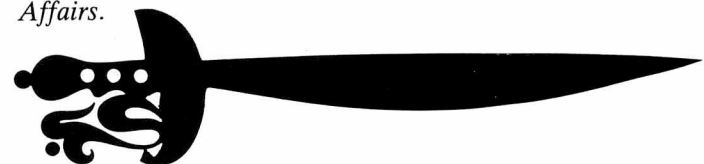
In 1978, the Agency warned both Club SeneX and the Seven Freedom Pharmacy that they were operating outside the law. Dr. Kratz admitted the Club might be considered to be circumventing the Food, Drug, and Cosmetic Act. However, on advice of their attorney, the Club and the Pharmacy continued to operate, but promised to change their promotional literature to delete any possible misrepresentations to the public and to state that prescriptions for GH 3 could be filled at any pharmacy.

These promises were not kept. In fact, during the period April to November 1978, promotional activities were expanded and membership increased tenfold. At last count more than 4,000 people were members of Club SeneX.

The preliminary injunction, handed down by Judge Sidney M. Aronovitz of the U.S. District Court of the Southern District of Florida, may put a stop to Club SeneX's present activities, but it apparently won't put an end to the misrepresentation that Gerovital, GH 3, or H 3, or whatever the substance is called, will cure or prevent the ills of the aging. Already, several organizations similar to Club SeneX have turned up in the Miami area. News reports from Miami tell of efforts being organized to legalize GH 3 in Florida as it has been in Nevada. In addition, one magazine, sold in some health food stores, is carrying ads to the effect that the European formula for Gerovital soon will be here.

It seems that people are willing to believe that time will stoop to some lures of man.

Annabel Hecht is a member of FDA's Office of Public Affairs.





Fructose: Questionable Diet Aid

The diet faddists once again have found the only true secret to easy weight reduction. This time it's fructose, which they say beats ordinary table sugar, is more "natural," and can be used by diabetics to avoid the problems ordinary sugar causes. But FDA and conventional medical authorities remain unconvinced.

by Chris Lecos

Fructose is a sugar that has spawned a number of rapid weight-loss schemes and a lot of misleading ideas about its usefulness in the diets of diabetics and others. It has been ballyhooed as a "natural" replacement for ordinary table sugar and saccharin, as an "elite sweet," as the "newest, most effective diet aid," as a suitable sugar substitute for diabetics, and as a hunger appeaser.

Although the scientific and medical community is by no means unanimous over the merits of fructose as an "ideal substitute" for table sugar, or sucrose, this is how most health professionals respond to such claims:

- The prevailing medical opinion, according to a report prepared for FDA, is that there are no "clinical advantages" in substituting fructose where diabetics are concerned.
- The available scientific data, according to a 1978 report to the Federal agency, is regarded as insufficient "to determine if fructose or any other carbohydrate has beneficial properties for the long-term dietary management of diabetes."
- There is a particular need for scientific studies that evaluate the long-term benefit of fructose when consumed as a part of the regular meal plan of a diabetic. Such studies, said the 1978 report, have not been conducted.
- The claim that fructose is a natural replacement for ordinary sugar can be misleading. Fructose occurs naturally, along with other sugars, in honey and fruits. The pure fructose sold commercially is produced from sucrose (refined sugar), which is comprised of fructose and glucose. Pure fructose should not be confused with high fructose sirups derived from corn.
- Fructose provides the same number of Calories—four per gram—as sucrose. Health experts say there is little if any advantage in using fructose for weight reduction, despite claims that fructose users would consume

fewer Calories because they would use less fructose to get the same sweetness as from sucrose.

A number of factors have sparked the public's interest in fructose, and other nutritive sweeteners as well, in recent years. First, is the growing public belief that it would be better for one's health to eat less refined sugar, namely sucrose. Second is the clouded future of saccharin, the only non-Caloric sweetener on the U.S. market today. Saccharin's future is murky because of FDA's proposal to restrict its use in foods based on evidence that it is a weak animal carcinogen. Third is the extensive publicity given to fructose in books, television, and other media.

Diabetologists, such as Dr. John Davidson, professor of medicine at Emory University and director of the Diabetes Unit at Grady Hospital in Atlanta, are particularly concerned about some of the claims being made for fructose.

"I object strenuously to misleading advertising of the type that some of these people have been engaging in, promising this and promising that," he declared. "It burns me up to see the public misled and taken advantage of and promised something that the product is not going to deliver." He is not alone in these concerns.

In recent months, the American Diabetes Association (ADA) has published a number of statements on fructose and other nutritive sweeteners, such as sorbitol, mannitol, and xylitol. All four have these two characteristics in common: They do not contain glucose, a sugar that diabetics should avoid in concentrated amounts to prevent sudden surges in blood sugar levels; and they are not metabolized in the same way as glucose.

During digestion in a normal, healthy individual, sucrose is broken down into equal parts of glucose and fructose. These components enter the bloodstream through the wall of the small intestine and the blood carries the sugars to the tissues and the liver. There they are used or converted into glycogen, which is stored until needed by the body. Insulin makes it possible for glucose, or blood sugar, to enter nearly all the cells of the body, where it is utilized.

The nonglucose sweeteners, such as fructose, are absorbed more slowly than glucose or sucrose and go directly to the liver without insulin. This does not mean, however, that insulin is not needed with fructose. Fruc-



The five most common food sugars—dextrose, fructose, lactose, maltose, and sucrose—are shown in liquid form in this photo supplied by ADM Corn Sweeteners, a division of Archer Daniels Midland Co. of Cedar Rapids, Iowa. Photo also illustrates the similar chemical nature of the sugars.

tose is absorbed from the intestinal tract into the bloodstream and then transported to the liver. The liver cells transform the major portion to glucose, which does require insulin for use by body cells.

The insulin response is less rapid with fructose than with glucose because of the slower intestinal absorption of fructose. It is this slower uptake and more moderate blood glucose response that has led to the claim that fructose is a better and easier sugar for diabetics to digest. Such claims are reinforced by reports that fructose, sorbitol, and xylitol are used widely in some European countries by diabetics. The nonglucose sweeteners generally do not leave the bitter after-taste of artificial sweeteners like saccharin. Studies also indicate that they are less cariogenic than sucrose—that is, contribute less to dental decay.

Xylitol had shown some real promise as a sweetener with a much lower cavity-causing potential. For all practical purposes, however, xylitol is no longer available in the United States. Chewing gum makers and other food manufacturers voluntarily ceased using it after FDA received studies that indicated it could cause tumors. Its status currently is under review by FDA.

Health experts in this country do not always accept the advantages cited for the nonglucose sweeteners. They note that most of the studies and experiments are short-term in duration or lacking in the kind of data considered necessary to demonstrate safety and effectiveness for diabetics.

Of particular importance to the American Diabetes Association and other diabetologists are long-term studies that measure the effects of consuming fructose and the other sweeteners along with the kinds of meals a diabetic would be expected to eat over an extended period. A recent ADA review paper on the nonglucose sweeteners points out that most studies focus on tests of these sweeteners in their pure form with animals and people who had been given no other food. Long-term studies correlating consumption of fructose with the mixed meals of diabetics are needed before firm recommendations can be made, the ADA review paper indicated.

As Davidson, the Atlanta diabetologist, put it:

"I am a hard scientist, and I don't think you should compromise by saying: 'Well, maybe it's all right, and maybe it's not.' Nobody has done anything except short term experiments, mostly on animals and a few humans."

When the Diabetes Association published an update of its 1971 Nutrition and Dietary Guidelines recently, the ADA noted that the amounts of fructose, xylitol, sorbitol, and mannitol acceptable in a food plan for diabetic

persons is "uncertain at present" and that there is not enough evidence to accept or reject the use of these substances by diabetics. Dr. Ronald A. Arky, ADA's president, acknowledged that his organization's published comments were aimed, in part, at discouraging the use of the nonglucose sweeteners by diabetics.

"My own feelings are that if you are going to use them, use them in moderation," he added. "But, it's the same old story. How do you get moderation from the public? And how can you be sure the public maintains consumption at a moderate level when you consider both individual eating tastes and needs as well as the volumes of products people can be exposed to with these sweeteners in them."

Dr. Victor Fratalli, assistant to the associate director for nutrition and food sciences at FDA, put it this way:

"You may have some bits and pieces of evidence here and there that some say demonstrate that the nonglucose sweeteners produce a beneficial effect. But let's not try to make any unqualified statements regarding benefits of substances to give people the wrong impression now, and then a couple of years later have to tell them to 'hold the phone' because there are some problems as a result of people consuming them in large amounts.

"It's almost impossible to reverse such trends. Once people get the notion through partly true statements that something may be useful, then they convince themselves that a thing is useful, and there isn't anything in the world that will turn them around."

A report prepared for FDA by the Federation of American Societies for Experimental Biology (FASEB), on the health aspects of fructose, indicated that most diabetologists, in this country at least, are not recommending its use to their patients. FASEB's 1976 study—which is based on a comprehensive review of scientific literature—expressed this conclusion: "It is the prevailing medical opinion that there are no clinical advantages of substituting fructose for glucose either orally or parenterally (intravenously) in any disease state."

The public misunderstanding and lack of unanimity in the medical and scientific community over the merits of fructose led Fratalli to comment:

"You are not dealing with a black-white issue here, and that is the whole problem. There is a difference in the way the body handles these nutritive sweeteners, but, as far as I'm concerned, the difference for diabetics is not so significant as to classify fructose as a substance apart from sucrose."

The same can be said, he added, on the use of the nonglucose sweeteners by nondiabetics. "Any argument one tries to develop that indicates these nutritive sweeteners are beneficial in weight reduction is very tenuous. What you are doing is substituting one carbohydrate for another."

The differences of opinion that may exist over the value of pure fructose are not apparent with high fruc-

tose corn sirup. Health experts view it as they do any other sugar that diabetics should restrict from their diet. Not all high fructose sirups are the same either. Some are produced with 42 percent fructose in them, others have 55 percent, still others have 90 percent. The balance is mostly glucose or dextrose as it is sometimes identified on food labels.

Davidson had this comment about the variations by manufacturers:

"Don't you think that's bamboozling the public? They don't tell them they've got glucose in them, yet they push the idea that fructose can be used by diabetics and obese people without telling them the consequences."

For diabetics, Davidson sees little difference between pure fructose and high fructose corn sirups. "Neither one is preferable," he said. "Over 90 percent of the diabetics in this country have what we call obesity-induced diabetes as a result of having ingested too many Calories. They cannot be treated effectively with insulin and pills. The only way they can be treated is to lose weight. Whereas there is a tremendous need by this segment of the population for a non-nutritive sweetener, such as saccharin, there is no need whatsoever for additional nutritive sweeteners, such as fructose, sorbitol, or what have you. These people need less food, not more."

Pure fructose is a dry, crystalline sugar that is produced from sucrose by separating it from the glucose component and then purifying it. To obtain pure fructose from such sources as honey (which is 40 percent fructose) and fruits would be "prohibitively expensive," according to one distributor.

Almost all the high fructose corn sirups are derived from the starch in corn. Extensive milling extracts the starch from the corn. The starch is liquefied and treated with enzymes to convert it into a glucose corn sirup. Further processing converts the glucose into the fructose sirup. The enzymatic transformation of glucose to fructose is known as isomerization.

Fructose can be purchased over the counter at health food stores and some supermarkets in liquid, powder, tablet, or granular form at a price considerably above that paid for regular table sugar. A recent check of four health food stores in the Washington, D.C., area indicated that:

- Granular or crystalline fructose—with 4 Calories per gram—was selling for \$3.70 to \$4.44 a pound.
- A box of 100 two-gram tablets (8 Calories to the tablet) were priced from \$3.95 to \$4.15. That's the equivalent of \$8.98 to \$9.43 a pound.
- A 5-ounce container with 50 packets of powdered fructose (11 Calories to a packet) was priced from \$1.90 to \$2.20. This amounts to \$6.08 to \$7.04 a pound.
- Liquid fructose sold for \$1.49 for a 16-ounce portion. Other stores sold a 23-ounce container for \$2.89 to \$3.13. A half teaspoon of the liquid provides 12 Calories. The liquid fructose, however, actually was a corn sirup with 90 percent fructose. On a dry weight basis, this would amount to \$3.85 to \$4.17 a pound.

The industrial use of fructose-sweetened products is growing and is of concern to many health professionals, particularly since most of the sugar that we consume is added to foods by producers. In other words, the consumer has less control over the amount of sugar in food as industrial use increases. The U.S. Department of Ag-

riculture reports that annual per capita consumption of high fructose corn sirups rose from less than a pound in 1970 to an estimated 15 pounds last year. The soft drink industry is the heaviest user of both high fructose corn sirup and refined cane and beet sugar.

Overconsumption of some of the nonglucose sweeteners also could have an unpleasant side effect, namely diarrhea, according to the ADA and various FASEB reports prepared for FDA. For example, these reports indicated that diarrhea could be induced by consumption, in a day, of 10 to 20 grams of mannitol, 20 to 30 grams of sorbitol, 30 to 40 grams of xylitol, and 70 to 100 grams of fructose. It is considered unlikely that most people would consume this much fructose in a day. However, the potential for the other three sweeteners to cause diarrhea tends to limit their usefulness.

Diabetologists and nutritionists also question whether using fructose as a substitute for sucrose is effective in reducing weight. The argument has been made that since fructose is sweeter than sucrose, one could use less fructose and get the same sweetening effect with fewer Calories.

However, fructose's sweetness depends on how it is used in food and drink. It can be 15 to 80 percent sweeter than sucrose, but its sweetness, according to one FASEB study, decreases as temperature, amount of fructose, and acidity are decreased. This was demonstrated with four prepared products in a 1978 study by Utah State University's Department of Nutrition and Food Sciences.

Sugar cookies, white cake, vanilla pudding, and lemonade were chosen for the study because they represented a wide variety of products, and their degree of sweetness and flavor would not be masked by other ingredients. That study concluded that fructose was not sweeter than sucrose in the cookies, cake, and pudding. Only in lemonade, when compared on an equal weight basis, was fructose considered sweeter by the taste panels who took part in the study.

The updated dietary guidelines of the ADA place much more stress on exercising total Calorie control and sticking to a carefully supervised diet than on which sugar one should use. It warned diabetics against all nutritionally imbalanced "fad" diets, especially the "commercially available, high protein mixtures that contain low quality protein for use in modified starvation diets."

As a general rule, the ADA said, a nutritionally adequate diet should include 12 to 20 percent protein, 50 to 60 percent carbohydrate (with emphasis on complex carbohydrate), and the balance fat. Saturated fatty acids should constitute less than 10 percent of the total Calories and polyunsaturated fats should supply up to 10 percent of intake, it recommended.

Although advocates of low carbohydrate diets believe such diets promote rapid weight loss, FDA nutritionists indicate that any weight loss usually is temporary and that lost pounds return rapidly when regular meal patterns are resumed. FDA's recommendation is that, for long-term reduction in weight, the most successful diet includes regular meals and only small changes in the foods usually eaten.

Next: Identifying sugars on food labels.

Chris Lecos is on FDA's public affairs staff.

The Color Additive Scoreboard

Why does the good, gray FDA have to be such a killjoy about the free and easy use of colors to put a little more excitement in foods, drugs, and cosmetics? The answer is that colors improperly used can harm or deceive; and the Agency, therefore, requires regulated industries to go by the book to keep the public's well-being uppermost.

by Harold Hopkins

As we look about us, almost everything we see or know can be sorted out not only by form, substance, texture, but also by color. Some colors—for instance, of trees, grass, a child's hair or cheeks, butter, oranges, and chocolate—come right out of Nature's paintpot with no human tinkering.

It's human nature that stirs up the pot, however, and artifice has a hand in the coloring or recoloring of many objects around us. Both the manufacturing industry and the consumer avail themselves of the wide spectrum of natural and synthetic coloring substances that can improve or vary the outcome from Nature's palette. Humans can and do make subtle distinctions among colors, natural or contrived; throughout their lives they rely on colors and gradations of colors to identify and assign values to the things they encounter and to enhance esthetic enjoyment or appreciation of their surroundings.

Although colors help make life more livable for mankind, there are some significant drawbacks. For instance, some chemical compounds used in coloring are harmful if swallowed and others if applied to the skin or other parts of the body, and some deceptive uses of color can fool

the consumer as to the value or the identity of the product he's buying.

That's where FDA enters the picture. The potential menace to health from the substances used in coloring comes when they are eaten in foods, taken internally in drugs, or applied to susceptible parts of the body in drugs or cosmetics. The misuse of color to deceive the buying public is amply documented in the history of food and drug regulation. The Food, Drug, and Cosmetic Act specifically prohibits the use of a color additive in foods, drugs, or cosmetics if it will deceive the consumer, conceal inferiority or damage, or otherwise result in misbranding or adulteration.

The potential for being harmed by exposure to coloring substances in FDA-regulated products exists because of the intimate way they are used. Physical exposure to a coloring substance in foods, drugs, or cosmetics is much more likely than to the paint or dye used in or on a building, a rug, or an automobile, for instance, or from an article of clothing or jewelry, a painting, or the printed or graphic contents of a book or magazine.

FDA keeps a scorecard on color additives. This was required by the 1960 Color Additive Amendments to the Food, Drug, and Cosmetic Act. Specifically, the law told the FDA umpires to maintain a list of color additives that the Agency had determined were safe for the intended uses. There is an individual FDA regulation for every color additive on the list, specifying its physical or botanical or chemical identity, the products or kinds of products in which it may be used, the quantities that may be used, and other conditions of use that FDA considers necessary to protect public health.

Oddly enough, the bulk of color additives can be obtained from a black substance—coal. About 90 percent of the total dyes used in the products FDA regulates are synthesized from a single, colorless derivative of benzene, called aniline, which in its pure or uncombined form is poisonous. These aniline dyes are also known as synthetic organic dyes or as “coal tar” dyes because aniline was once obtained from bituminous coal. Aniline dyes today come mainly from petroleum, but the statute and FDA regulations still refer to them as “coal tar” dyes.

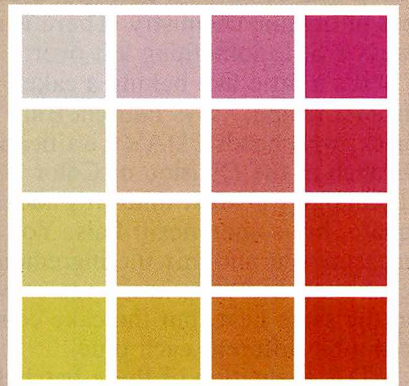
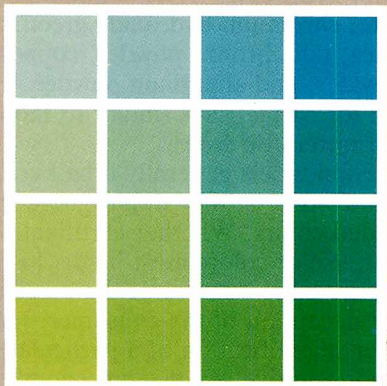
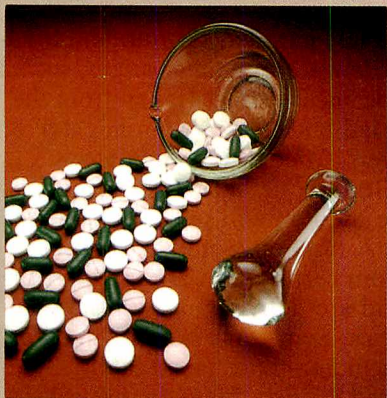
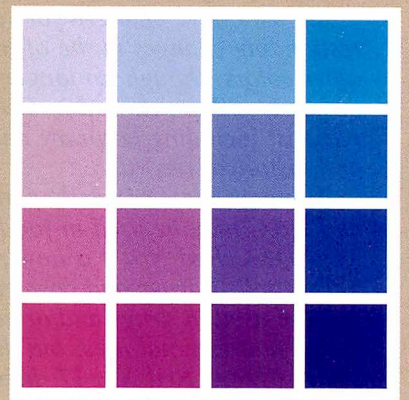
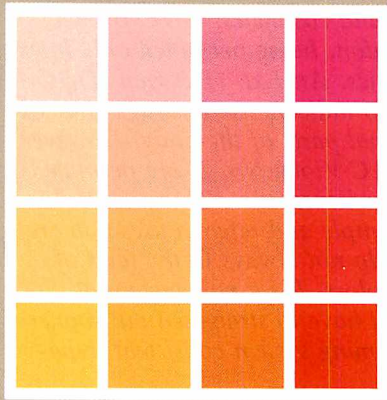
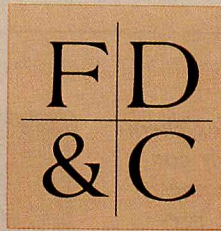
Color additives are divided into two main classes:

(1) Those consisting mainly of aniline-derived color additives, each manufactured batch of which is tested and certified by FDA;

(2) Those exempted from certification requirements because, in the form they are used, FDA does not consider batch certification necessary to protect public health. These consist of, or are closely related to, substances derived from vegetable, animal, or mineral products.

Color additives come in two categories: “permanent” and provisional. Those on the so-called permanent list are colors whose safety has been assured by data the manufacturer has collected from tests in laboratory animals. The provisional list—a category eventually to be abolished—consists of colors in use when the Color Additive Amendments were enacted in 1960 and which have not yet qualified for “permanent” listing because all the safety tests FDA requires for such listing have not been completed for these colors; nevertheless, FDA has no information to indicate that they are unsafe.

FDA analyzes every newly synthe-



Aniline and other coal tar dyes have complex chemical names and formulas. So, long ago, for convenience, FDA gave them simplified official names, consisting of the primary color and a number, preceded by the letters F, D, and C (FD&C) to designate the particular color's use in foods, drugs, and cosmetics. Other colors were preceded by D&C to denote use in drugs and cosmetics only and some by Ext. (External) D&C to indicate use in drugs and cosmetics applied to external parts of the body, such as the hair, nails, and skin. A few names, such as Citrus Red No. 2, are more specialized and explicit.

But uses have changed for some colors without corresponding changes in the official appellations, and other colors, though no longer used in any regulated product, still are carried in FDA records for many reasons, including accuracy and continuity of research and historical records.

Although most currently permitted colors designated as FD&C may be used in foods, drugs, and cosmetics, FD&C Red No. 4 is now permitted only in externally applied drugs and cosmetics. Most D&C colors may be used in drugs and/or cosmetics for both ingested and external uses, but there are exceptions, such as D&C Red No. 17, being permitted only in ex-



ternally applied drugs and cosmetics. D&C Brown No. 1 is another exception, being permitted only in externally applied cosmetics. An Ext. (External) D&C color is so designated to indicate use in drugs and cosmetics applied to external parts of the body. However, some, such as Ext. D&C Violet No. 2, are permitted only in externally applied cosmetics. Thus, while the names are ostensibly simple and refer to uses that are apparently clear, they do not always fit the facts of current usages of the colors. It's a nomenclatural scramble that FDA will have to straighten out sooner or later to make the naming system consistent, reliable, and more useful.

sized batch of color additives subject to certification to determine how well the concoction matches FDA's standards—that is, how well it matches the chemical formula that has been found to produce no harmful effects on laboratory animals exposed to it. Batch-by-batch certification is considered necessary because of the complex organic chemical reactions that take place during the synthesizing process. Matching the standard is always an unrealized ideal, for every new batch will be somewhat different from the last, since there is no such thing as a completed chemical process in organic chemistry. There is always a little something left over.

"It's a little like baking a cake from a recipe," says Patricia Bulhack, who heads FDA's Certification Branch in the Division of Color Technology. "Most times it's adequate, but sometimes it fails. You measure out and mix the ingredients each time and bake in the same oven at the same heat, but the cake comes out a bit different each time."

FDA evaluation of these batches is getting sharper: The Agency is increasing the safety margin of its cer-

tifications year by year by continuing to improve the sensitivities of its testing methods. In the 12 months ending September 30, 1979, for instance, the Agency tested and certified samples from 4,412 color additive batches and rejected 112 batches. The rate of rejections rose over one percentage point, from 1.2 to 2.5 percent.

The color additives for which certification is not required are mostly dyes or pigments of vegetable, animal, or mineral origin and generally require less processing for use than do certifiable color additives, though some require more than others. Some have been used traditionally with no substantial questions of their safety. However, FDA regulations specify the conditions of use and the amounts that may be used in foods, drugs, and cosmetics. Because substances that occur naturally often contain impurities, limits have been established for impurities.

Most of the 25 certification-exempt color additives permitted in foods are vegetable compounds—beet powder, caramel, beta-carotene, grapeskin extract, juices of edible fruits or vege-

tables, paprika, saffron, and the like. A few are of animal origin, such as cochineal extract (taken from the dried bodies of certain insects). Some are restricted to certain foods. Ultramarine blue, for instance, may be used only in salt for animal feeds.

A total of 28 additives exempt from certification are used in drugs, and are derived mostly from minerals. Some may be used in all drugs, including those taken internally (or used in such things as surgical sutures); others are only for external use. Some examples are dried aluminum hydroxide, ferric ammonium citrate, chromium hydroxide green, mica, talc, bronze powder, copper powder, and aluminum powder. The list for cosmetics is similar to those permitted for drugs.

Food labels generally aren't color blind—that is, they don't ignore the added colors. Whether certifiable or not, use of colors must be disclosed on the label because of the possibility for deception of the consumer. However, identification of a particular color additive is not required unless it has been determined that it's necessary to protect public health.

FD&C Yellow No. 5 (also known as tartrazine) is a recent example. It can cause many people to have allergic-type reactions. So last year, FDA required listing of FD&C Yellow No. 5 by name on the labels of foods and ingested drugs. The labels on cosmetics were already required, in the list of ingredients, to give the name of each color additive used.

Butter, cheese, and ice cream are exempted by law from any general requirement to disclose whether color has been used in these products—except when there is a question of safety—as there was in the case of FD&C Yellow No. 5. In standardized foods—those with common ingredients that do not need to be listed on the label because they are required to be used by regulation—the use of color additives must be declared on the label because they are considered optional in all cases.

Color can be essential to users of either prescription or nonprescription drugs. It can provide identification of the product or brand, or of the dosage category. Therefore, the hue often fulfills a useful and sometimes critical function that can help prevent use of the wrong drug. Since deceptive or misleading information is not a factor, colors need not be listed on drug labels—FD&C Yellow No. 5 being a notable exception.

Although Congress was explicit in forbidding deceptive uses of color by manufacturers, it avoided one arena where consumers may practice “deceptions” upon each other. The law specifically exempts aniline hair dyes, also known as coal-tar or permanent hair dyes, from the restraints imposed on the use of colors in foods, drugs, and other cosmetics. Consequently, the marketing of these dyes is permitted by law even though they may be harmful or cause adverse reactions in many people. The law requires only that their labels carry warnings against use in the area of the eye and of possible adverse reactions, and that they instruct consumers how to test a small patch of skin with a bit of the product for adverse reactions before applying the rest of the product to their hair.

After it was found that one chemical compound used in some of these dyes, 4-methoxy-m-phenylenediamine, and its sulfate, caused cancer in laboratory test animals, FDA

adopted a regulation in 1979 requiring that permanent hair dyes containing this ingredient bear a label warning. Most (but not all) makers had discontinued using this substance in their hair dyes by the end of 1979. In the meantime, FDA announced that it was looking at other suspected cancer-causing chemicals in permanent hair dyes.

Colors come and go, and some just fade away. Both certifiable and non-certifiable types can become has-beens. Such changes have resulted from industry trends and practices, from findings that the colors may be harmful to health, or from lack of interest or inability of sponsors to demonstrate that the color additive can be safely used.

About a decade ago scientific questioning of the safety of some food additives, including colors, intensified. The questioning helped rouse that sleeping giant, consumerism. The heightened public and scientific concern has led to the banning of several colors.

A color that drew particular attention was FD&C Red No. 2, because of its extensive use in foods, drugs, and cosmetics for many years. Researchers in Russia had reported that this color, also known as amaranth, caused cancer in rats. Although FDA was never able to determine the purity of the amaranth tested in Russia, these reports led to FDA investigations and a series of tests that eventually resulted in withdrawal of FD&C Red No. 2 from the FDA provisional list in 1976 because its sponsors were unable to prove safety. That year, the Agency also terminated its provisional approval for use of FD&C Red No. 4 in maraschino cherries and ingested drugs and of carbon black for all direct uses, both because of unresolved safety questions.

It's FDA's aim to abolish its provisional list when safety tests are completed for all the colors. They will either be moved to the “permanent” list, or—if not found safe—be taken off provisional status and prohibited from further use. All color additives, provisional or “permanent,” used in foods or internally taken drugs are also being examined by FDA in its overall review of all classes of food additives. The appearance of a color on FDA's “permanent” list is no as-

surance that it will not be outlawed if serious questions arise about its safety.

Some concerned consumer-oriented spokesmen have said that FDA has been looking at the world of color additives through rose-colored glasses. They suggest that drastic action be taken against the use of color additives in food. Some have recommended blanket prohibition of all color additives. The argument is that the added colors contribute nothing to food safety or nutrition and are used principally to give the products better sales appeal. They maintain that food processors are too often more concerned with making their products more competitive in the marketplace than with the possible risks to public health from use of potentially harmful color additives. Color additives, moreover, increase the cost of the food somewhat and can mislead some consumers and give them a false sense of security about a food's safety and economic values, they say.

Industry and other spokesmen reply that the consumer wants food to be esthetically pleasing and appetizing and that the food industry's use of color simply gives the consumer what he demands. Much of the processing, preservation, packaging, and storage that is necessary to make food available and acceptable would cause it to be esthetically unacceptable were it not for the color additives used in food, they maintain. They suggest that public protest would be loud and long if many uses of color were discontinued. People would be reluctant to eat margarine, for instance, without the coloring that makes it resemble butter, they say.

So the controversy rages—spirited, serious, and—you'll excuse the expression—sometimes colorful. But then it's hardly a drab subject. Neither is it a drab world. Just bask in the beauty of a setting sun—spectacular, free, made for enjoyment. Or enjoy the visual feast of a tropical sea environment—gaudy fish, many-hued plantlife, the brilliant tints of coral. Of course, the latter may be deadly to touch—it seems that Nature hasn't settled the color argument either.

Harold Hopkins is editorial director of FDA CONSUMER.

Regional Reports

PCB's . . . A Middle Chapter

Snow white, purely crystalline, deadly toxic. These words describe the group of related industrial chemical substances called PCB's (polychlorinated biphenyls). The story of PCB's has a beginning and a number of chapters, many of them melancholy, and the end is not yet in sight.

This chapter concerns 200 gallons of PCB-containing insulating fluid that leaked from a damaged transformer, which had been in storage for 9 years at the Pierce Packing Co., an animal feed distributor in Billings, Mont. This contaminant got into the food production chain, spread across 19 States—plus Japan and Canada—and required the destruction of more than 325,000 chickens; 4 million eggs; 41,000 pounds of meat and bonemeal; 12,000 cases of frozen strawberry cakes; 184,000 pounds of concentrates and finished feed; and 3,375 hogs.

When the transformer was built, nobody guessed it could be so dangerous. PCB's—a group of chemical compounds once thought to be harmless—had certain properties that made them ideal for use in insulating fluids in electrical transformers, capacitors, and heat transfer systems. They were insoluble in water, resistant to biological and chemical breakdown, and stable at temperatures up to 862 degrees Celsius. Their safety was not seriously questioned in the years between 1929—when they were first manufactured—and the early sixties. During these 30-odd years they were widely used in transformers and capacitors and a multitude of consumer products: adhesives, sealants, caulking, paints and varnishes, insulating tape and protective lacquers, lubri-

cants, printing ink, and carbonless copy paper. During these 30 years, according to SCIENCE NEWS, about 750 million pounds of PCB's were produced, and most are believed to have been discharged into the environment.

In 1968, a large number of people in Japan developed a number of unpleasant and unhealthy reactions from eating rice that had been contaminated by PCB's. Studies of PCB's since then have turned up some alarming data. In lab tests on animals, PCB's have been shown to cause liver damage and tumors, reproductive problems, acne, hair loss, and eye inflammations. A study at the University of Wisconsin showed that offspring of female monkeys exposed to PCB's had behavioral and learning disabilities. Other studies have suggested the possibility that PCB's may cause cancer and male sterility. And PCB's (which can be ingested, inhaled, or absorbed through the skin) accumulate in the liver and body lipids, are poorly metabolized, and have a half-life of about 20 years (that is, in 20 years half the PCB's you ingest today will still be in your body).

In 1973, FDA set tolerances for PCB's for certain products (milk, dairy products, eggs, poultry, fish, baby foods, animal feed, ingredients used in animal feed, and paper food packaging materials) and banned the use of PCB's in establishments that handle food, feed, and food packaging materials. However, the FDA ban was not applied to closed electrical equipment—such as transformers—mainly because there were no suitable replacement chemicals.

The problem at Billings, Mont., was first discovered by the U.S. Department of Agriculture (USDA) during routine residue monitoring at a large chicken processing plant in Utah. USDA officials notified FDA, and the Agency's Seattle and Denver districts began an intensive search for the source of the contamination, finally tracing it to the Montana firm. Denver investigators discovered the damaged transformer and deduced the chain of events: The insulating liquid leaked into the plant's waste water drainage system. The plant then salvaged the fats, grease, and other edible products from a catch basin in that drainage system and used them in the manufacture of meatmeal and animal feed. The feed, contaminated with the PCB's, was shipped to the Idaho chicken farm, as well as a large number of other farms and animal feed manufacturers. It was fed to hundreds of chickens, got into the eggs, and into products made with the chickens and eggs. Some 1,400 firms may have received the contaminated meatmeal or feed made from it.

The magnitude of the problem triggered expressions of concern from news media, consumers, and Congress that the agencies responsible—USDA and FDA—may not have acted promptly enough.

"Detection of one particular incident is very much a matter of chance," said Carol Tucker Foreman, assistant secretary for food and consumer services, USDA, before a House subcommittee. "It is entirely possible that an occurrence such as the recent PCB incident could go undetected by our monitoring system for

a long period of time. It is also possible that a single incident of this size could go entirely undetected.

"We do not test every animal carcass for every possible chemical residue [because] the costs of doing so would be prohibitive. Some 120 million livestock and 3.5 billion poultry are inspected and marketed each year. The cost of testing all of them would be about \$100 billion."

The number of animal carcasses actually tested for chemical residues, according to Foreman, is about 20,000 each year.

"It is very likely," the assistant secretary said, "that there are a number of localized incidents of contamination (PCB's included) each year that we never know about."

Yet the incidents we do know about are disquieting, such as: PCB contamination of milk in West Virginia (1969); PCB residues in meatmeal in Illinois and in fishmeal in North Carolina (1971); and massive contamination of the fish in the Hudson River and Great Lakes (1975), and of fishmeal in Puerto Rico and Ralston Purina Poultry Feed (1977). In the year 1979 alone, PCB contamination was found in a herd of Kansas feeder cattle, in Maine lobsters, along some 200 miles of North Carolina roadsides, and in the breastmilk of a Lafayette, Colo., farm woman.

Still other disquieting items slip by, forming incomplete parts of a larger picture:

- A study by a DePaul University scientist showing that samples of dust in his Chicago apartment contained 8 parts per million of PCB's

- A newspaper report that recent Government tests show PCB's in the snows of Antarctica

- An EPA estimate that across the country there are more than 30 million transformers that contain PCB's

How to deal with PCB's—so stable, so heat resistant and water resistant, so indestructible? Monsanto Co., the only U.S. manufacturer of the chemical, in 1971 limited the manufacture of PCB's to those used in closed systems only, such as transformers. In 1976, the Toxic Substances Control Act banned the production and distribution of PCB's altogether. Just before the Billings, Mont., event, FDA proposed reducing existing tolerances for PCB's, and all but one have since gone into effect. FDA and USDA are now considering banning existing transformers that contain PCB's from use in food plants; and the two agencies plus EPA are asking food manufacturers and related industries to take voluntary steps to help prevent accidental contamination of food with PCB's until regulations dealing with the existing transformers can be put into effect.

Old transformers that are not stored away in a corner—such as the one at the Montana firm—are usually trucked to municipal incinerators or sanitary landfills. But the operating

temperatures of the incinerators are usually too low to burn and destroy the nonflammable PCB's. And, according to some scientists, when the transformers break open, the chemicals slowly evaporate and mix with other decay gases rising from the landfill or incinerator, getting into the air, into the water.

And what about that 750 million pounds of PCB's already manufactured and, possibly, in the environment? Analytical chemist Louis Pytlewski of Drexel University (Philadelphia) has developed what may be a workable method for chemically breaking down—or detoxifying—PCB's into salt and a relatively harmless chemical, polyhydroxylated biphenyl, which is similar to BHT. Pytlewski is working under a grant from the Environmental Protection Agency now and says that with luck he can design and build a pilot-scale detoxification reactor in 5 years or so. Unfortunately, the method works only for pure PCB's or PCB's mixed with oil, not for PCB's already in the body. The process, although yielding a usable by-product, also would be expensive.

The PCB contamination incident in Montana is now a closed chapter. But unfortunately it is only a single episode in the tragic saga of PCB's.

Regional Reports consists of information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA's regional and district field offices across the country to provide protection to consumers under Federal laws.

REGION I

Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

FDA's **Boston District** detained approximately \$550,000 worth of shrimp from India, Indonesia, Thailand, and Taiwan during November

1979. FDA districts are automatically detaining all shipments of shrimp from these countries—as well as from Hong Kong and Bangladesh—because of the high rate of *Salmonella* contamination, decomposition, and filth previously found in this product. The shrimp is detained at the point of entry, in this case the Port of Boston, even though it is not first tested and found violative. The importers recondition the shrimp and, if subsequent analysis of the product by FDA demonstrates the shrimp is safe to eat and free of filth and decomposition, it is released for distribution. The automatic detention eliminates some time-consuming steps, such as sampling and analysis prior to detention.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

A rare strain of malaria posed a problem that was solved by the Center for Disease Control (CDC) in Atlanta and FDA's **New York District**. The disease, infecting many Cambodian and Laotian refugees in America, proved resistant to all drugs—except quinine. The problem was that quinine, once the principal drug used to treat malaria, has been replaced by more modern drugs and is not currently being manufactured in this country. CDC finally located a stock of the drug in a Department of Defense depot, but then found the ampules of injectable quinine had an

expiration date only a few months ahead. At CDC's request, the FDA New York laboratory analyzed the quinine—to make sure it really was quinine and was still potent and sterile—and found that it was all three. CDC distributed the drugstocks to State health departments for treatment of the refugees. FDA is continuing to help CDC hunt for other supplies of this old-fashioned but essential drug.

One broken lightbulb led to the recall of over 70,000 5-pound bags of sugar by Amstar Corp., American Sugar Division, New York City. The broken lightbulb was located over a filling lane in the firm's Philadelphia packing plant and was not discovered by the company for several weeks. With the discovery, the firm took samples of the sugar and found some contained particles of glass. The New York District, notified by the firm, supervised the recall.

A wholesale candy/sundries warehouse destroyed approximately \$1,-000 worth of stored products following an inspection by FDA's **Buffalo District**. District investigators found candy defiled by rodents, cans of fruit drink that were swollen and rusty, and canned Liquid Pre-digested Protein Supplement that was in violation of FDA labeling requirements. A total of 208 quarts of the supplement, 185 cases of fruit drink, and 32 cases of candy were destroyed.

Only FDA and State and local health officials were interested in the final disposition of a railcar of contaminated flour, shipped by International Multifoods, Buffalo. The railcar was rejected by its New York consignee because it was infested by insects. The flour was returned to Buffalo where District investigators took samples, which were found to contain insect larvae. While the District was waiting for approval of its request for seizure, the firm tried to reject the railcar to the railroad. At the District's request, the New York Department of Agriculture and Markets placed the product under embargo until the seizure of the flour—worth about \$9,000—could be made.

A deputy U.S. marshal seized about \$8,000 worth of candy at Biermann Marzipan Co., North Bergen, New Jersey, after several inspections by FDA's **Newark District** investigators revealed the firm was using two illegal color additives. One of the additives, FD&C Red No. 2, was banned by FDA several years ago for use in food. The other, External D&C Orange No. 3, has never been approved for use in food. "External" means for use only in drugs or cosmetics applied to external parts of the body.

Panificadora Jerezana, Inc., a bakery in Santurce, Puerto Rico, was fined \$2,000 in the U.S. District Court of San Juan for continued insect and rodent infestation in its bakery and processing equipment. A two-count prosecution was brought against the firm after FDA's **San Juan District** conducted several inspections and the firm failed to correct the problems.

REGION III

Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia

Intraocular lenses (IOL's) were seized at Coburn Optical Industries, Inc., Colonial Heights, Virginia, because a nonapproved sterilization method was used on them. IOL's are artificial lenses used as a replacement by some patients who undergo cataract surgery for removal of their diseased natural eye lenses. Firms shipping IOL's across State lines must have an Investigational Device Exemption (IDE) from FDA. Coburn, which was shipping the lenses to physicians in Canada for investigational purposes, had such an IDE. However, the British manufacturer had used a sodium hydroxide sterilizing system on the lenses instead of one for which safety data was available under the IDE. Coburn Optical tried resterilizing with the approved ethylene oxide system but this "reprocessing" was unacceptable because of the lack of safety data relating to the reprocessing. Equally unacceptable was Coburn's failure to inform FDA, the Canadian government, or the Canadian physicians of

the situation. When FDA's **Baltimore District** discovered the IDE violation during an inspection of the firm's records, it initiated seizure of the firm's remaining stocks of IOL's, worth \$76,725, and informed the Canadian government of the firm's actions.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

A U.S. marshal made a mass seizure at the Philip Quaglin Tobacco Co., New Orleans, after an inspection by FDA's **New Orleans District** revealed extensive rodent contamination of candy and cheese products. The firm operates as a wholesale distributor of foods (mostly candy), cosmetics, nonprescription drugs, and tobacco products. All foods in permeable containers—worth about \$115,000—were seized.

REGION VII

Iowa, Kansas, Missouri, Nebraska

A U.S. marshal destroyed \$730 worth of rice at Sharp Grain and Supply Co., Crocker, Missouri. The U.S. District Court for the Western District of Missouri had ordered the rice destroyed after a routine inspection by FDA's **Kansas City District** revealed rodents were inhabiting several food storage buildings used by the firm. FDA investigators found three lots of rice in two of the buildings contaminated by rodent hairs, droppings, and urine stains.

REGION VIII

Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

A U.S. marshal seized 9,000 pounds of insect-contaminated products, valued at \$2,700, following a joint inspection by FDA's **Denver District** and the Colorado Department of Health. The inspection was made after a Denver firm notified the health department that various grains, flours, and beans that had arrived in their company truck were contaminated with insects. The truck driver had noticed the problem when he picked up the cargo at Diamond K Enterprises, Inc., St. Charles,

Minnesota. When the seller refused to take back the products, the driver brought them to the Denver firm where they were stored outside the building until food and drug officials could be notified.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

Yamamoto Bros., a produce grower in Glendale, Arizona, destroyed the remaining parsley crop after a routine inspection by FDA's **Phoenix Resident Post** revealed the crop had been sprayed with Dacthal,

a pesticide not approved by the Environmental Protection Agency (EPA) for use on parsley. EPA, alerted to the problem by FDA, turned the matter over to the Arizona Board of Pesticide Control. When subsequent investigation by the board confirmed FDA's findings, the board brought action. The Arizona grower agreed in court to stop using the pesticide inappropriately.

REGION X

Alaska, Idaho, Oregon, Washington

The test of the nose was the final proof needed to seize over 4,000

pounds of decomposed frozen salmon, shipped from Pelican, Alaska, by Pelican Cold Storage Co. Investigators from FDA's **Seattle District** discovered the problem with the fish during a field examination at Bellingham Cold Storage Co., Bellingham, Washington. The organoleptic specialists in the District laboratory (who examined the fish by smelling it) confirmed that the salmon was decomposed, and the District initiated the seizure. The seized fish were valued at \$10,300.

State Actions

State Actions reports on regulatory and administrative actions conducted by State and local government agencies to provide health and economic protection to consumers of foods, drugs, cosmetics, and medical devices.

Telltale Smell

The complaint—made by merchants in North Boonville, Missouri—was of “rats” and “bad odors.” The charge—made by the Springfield City/County Health Department—was violating city air quality standards and public nuisance ordinances. The firm—MFA Milling Co.—was fined \$671 in the Springfield Municipal Court. City/County health officials used a search warrant to gain entry to the North Boonville feed mill after neighboring businesses complained to the department. The investigators collected bags of dead rats, rat droppings, and maggot-infested feed, then took legal action. The firm is still being monitored by the health department, which reports an improvement in the conditions.



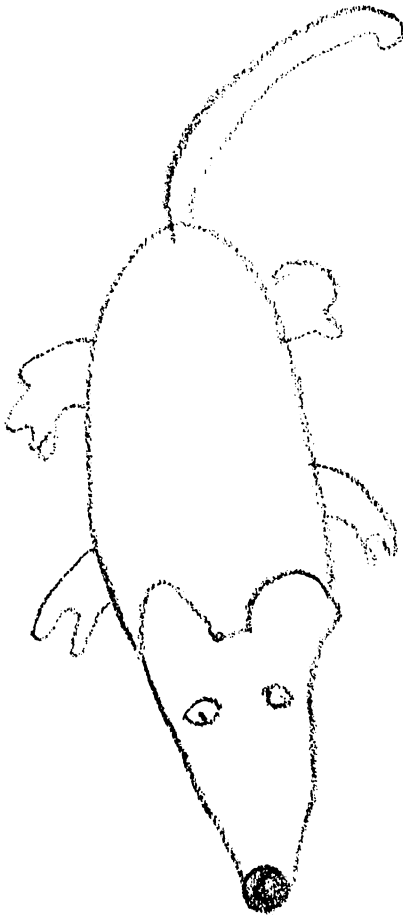
Fish That Wasn't & Didn't

Meredith Fish Co., Sacramento, California, tried to sell cod as sea bass and ended up being fined \$50,000 in the California Superior Court on charges of violating State laws against economic fraud. Investigators from the California Department of Health unraveled the firm's deceptions: the company said its products were sea bass and perch, which they weren't; that they originated in the

United States, when they didn't; that they had been certified by the California Department of Health, when they hadn't; and that there was more in the packages than there was. FDA's San Francisco laboratory—specially equipped to distinguish one fish species from another through electrophoretic identification—assisted the health department and confirmed that a substitution had been made. After a lengthy investigation, the State turned its findings over to the Sacramento County district attorney's office, which filed for injunction and civil penalties. The superior court fined the firm—known both as Meredith Fish Co. and as Ocean Beauty Seafoods—and ordered it to stop all violative practices.

Food Becomes Feed

Intervention by the Arizona Department of Health Services stopped the distribution of rodent-contaminated food to Arizona public schools. State officials obtained a Federal court injunction against Schade Refrigerated Lines, Phoenix, after an



inspection revealed extensive rodent contamination of products stored by the firm. The firm is a public storage warehouse that distributes U.S. Department of Agriculture (USDA) surplus commodities, such as grain and powdered milk, to Arizona schools under the Federal Food and Nutrition Program. Two earlier inspections by the State department had resulted in the destruction of over 13,000 pounds of food. Representatives from the Arizona Department of Education, Department of Health Services, and USDA met with Schade officials and toured the warehouse. After observing defiled merchandise and signs of rodent infestation, they agreed that all food products should be reconditioned or destroyed. Almost 92,000 pounds of food was subsequently reprocessed as animal feed. Under the terms of the injunction, the firm must set and make daily checks of at least 300 snap traps in the food storage area.

Baked Goods No Good

The Arizona Department of Health Services filed a complaint for

permanent injunction against R & S Mexican Food Products, a Mexican foods bakery in Phoenix, after two inspections revealed continued rodent and insect infestation. The bakery is one of 104 firms subject to periodic inspection under a contract between FDA and the State. The State obtained a cease and desist order after the first inspection turned up contaminated food products, construction deficiencies, improper storage of toxic materials, and continuing insanitary conditions. The injunction—prohibiting the firm from distributing contaminated foods—was sought after a later inspection showed conditions had remained virtually unchanged and over 1,000 pounds of raw ingredients and finished products were contaminated.

Truck Spill Spoils Cargo

Traveling through heavy rains and slippery conditions, a 45-foot refrigerated truck slid off a highway near Lewistown, Montana, and fell into surrounding floodwaters. The double semitrailer truck was en route to Chicago, after picking up 300 cases of frozen king crab parts from Seattle, when the accident occurred. The Central Montana Health District supervised the transfer of 226 uncontaminated cases of the product to another refrigerated van, which continued on to Chicago. The remaining 74 cases, which were thawing and contaminated by floodwater, were brought by the original carrier to a warehouse in Billings, Montana, where the Montana State Health Department placed them under embargo. The cargo was subsequently seized by a U.S. marshal at the request of FDA's Denver District.

Only Sugar Survives

When a Colorado Specialty Foods carrier truck caught fire, damaging almost 10,000 pounds of foodstuffs, the firm's traffic manager asked assistance from the Colorado Health Department in disposing of the fire-damaged products. Under the supervision of the health department and FDA's Denver office, approximately

\$17,000 worth of foods, vitamin products, and cosmetics were destroyed voluntarily by the Denver firm. The only products to escape a trip to the dump were some 50-pound bags of fructose crystals. Only two bags were damaged.

Clams Destroyed

Over 3,000 pounds of clams were destroyed by a New York importer after investigators from the New Jersey Department of Health discovered the shellfish had been imported from Brazil. Under the terms of the National Shellfish Sanitation Program (NSSP), foreign suppliers of shellfish must have the endorsement of FDA. Brazil is not so endorsed.

The NSSP was established over 50 years ago following a typhoid fever outbreak traced to the consumption of oysters from contaminated waters. Under the program, the Federal Government, States, and shellfish industry agreed to cooperate to ensure that shellfish, which are particularly vulnerable to contamination, are safe to eat.

Death on the Farm

Aflatoxin-contaminated corn caused the deaths of 240 hogs in the Marianna, Arkansas, area. A joint investigation by the U.S. Department of Agriculture (USDA) and Arkansas Health Department tied the hog deaths to corn from the 1979 crop, which had been inadequately dried prior to storage. Samples of the corn contained as high as 5,741 parts per billion aflatoxin. Only two of four farmers who had fed the corn to their hogs suffered losses. The hogs were embargoed by State officials, and three hogs from each farm were slaughtered, under USDA supervision, at a Little Rock packing plant. If analysis of a composite sample of kidney, liver, fat, and muscle from each hog proved negative for aflatoxin, the health department released the hogs from embargo. The contaminated corn was processed for alcohol at a gasohol plant, and the spent grain destroyed. The dead hogs were disposed of by burial on the farms.

The Notebook

■FDA has given the National Cancer Institute the go-ahead to start a clinical trial of **Laetrile**, provided two preliminary tests are successful. The first test, in rabbits, is to find out whether Laetrile causes fever; the second is a test in six patients to determine the toxicity of the cyanide that occurs naturally in the substance.

It will be at least a year after the clinical trial begins before results will be available. Dr. Jere Goyan, FDA Commissioner, said his agency will "objectively and promptly" evaluate any data produced by the study. In the meantime he cautioned cancer patients not to delay or abandon conventional treatment and turn to Laetrile.

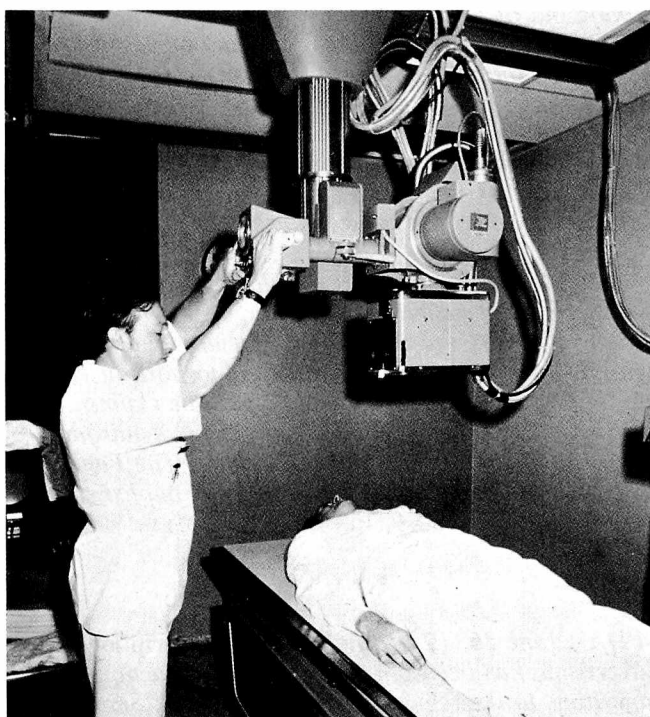
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■The Office of Technology Assessment (OTA), an advisory arm of Congress, has called for various changes in the Federal system for protecting the food supply from **environmental contaminants**, such as organic chemicals, heavy metals, and radioactive material.

In a report, released December 16, 1979, OTA recommended establishment of a national monitoring system for detecting chemicals that might enter the environment before contamination of food occurs; better coordination of Federal and State agencies in responding to contamination incidents; simplification of the process by which FDA sets tolerances on the amount of a chemical allowed in food; and clarification of the extent to which economic factors may be considered in setting tolerances.

* * * * *

■FDA was called to task by the General Accounting Office (GAO) for not making follow-up visits after it finds an x-ray unit has failed to meet Agency **x-ray performance standards**. In a report, "Radiation Control Programs Provide Limited Protection," the GAO also criticized the joint FDA/State program to reduce patient exposure from dental and breast x rays, saying nearly half of the mammography units and one-third of the dental x-ray machines checked in an eight-State



survey emitted either too much or too little radiation.

In response, FDA says it does not routinely make follow-up visits unless an x-ray machine poses an imminent health hazard, relying instead on documentation from the repair company. The under- and overexposure cited in the GAO report is mainly due to operator technique rather than faulty equipment, FDA says, pointing out that the Agency cannot regulate how medical and dental radiation is used.

To a further criticism that FDA doesn't know how often State inspectors visit facilities with faulty machines to help correct problems, the Agency says it does not keep case-by-case records of State follow-up visits but both the breast and dental x-ray programs call for such followups and State officials routinely visit facilities where there are problems and advise physicians and dentists on how to correct them.

* * * * *

■A recent addition to the growing number of reports coming out of FDA's review of over-the-counter (OTC) drugs is the Miscellaneous Internal Drug Product Panel's findings on **drugs for exocrine pancreatic insufficiency**, a condition which leaves the patient unable to digest food properly. Two preparations obtained from the pancreas of hogs—pancreatin and pancrelipase—are safe and effective to treat this condition, the Panel said. Hemicellulase is of no value, the group said.

Labeling for the products should say they are "for the treatment of exocrine pancreatic insufficiency when conducted under the care of a physician" and should warn against use by a patient allergic to pork, according to the Panel. Not acceptable would be claims of effectiveness for enteritis, postgastrectomy syndrome, chronic hepatitis, or gallbladder disease. The Panel's report, as yet unevaluated by FDA, was published in the December 21, 1979, FEDERAL REGISTER.

* * * * *

■FDA's June 26, 1979, final rule on **prescription drug advertising** has been put on hold pending action on objections to the regulations filed by Merck Sharp and Dohme; the Schering Corp.; the Association of Independent Clinical Publications, Inc.; the Pharmaceutical Manufacturers Association; the Upjohn Co.; the Pharmaceutical Advertising Council, Inc.; and Johnson and Johnson. Other sections of the June ruling, which pertain to labeling of prescription drugs, are not affected. Stay of the prescription drug advertising regulations was announced in the December 18, 1979, FEDERAL REGISTER.

* * * * *

■FDA has issued a proposal to declare that **nitrites in bacon** are not "color additives" under the Food, Drug, and Cosmetic Act because they qualify for the exception in the color additives definition, which covers substances used solely for purposes other than coloring. In a December 21, 1979, FEDERAL REGISTER notice the Agency points out that although nitrites do impart color the clearly predominant purpose for add-

ing them to bacon, as reflected by the amount used, is not coloring, but preservation. A level of about 120 parts per million (ppm) is needed for preservation, but only 10 to 30 ppm is required for color.

A similar exception will be made for nitrites used in other meat products if manufacturers, or other interested persons, can demonstrate that these other uses qualify for the exception in the same way that nitrites in bacon do.

FDA also proposed to declare that no prior sanction granted under the FDC Act exists for nitrites in poultry. Resolution of this issue will help determine under whose authority—FDA or USDA—these substances are to be regulated.

The proposed rule is a response to a petition filed by Public Citizen, Inc., and four others, asking FDA to declare that nitrites in bacon are color additives and, therefore, may not be used until they have been approved under the color additive provisions of the Food, Drug, and Cosmetic Act.

* * * * *

■**Saccharin and cyclamates** are not strong carcinogens—cancer-causing agents—but they should be regarded as potential risk factors for human bladder cancer. So say the authors of a \$1.5 million epidemiological study conducted by the National Cancer Institute (NCI) under an interagency agreement with FDA.

The study found an increased risk of bladder cancer among frequent users of artificial sweeteners and also among habitual cigarette smokers who also make heavy use of the artificial sweeteners. Women who normally would be at low risk for bladder cancer but who consumed sugar substitutes or diet beverages twice or more a day also had a greater risk of this cancer than similar women who did not use artificial sweeteners. The study was prompted by the Saccharin Study and Labeling Act of 1977, which prohibited FDA from banning saccharin in diet sodas and other diet foods but ordered further study of the popular product.

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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 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 70 actions to remove from the consumer market products charged to be violative was reported in January. These actions included 5 of foods; all involved charges concerning contamination. Others included 1 of color additives, 3 of drugs, and 61 of medical devices.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Contamination, Spoilage, Insanitary Handling		
Crabmeat/U.S. District Court for the District of New Jersey 10/16/79	Shell Key Packing Co./Baldwin, La.	Packed and held under insanitary conditions.
Crab pieces, frozen/U.S. District Court for the District of Montana 9/19/79	Shipped from truck wreck near Ryegate, Mont.	Contains decomposed crab, and is contaminated with <i>Escherichia coli</i> .
Ginseng, cinnamon quills, and turmeric/U.S. District Court for the Northern District of California 10/30/79	Presco Food Products, Inc./San Francisco, Calif.	Held under insanitary conditions; rodent contaminated.
Olives/U.S. District Court for the Southern District of Florida 10/18/79	Agrucapers S.A./Aguilas, Murcia, Spain	Contains moldy, decomposed olives.
Wheat/U.S. District Court for the Western District of Oklahoma 10/24/79	Shipped from Tipton, Kans.	Insect contaminated.
COLOR ADDITIVES		
Guava shells, canned/U.S. District Court for the Middle District of Florida 10/26/79	Imported from Mexico.	Contains nonconforming color additives (External D&C Red #10 and Color Index #16255).
DRUGS/Human Use		
Diethylpropion hydrochloride, 75 mg T.D. tablets/U.S. District Court for the Northern District of California 10/31/79	Pharmadyne Laboratories, Inc./Hackensack, N.J.	New drug without an effective approved New Drug Application.
Ephedrine hydrochloride tablets, unlabeled/U.S. District Court for the District of Montana 9/14/79	Shipped from outside the State of Montana.	Label fails to bear: name and place of business of manufacturer, packer, or distributor; accurate statement of quantity of contents in terms of weight and measure; and established name of drug. Labeling lacks adequate directions for use, and adequate warnings against unsafe use.
Hydroxyzine hydrochloride tablets, and hydroxyzine pamoate capsules/U.S. District Court for the Southern District of Florida 10/2/79	Darby Drug Co., Inc./Rockville Centre, N.Y.	New drug without an effective approved New Drug Application.

PRODUCT, DISTRICT & DATE FILED	FIRM AND PLACE OF BUSINESS	CHARGES
MEDICAL DEVICES		
Hair implant assemblies, and implant syringes/U.S. District Court for the Western District of New York 10/19/79	Creative Enterprise/Hollywood, Fla.; and Hair Replacement Survival Center/Tonawanda, N.Y.	False and misleading claim as to FDA registration number; labeling fails to reveal material facts: that implantation of these fibers into scalp may result in infection, rejection, and permanent scarring; fails to bear adequate directions for use; and lacks adequate warnings against unsafe use.
Ovultron for "L-Field" measurement/U.S. District Court for the District of Oregon 10/23/79	Ovultron Corp./Las Vegas, Nev.	Labeling contains false and misleading claims for detecting preparation for and act of ovulation, for being designed to indicate changes in the female electrodynamic field, or "L-Field," and other similar false and misleading claims.
X-ray unit, Traceray III, 10 actions/U.S. District Court for the District of Minnesota 10/2/79	Western States Supply Ltd./Pueblo, Colo.	Article's quality falls below the component certification since the article fails to comply with the standards. Dangerous to health when used as directed, because emits radiation beyond pre-set exposure time.
X-ray unit, Traceray III/U.S. District Court for the Eastern District of Wisconsin 10/5/79	"	"
X-ray unit, Traceray III, 4 actions/U.S. District Court for the Northern District of California 10/5/79	"	"
X-ray unit, Traceray III/U.S. District Court for the Western District of Wisconsin 10/10/79	"	"
X-ray unit, Traceray III, 6 actions/U.S. District Court for the Southern District of Florida 10/10/79	"	"
X-ray unit, Traceray III, 3 actions/U.S. District Court for the Eastern District of California 10/10/79	"	"
X-ray unit, Traceray III, 2 actions/U.S. District Court for the District of Minnesota 10/10/79	"	"
X-ray unit, Traceray III, 2 actions/U.S. District Court for the Middle District of Florida 10/12/79	"	"
X-ray unit, Traceray III/U.S. District Court for the District of Hawaii 10/15/79	"	"
X-ray unit, Traceray III/U.S. District Court for the Northern District of Florida 10/15/79	"	"
X-ray unit, Traceray III, 3 actions/U.S. District Court for the District of Minnesota 10/15/79	"	"
X-ray unit, Traceray III, 9 actions/U.S. District Court for the Western District of Washington 10/16/79	"	"
X-ray unit, Traceray III, 2 actions/U.S. District Court for the District of Hawaii 10/17/79	"	"
X-ray unit, Traceray III, 4 actions/U.S. District Court for the District of Oregon 10/17/79	"	"
X-ray unit, Traceray III, 3 actions/U.S. District Court for the Eastern District of Washington 10/19/79	"	"
X-ray unit, Traceray III/U.S. District Court for the Western District of North Carolina 10/22/79	"	"
X-ray unit, Traceray III/U.S. District Court for the Middle District of Florida 10/24/79	"	"
X-ray unit, Traceray III/U.S. District Court for the Middle District of Florida 10/26/79	"	"
X-ray unit, Traceray III, 4 actions/U.S. District Court for the Eastern District of Kentucky 10/31/79	"	"

Complaints Filed by Law Department Under 39 U.S.C. 3005 (False Representation)

- July 25, 1979: **Fenby Brown**, P.O. Box 711, Palm Harbor, Illinois. Advertising and sale through the mail of the product "Dr. Fenby's Formula-X," representing the ability to relieve arthritis, rheumatism, bursitis, and generally improve your health by increasing your body's potential to heal itself.
- August 9, 1979: **Bio-Cosmetics, Inc.**, 720 Stewart Avenue, Garden City, New York. Advertising and sale through the mail of the product "Weight Loss," representing the ability to burn Calories and make fat pads disappear.
- August 10, 1979: **Standard Research Labs**, P.O. Box 9547, Fort Lauderdale, Florida. Advertising and sale through the mail of the products "Nucleic Hair Regenerator" and "B-15," representing the ability that hair growth can be revitalized and B₁₂ can keep you younger longer and relieve pain and discomfort of heart problems.
- August 10, 1979: **Hauser International, Inc.**, 3198-J Airport Loop Drive, Costa Mesa, California. Advertising and sale through the mail of the product "Par-O-Star Hair Care Kit," representing the ability to promote hair growth.
- August 10, 1979: **Ruhe Research Group**, 2016 Apache Trail, Chatsworth, Georgia. Advertising and sale through the mail of the product "Swiss Formula," representing the ability to stop hair loss, promote vibrant new growth, and make hair healthier and thicker.
- August 17, 1979: **Sunset House**, 314 Sunset Blvd., Beverly Hills, California. Advertising and sale through the mail of the product "Sip and Slender Tablets," representing the ability to cause weight loss.
- August 23, 1979: **Sunset House**, 314 Sunset Blvd., Beverly Hills, California. Advertising and sale through the mail of the product "Nutra Nail Conditioner," representing the ability to grow nails.
- September 7, 1979: **Standard Research Labs**, P.O. Box 9667, Fort Lauderdale, Florida. Advertising and sale through the mail of the product "Jojoba Extract," representing zero hair loss.
- September 9, 1979: **E.R.R. (E. R. Renner)**, P.O. Box 344, Cleveland, Ohio. Advertising and sale through the mail of the product "Salvation for Arthritis," representing the ability to relieve arthritis pain.
- September 27, 1979: **Eric Lawrence**, 5 N. Park Avenue, Rockville Centre, New York, New York. Advertising and sale through the mail of the product "Jojoba Energizer," representing the ability to stop hair loss and grow new hair.
- September 28, 1979: **Hair-Gro**, 408 N. High Street, Salem, Indiana. Advertising and sale through the mail of the product "Hair Treatment," representing the ability to treat for thin and falling hair.

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

- July 19, 1979: Against **Wilmont Products**, 8831 Sunset Blvd., Suite 300, Los Angeles, California. Satisfactory evidence was presented to the Postal Service that Wilmont Products and their agents are engaged in conducting a scheme or device to obtain money through the mails by means of false representation. This firm was advertising the product "STUD," representing the ability to renew sexual drive, increase the size of the penis, and give harder erections.
- July 30, 1979: Against **Viaids Laboratories**, 225 W. 34th Street, New York, New York. Satisfactory evidence has been presented to the Postal Service that Viaids Laboratories and their agents are engaged in conducting a scheme or device to obtain money through the mails by means of false representation. This firm was advertising various aphrodisiacs, sex stimulants, and sexual aids.
- August 31, 1979: Against **Acu-Velop, Inc.**, P.O. Box 1356, Clearwater, Florida. Satisfactory evidence has been presented to the Postal Service that Acu-Velop, Inc., and their agents are engaged in conducting a scheme or device for obtaining money or property through the mails by means of false representation with respect to the Breast Enlargement Technique. The product guarantees with this technique to actually activate areas of your body causing your breast to enlarge naturally, which is what you want.
- September 5, 1979: Against **Esoteric of the World**, P.O. Box 8639, Hollywood, Florida. Satisfactory evidence was presented to the Postal Service that Esoteric of the World and their representatives are engaged in conducting a scheme or device to obtain money through the mails by means of false representation. This firm was advertising a booklet on new hair growth. It states it has found a new and easy and inexpensive way to stimulate new hair growth by reading this booklet.

Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Contamination, Spoilage, Insanitary Handling

Basil, dehydrated pineapple rings, mustard seed, and pistachios and filberts, at New York, S. Dist. N.Y.

Charged 1-19-79: while held by Baker & Williams Warehouse, New York, N.Y., the pineapple rings, the basil, the mustard seed, and the pistachios contained rodent filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). The basil was not claimed and a default decree of condemnation ordered the basil destroyed. A consent decree of condemnation ordered the dehydrated pineapple rings destroyed. A consent decree authorized release of the mustard seed to Transit Trading Corp., New York, N.Y., for salvaging. Another consent decree for the pistachios and the filberts authorized release to J. F. Braun & Sons, New York, N.Y., for salvaging. (F.D.C. No. 61970; S. No. 78-146-837 et al.; N.J. No. 1)

Beans, red and black, dried, at Brooklyn, E. Dist. N.Y.

Charged 1-19-79: while held for sale, the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Japan Food Corp., Brooklyn, N.Y., for salvaging. (F.D.C. No. 62090; S. No. 79-185-046; N.J. No. 2)

Beer, soft drinks (e.g., gingerale), and other foods (including paper and Styrofoam cups), at Rock Springs, Dist. Wyo.

Charged 4-5-79: while held by Western Wyoming Beverages, Inc., Rock Springs, Wyo., after a warehouse fire, the articles had been held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 62248; S. No. 79-196-331 et al.; N.J. No. 3)

Coconut, desiccated, at Miami, S. Dist. Fla.

Charged 12-20-78: while held by Francois Jacquemoux, Inc., Miami, Fla., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61974; S. No. 79-193-237; N.J. No. 4)

Crab legs, claws, and broken bits, at Billings, Dist. Mont.

Charged 9-19-79: while held for sale, the article, which had been involved in a truck wreck, contained decomposed crab and *E. coli*; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62465; S. Nos. 79-117-518/9; N.J. No. 5)

Flour, at St. Croix, Dist. V.I.

Charged 11-5-79: while held by Scotty's Bakery, St. Croix, V.I., the article had been held under insanitary conditions and contained insect filth; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61963; S. No. 79-157-375; N.J. No. 6)

Flour, rolled oats, nonfat dry milk, rolled wheat, and instant mashed potatoes, at North Little Rock, E. Dist. Ark.

Charged 6-21-79: while held by Arkansas Food Distribution Division, North Little Rock, Ark., some of the articles contained rodent filth, and all 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. 62212; S. No. 79-137-532 et al.; N.J. No. 7)

Lentils, pinto beans, and birdseed, at El Paso, W. Dist. Tex.

Charged 6-8-79: while held by Economy Cash & Carry, Inc., El Paso, Tex., the lentils and the pinto beans contained rodent filth—402(a)(3); all of the articles had been held under insanitary conditions—402(a)(4); and when the lentils were shipped by J.W. Crowley & Sons, Monticello, Utah, and the pinto beans were shipped by Wallace Grain & Pea Co., Polouse, Wash., the pinto beans lacked the common or usual name of the food and lacked a quantity of contents statement, and the pinto beans and the lentils lacked the name and place of business of the manufacturer, packer, or distributor—403(e)(1), 403(e)(2), 403(i)(1). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62333; S. Nos. 79-180-882/4; N.J. No. 8)

Peas, black-eyed; dog food; and other foodstocks, at Griffin, N. Dist. Ga.

Charged 7-27-79: while held by Griffin Grocery Co., Griffin, Ga., some of the articles 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. 62392; S. No. 79-163-127 et al.; N.J. No. 9)

Poppyseed, at Brooklyn, E. Dist. N.Y.

Charged 1-9-79: while held by Coastal Warehouse, Inc., Brooklyn,

N.Y., 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 B. C. Ireland, San Francisco, Calif., for salvaging. (F.D.C. No. 62071; S. No. 79-184-800; N.J. No. 10)

Potato flakes, instant, at Louisville, W. Dist. Ky.

Charged 4-25-79: while held by Davis Cookie Co., Louisville, Ky., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 62265; S. No. 79-132-712; N.J. No. 11)

Shrimp, frozen, at Walnut Creek, N. Dist. Calif.

Charged 11-23-76: while held for sale, the article contained decomposed shrimp; 402(a)(3). A consent decree of condemnation authorized release to Summertime Products, Walnut Creek, Calif., for export to the original foreign supplier in lieu of destruction. After a number of stipulations and orders for additional time to comply with the conditions of exportation, a superseding consent decree was entered ordering the article destroyed. (F.D.C. No. 60971; S. No. 77-49-143; N.J. No. 12)

Sunflower seed, at Los Angeles, C. Dist. Calif.

Charged 8-20-74: while held for sale, the article contained insect filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59899; S. No. 66-950 H; N.J. No. 13)

FOOD/Economic and Labeling Violations

"Honey," Wild Mountain, and unlabeled orange "honey," at Campbell, N. Dist. Calif.

Charged 12-19-78 and amended 2-26-79: when shipped by H. W. Pilgrim, DeKalb, Miss., the articles (including articles labeled in part "Wild Mountain Brand 100% Pure . . . HONEY . . . U.S. Grade A [or "Chunk Comb Honey U.S. Unclassified" or "Orange 100% Pure Honey"] Roger Pond Campbell, Ca.") had had corn syrup substituted for honey—402(b)(2); the unlabeled lot of orange "honey" lacked the common or usual name of the food, lacked the name and place of business of the manufacturer, packer, or distributor, and lacked a quantity of contents statement—403(i)(1), 403(e)(1), 403(e)(2); and the six labeled lots were in violation of the Fair Packaging and Labeling Act, as follows: the 1-lb lot, 2-lb lot, 1 1/2-lb lot, and 3-lb lot expressed the quantity of contents as "Net Wt. 1 lb. [or "2 lbs." or "1 1/2 lbs." or "3 lbs.]" instead of "Net Wt. 16 oz (1 lb.) [or "32 oz. (2 lbs.)" or "24 oz. (1 1/2 lbs.)" or "48 oz. (3 lbs.)]"—15 U.S.C. 1453(a)(3)(A)(i); the quantity of contents statements appearing in the principal display panel areas of the 1-lb, 2-lb, and 1 1/2-lb lots of the articles (which areas were more than 5 square inches), were in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(3)(C)(i); and the quantity of contents statements appearing on the principal display panel areas of the 3-lb, 5-lb, and orange 5-lb lots of the article (which areas were more than 25 square inches) were in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(3)(C)(i). The Government requested and was granted an order to take postseizure samples of the articles to determine the specific level of adulteration. A default decree of condemnation authorized donation of the articles to charitable institutions. (F.D.C. No. 61982; S. Nos. 78-145-147/9 et al.; N.J. No. 14)

Tea, and tea in individual bags, at Nashville, M. Dist. Tenn.

Charged 12-4-73: when the tea in individual bags was shipped by Southern Tea Co., Atlanta, Ga., and while packages of loose tea were held by Colonial Coffee Co., Nashville, Tenn., who had repacked and relabeled the loose tea, the articles were in violation of the Fair Packaging and Labeling Act, as follows: the quantity of contents declaration for the tea in individual bags was not duplicated on the alternate principal display panels on the two sides of the packages—15 U.S.C. 1453(a)(2); the quantity of contents declaration on the principal display panel areas on the top and bottom of the packages of both lots of tea was not separately stated as required by regulations, since such declarations were not within the bottom 30 percent of such display panel areas—15 U.S.C. 1453(a)(3)(C)(i); and the quantity of contents statement, on the packages containing the tea bags and having principal display panel areas of more than 5 square inches, was in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(3)(C)(i). Consent decree authorized release to the dealer for reconditioning. The packages of loose tea were reconditioned, but such reconditioning of the tea in individual bags did not prove feasible, and the court authorized the donation of such article to a charitable institution. (F.D.C. No. 59568; S. Nos. 6-981/2 G; N.J. No. 15)



DRUGS/Human Use

Amygdalin injectable and tablets, Wobe-Mugos tablets, Katalyse eye-drops, Gluconic calcium gluconate combination tablets, Pancreas Compound tablets, Bromelain tablets, Calpam 15 calcium pangamate tablets, Pangamic Acid solution, calcium orotate tablets, Zinc Diorotate tablets, Hydrazine Sulfate capsules, and other unlabeled tablets and capsules, at Cincinnati, Dist. Ohio.

Charged 10-23-78; while held for sale, the Amygdalin tablets and injectable, Wobe-Mugos tablets, Katalyse eye-drops, Gluconic tablets, Pancreas Compound tablets, Bromelain tablets, Pangamic Acid solution, and calcium orotate tablets were new drugs without effective approved New Drug Applications—505(a); unlabeled containers of Amygdalin and other unlabeled tablets and capsules lacked the name and place of business of the manufacturer, packer, or distributor, lacked an accurate statement of quantity of contents and lacked the established name of the drug and/or its active ingredients—502(b)(1), 502(b)(2), 502(e)(1); and all of the articles (except the Katalyse eye-drops and the Pangamic Acid solution) lacked adequate directions for their intended use in treating cancer and lacked the prescription legend—502(f)(1), 503(b)(4). A motion for summary judgment was filed by O. Steven Michaelis, Cincinnati, Ohio. The court granted the motion for summary judgment and dismissed the seizure action saying:

"This matter is before the Court on the motion of claimant, O. Steven Michaelis, for summary judgment in a forfeiture proceeding instituted by the United States to take possession of claimant's property.

"The property which is the subject of this proceeding was also the subject of an earlier proceeding in this Court. Originally seized from the home and business premises of the claimant, in Hebron, Ohio, on July 14, 1977, it consists of records, drugs and other property allegedly evidencing criminal activity relating to receipt and distribution of drugs in interstate commerce in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §3301 *et seq.* After the seizure, Michaelis moved for return of property pursuant to Fed. R. Crim. P. 41(e). This Court issued a memorandum and order on June 29, 1978, holding that the seizure of articles from Michaelis' home and business was unlawful as undertaken pursuant to an invalid warrant. The illegality of the search and seizure was a function of prior illegal intrusions into Mr. Michaelis' privacy by the opening of packages mailed to or by Michaelis. On the basis of information obtained by those acts, which were themselves warrantless searches, the federal investigators gathered sufficient information to enable them to obtain from the federal magistrate a search warrant for Michaelis' home and business. That search warrant was defective in that it was obtained in sole reliance on the prior illegal, warrantless searches. So finding, this Court ordered the seized property returned to Mr. Michaelis.

"On August 29, 1978, this Court stayed execution of judgment pending an appeal by the United States. Upon receipt of a notice of voluntary dismissal of the appeal by the United States on October 16, 1978, this Court withdrew the stay order and reinstated the original order and judgment of June 29, 1978, thereby again requiring the United States to return the seized property to Michaelis.

"One week later, without returning the property, the United States began forfeiture proceedings by way of a Libel in Rem to attach and detain certain property identified as 'at Columbus, Ohio, in the possession of the Food and Drug Administration, 85 Marconi Boulevard, Room 227, . . . which [are] articles of drug . . . shipped in interstate commerce . . . prior to July 14, 1977.' Notice of the complaint for forfeiture was published indicating that any person claiming to have an interest in that property should file his claim. On November 15, 1978, claimant, O. Steven Michaelis, filed the motion for summary judgment that is presently before the Court in the instant forfeiture action.

"The primary issue confronting the Court is whether the government is collaterally estopped from proceeding in forfeiture by virtue of the Court's final judgment in the prior proceeding. The United States Supreme Court, while not enamored of the phrase 'collateral estoppel,' has reaffirmed the significance of the doctrine in *Ashe v. Stevenson*, 397 U.S. 436 (1970), holding that in criminal prosecutions the principle is an essential ingredient of the constitutional guarantee against double jeopardy of the Fifth Amendment. The Court in that case explicated 'collateral estoppel': 'It means simply that when an issue of ultimate fact has once been determined by a valid and final judgment, that issue cannot again be litigated between the same par-

ties in any future lawsuit.' *Id.* at 442. The *Ashe* court also recommended that the rule of collateral estoppel not be applied with 'the hypertechnical and archaic approach of a 19th Century pleading book but with realism and rationality.' *Id.* at 444. It is in this spirit that the applicability of collateral estoppel will be examined in this case.

"As discussed hereinabove in the prior action, the Court was concerned with the legality of the search and seizure under the Fourth Amendment to the United States Constitution. In granting the motion for return of property, this Court ruled that, 'Whether the search is characterized as administrative or criminal, it is encompassed by the Fourth Amendment.' *Michaelis v. United States*, No. C-2-77-771 (S. D. Ohio June 29, 1978), opinion at 5. The first question that arises is whether the Fourth Amendment is also applicable to the instant proceeding.

"The government contends that Fourth Amendment considerations do not apply to forfeiture proceedings against products seized under the Food, Drug and Cosmetic Act, 21 U.S.C. §330, *et seq.* I find this position unpersuasive. A forfeiture proceeding is an action in rem and as such is governed by admiralty principles, the special provisions of which are set out in Fed. R. Civ. P., Supplemental Rule C. Instead of imposing the full panoply of procedural precautions against unreasonable searches and seizures, Rule C requires that complaints in actions in rem be verified on oath or affirmation and describe with 'reasonable particularity the property that is the subject of the action.' The existence of this procedure does not mean that the Fourth Amendment plays no role in forfeiture; but rather, that in the ordinary case, its requirements are satisfied by the streamlined procedures of Rule C. As Judge Wright observed upon examination of the same seizure provision of the Food and Drug Act that is at issue in this case, (21 U.S.C. §334): 'Though warrants are generally necessary for arrests of persons and for searches, the warrant requirement has not traditionally been imposed upon seizures of the type involved in this case—attachment of property in the course of civil proceedings. This does not mean that the Fourth Amendment does not apply to such seizures, in both its substantive prohibition against unreasonable seizures and its procedural requirement of judicial or quasi-judicial review of the decision to seize. It means merely that judicial restraint is imposed through a different form of proceeding than the showing of probable cause before a magistrate.' *Founding Church of Scientology v. United States*, 409 F.2d 1146, 1150 (D.C. Cir. 1969), *cert. denied*, 396 U.S. 963 (1969).

"All the cases relied upon by the United States in this case pertain to instances in which there was so little intrusion into privacy that the admiralty procedure sufficed to satisfy Fourth Amendment standards. The government places primary reliance, for example, on *United States v. Articles of Hazardous Substance*, No. 78-1066 (4th Cir., decided October 30, 1978). This reliance is misplaced, for that opinion expressly disavows extending its principle to intrusive searches. Distinguishing *Camara v. Municipal Court*, 387 U.S. 523 (1967), the Court of Appeals stated 'that case dealt with the warrantless search of a private home, while the case before us involves a seizure pursuant to a warrant in a store which concededly was open to the public.' In footnote 1 the court points out that 'Since the premises in which the merchandise was seized were open to the public, there was no impermissible governmental intrusion in this case, and the seizure "did not involve an invasion of privacy." See *G. M. Leasing Corp. v. United States*, 429 U.S. 338, 351 (1977).'

"Similarly, the other cases cited by the government to support this general proposition are distinguishable from this case in that they deal with routine inspections, with consent, (e.g., *United States v. 75 Cases . . . Peanut Butter, et al.*, 146 F.2d 124 (4th Cir. 1944)), or with seizures from factory or business premises (e.g., *United States v. 935 Cases . . . Tomato Puree*, 136 F.2d 523 (6th Cir. 1943)), or are otherwise inapposite.

"The Supreme Court's decision in *Plymouth Sedan v. Pennsylvania*, 380 U.S. 693 (1965) supports the conclusion that Fourth Amendment protections should apply to this forfeiture proceeding. In *Plymouth Sedan*, the Court addressed an identical issue: whether illegally seized evidence already in the government's possession—by virtue of an unreasonable search—was admissible to sustain a forfeiture. The Court's holding that the Fourth Amendment applied to the forfeiture proceeding might be deemed distinguishable on the ground that the court found that particular forfeiture proceeding to be quasi-criminal in nature. The government in that case had arrested the owner of an automobile and charged him with violation of a criminal statute. It



then filed separate forfeiture petitions on the automobile and on the untaxed liquor he had been transporting in the car. Forfeiture of the liquor was upheld by the trial court, not challenged on appeal, and not addressed by the court. The trial court dismissed the action on the automobile, on the ground that the validity of its forfeiture depended upon the admissibility of evidence obtained without probable cause. The court noted that the object of the forfeiture proceeding, like a criminal proceeding, 'is to penalize for the commission of an offense against the law.' *Id.* at 700. The loss of the automobile would have subjected its owner to a greater deprivation monetarily than the maximum penalty for the crime charged. The court stated: 'It would be anomalous indeed, under these circumstances, to hold that in the criminal proceeding the illegally seized evidence is excludable, while in the forfeiture proceeding, requiring the determination that the criminal law has been violated, the same evidence would be admissible.' *Id.* at 701. The court was also influenced by the nature of the property forfeited: the Plymouth sedan was not illegally possessed; it was an allegedly illegal use to which the car was put that made it forfeitable; and the government in that case conceded that the illegal use could not be proven without the illegally obtained evidence. The court found that 'the return of the automobile to its owner would neither subject him to criminal liability nor frustrate any public policy concerning automobiles, as automobiles.' *Id.* at 699.

"The instant case is in some respects distinguishable from *Plymouth Sedan*. No criminal proceedings have ever been instituted against plaintiff Michaelis. The government's ostensible object is not to penalize for the commission of an offense against the law, but rather to protect the public from the dangers of misbranded and untested drugs. To this end, 21 U.S.C. §334 provides for the seizure and destruction of such articles. Moreover, the government argues that this property is by its nature unlike the automobile, and more like 'contraband per se' in that its return would frustrate the public policy to remove the drugs from the stream of commerce.

"The extent to which these differences actually distinguish *Plymouth Sedan* from this case—and, indeed, whether *Plymouth Sedan* can, after *Camara, supra*, logically rest on its own distinction between the criminal and the civil nature of the proceedings—is, in my opinion, questionable. In any event, I believe this proceeding has sufficient indicia of criminality to come within the *Plymouth Sedan* holding.

"First, the Act provides a criminal penalty in addition to its confiscation provision. Even though no criminal charge has been forthcoming, it is not at all clear that the original search and subsequent seizures were not accompanied by an intention to prosecute criminally. In fact, in its earlier order, this Court found that the July 14 search was personal and directed at the discovery of evidence of a crime and refused to categorize the search as either criminal or civil. The maximum penalty for criminal acts under 21 U.S.C. §331 is one year imprisonment or a fine of not more than \$1,000, or both, 21 U.S.C. §333. While the value of the property cannot be compared with the penalty of incarceration, it is instructive to note that the claimant values the property held by the government in excess of \$10,000, ten times the maximum monetary penalty for the criminal violation. Moreover, this forfeiture proceeding would require proof of the same elements that constitute a violation of the criminal law, and it would be inconsistent to apply the Fourth Amendment to the one proceeding and not the other.

"The government's position rests ultimately on the distinction drawn on the basis of the nature of the property, between contraband per se and 'innocent' property. This distinction was acknowledged by the Supreme Court in *Plymouth Sedan, supra*, at 698–99, discussing *United States v. Jeffers*, 342 U.S. 48, 54 (1951) and *Trupiano v. United States*, 334 U.S. 699, 710 (1948): '*Jeffers* and *Trupiano*, unlike *Boyd*, were not forfeiture cases. They were federal criminal prosecutions. In both cases the Court held that evidence seized in violation of the Fourth Amendment was not admissible notwithstanding the fact that the evidence involved was contraband. By way of dictum, however, since the point was not before it, the Court stated in these cases that its ruling that the contraband was excludable as illegally seized did not mean that the Government was required to return the illegally imported narcotics to Jeffers or the unregistered still, alcohol and mash to Trupiano.

"The nature of the contraband involved in these cases clearly explains these statements of the Court. Both *Trupiano* and *Jeffers* concerned objects the possession of which, without more, constitutes a crime. The repossession of such per se contraband by Jeffers and Trupiano would have subjected them to criminal penalties. The return of the contraband would clearly have frustrated the express public

policy against the possession of such objects.'

"While the line between narcotics, on the one hand, and an automobile on the other, may be an easy one to draw, it is difficult to determine on which side of it Michaelis' allegedly misbranded and unregistered drugs fall. The government's contention that this property is contraband per se is grounded upon its allegation that the property moved in interstate commerce before arriving in Michaelis' possession. If this is true, then if these articles are, in addition, adulterated, misbranded, or untested, they would be seizable under the Act. These items would then be 'contraband per se' rather than mere objects of illegal use and could be retained by the government notwithstanding constitutionally defective seizure. I am not prepared to find that the alleged interstate transportation of these articles so modifies their nature so as to make them contraband in and of themselves. Their interstate transportation more closely resembles the use of the automobile and would need to be established by proof in court before the government's right to forfeiture could be sustained. The mere possession of these articles, without proof of their interstate transportation, is not illegal. Moreover, the difficulty with the government's argument is that it would of necessity be using its own illegality to establish the nature of the property as subject to forfeiture. It demands that the Court engage in circular reasoning and disregard totally the legal conclusion that the property was seized in violation of the Fourth Amendment.

"The effect of finding that the Fourth Amendment's substantive prohibition of unreasonable searches and seizures applies in forfeiture proceedings does not mean that the procedural device for its enforcement—the exclusionary rule—should automatically apply. *Stone v. Powell*, 428 U.S. 465 (1976) indicates that the exclusion of evidence obtained illegally is proper only when its deterrent effect outweighs societal interests. The United States argues that the exclusion of such evidence in criminal proceedings is a sufficient deterrent to the FDA practices at issue and that the social interest in removing the articles from commerce weighs heavily in the balance. For the reasons stated in *Plymouth Sedan* and in discussion of that case above, however, I do not believe the rule's usefulness is outweighed in this case. The United States Supreme Court, in *United States v. Janis*, 428 U.S. 433 (1976) refused to apply the exclusionary rule where evidence was illegally seized by one sovereign and another sovereign wished to use that evidence. The rationale of the Court in that case was that the deterrent effect of the exclusionary rule could not be expected where the sovereigns were separate. In this case, the sovereign is the same and the effectuation of the Fourth Amendment by way of the exclusionary rule is most appropriate.

"The Court finds the situation in this case to be precisely that in which the exclusionary rule can have its heuristic effect thus protecting the citizens' privacy against illegal intrusions by the government and its agents. I am not confident that the beneficence of the purpose served by this forfeiture—the protection of the public by removal of the property from private hands—so mitigates the significance of the purpose served by the exclusionary rule that the rule should not apply to this proceeding. The Court's earlier order held that the property should be returned because probable cause had been obtained through illegal warrantless searches of packages in which Michaelis had a substantial privacy interest. The fact of a substantial governmental intrusion has not changed. The mere filing of a subsequent Libel in Rem action, with its weaker requirements consisting only of an oath or affirmation by a United States Attorney and a sufficiently particularized stipulation of property to be seized, cannot cure the defect in the original warrant. The filing of the Libel in Rem cannot erase the history of the proceedings nor convert them into less intrusion into the claimant's privacy.

"If the libel proceedings had the support of evidence independent of the illegal intrusions into the claimant's privacy, perhaps this Court could have been persuaded that the action was without the taint of violations of the claimant's constitutional rights under the Fourth Amendment. However, when property is illegally seized, the justification for its continued possession by the government must be shown by evidence derived independently of the illegal seizure. *United States v. One (1) 1971 Harley-Davidson Motorcycle Serial No. 4A25791H1*, 508 F.2d 351 (9th Cir. 1974); *Mayo v. United States*, 413 F. Supp. 160 (E.D. Ill. 1976).

"To the extent that the United States began forfeiture proceedings against the property which this Court had already ordered be returned to the claimant without providing or offering to provide correction of the defect which was the source of this Court's decision in *Michaelis v. United States, supra*, by way of untainted independent evidence,



the forfeiture proceeding in essence is an attempt by the United States to relitigate a matter which has already come to final judgment.

"The government has never returned the property to Michaelis. It has been seized only once. It simply instituted this forfeiture action on the property that was in its possession as a result of the July 14, 1977, seizure. Thus, notwithstanding the fact that the property at the time of the institution of the forfeiture proceeding was not in the hands of the claimant but was still being held by the government, the legality of its continued possession is contingent upon the validity of the original seizure. And this is precisely the question addressed in this Court's July 29, 1978, order.

"Although the Court recognizes that this forfeiture proceeding is an action independent of the earlier action concerning this property, nevertheless there is an identity of the property and an identity of defect in the two proceedings. The articles of drug specified in the libel are precisely those which were illegally seized on July 14, 1977, and they are described in a manner so as to make that identity unquestionably apparent.

"There is but a superficial ambiguity as to whether the same parties are involved in the two proceedings since in forfeiture the United States is proceeding against the property and not against the owner. However it is only an *appearance* of different parties. As the Supreme Court noted in *Boyd v. United States*, 116 U.S. 616, 638 (1886): '[A]lthough the owner of goods, sought to be forfeited by a proceeding *in rem*, is not the nominal party, he is, nevertheless, the substantial party to the suit; he certainly is so, after making claim and defense; and . . . he is entitled to all the privileges which appertain to a person who is prosecuted for a forfeiture of his property by reason of committing a criminal offense.' See also, *McKeehan v. United States*, 438 F.2d 739, 745 (6th Cir. 1971), which counsels disregarding the *in rem*, in personam distinction when its application acts to deny constitutional protections.

"Just as the *Ashe* court eschews a 'hypertechnical and archaic approach of the 19th Century pleading book,' this Court decides the case before it not on mere technicalities but with an eye to the ultimate character of the litigation. In that light this Court holds that as to the ultimate dispute, absent any showing of independently obtained evidence, there can be no genuine issue of material fact at issue between these parties because the Fourth Amendment applies fully to this proceeding as it did in the earlier proceeding. All evidence illegally seized by the United States is excluded in the instant proceeding by reason of collateral estoppel.

"The United States has failed to clear this proceeding of the taint which made the original seizure illegal. To treat the two proceedings as so entirely separate and independent and allow in the excluded evidence and to allow the government to declare forfeiture of illegally seized property would be to participate in the violation of claimant's constitutional rights under the Fourth Amendment. Accordingly, the claimant's motion for summary judgment and dismissal is GRANTED." (F.D.C. No. 61930; S. No. 78-112-789; N.J. No. 16)

Chlorpropamide tablets, at Ferndale, E. Dist. Mich.

Charged 12-14-78: when shipped by Premo Pharmaceutical Laboratories, Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 61983; S. No. 79-135-715 et al.; N.J. No. 17)

Colchicine tablets, and phenytoin capsules, at Brewster, S. Dist. N.Y.

Charged 6-1-76: while held by Consolidated Midland Corp., Brewster, N.Y. (who was repacking the articles from bulk stocks), the methods, facilities, and controls used for the packing of the articles failed to conform with current good manufacturing practice—501(a)(2)(B); the label of the phenytoin timed-disintegration capsules which had been repacked into 6-capsule packets bore the false and misleading statement "100 capsules," since the packets contained only 6 capsules—502(a); the labels of all lots of phenytoin capsules lacked the established name of the drug—502(e)(1)(A)(i); and, when the colchicine tablets were shipped by Barr Laboratories, Northvale, N.J., and when the phenytoin capsules were shipped by Ormont Drug & Chemical Co., Inc., Englewood, N.J., the articles were new drugs without effective approved New Drug Applications—505(a). The articles were claimed by the repacker who denied the charges.

The parties served written interrogatories on each other. Subsequently, the case came on for trial before the court. The court found for the Government and ordered the articles destroyed. (F.D.C. No. 60743; S. No. 76-58-681; N.J. No. 18)

Dipyridamole tablets, and other name tablets and capsules, at Baton Rouge,

M. Dist. La.

Charged 11-9-78: while held by Medi-Save Pharmacies, Inc., Baton Rouge, La., who was repacking the articles, the articles were packed and held under circumstances lacking current good manufacturing practice—501(a)(2)(B); and the articles' labels bore expiration dates which were false and misleading as to the stability of the articles, since such dates were not supported by adequate stability data—502(a). Consent decree ordered destruction. (F.D.C. No. 61918B; S. No. 78-136-012 et al.; N.J. No. 19)

Ephedrine hydrochloride tablets, unlabeled, at Kalispell, Dist. Mont.

Charged 9-14-79: while held for sale, the article lacked a label bearing the name and place of business of the manufacturer, packer, or distributor—502(b)(1); the article lacked a label containing a quantity of contents statement—502(b)(2); the article lacked labeling bearing adequate directions for use—502(f)(1); the article lacked labeling bearing adequate warnings against unsafe use—502(f)(2); and the article lacked a label containing the established name of the drug—502(e)(1)(A)(i). Default decree ordered destruction. (F.D.C. No. 62434; S. No. 79-117-513; N.J. No. 20)

Insulase chlorpropamide tablets, at Phoenix, Dist. Ariz.

Charged 6-5-79: when shipped by Premo Pharmaceutical Laboratories, Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 62312; S. No. 79-171-354; N.J. No. 21)

Papain tablets, in bulk and in retail bottles, at Detroit, E. Dist. Mich.

Charged 6-7-79: while held by Health Supreme Inc., Detroit, Mich., who was packaging the bulk tablets (which had been shipped in interstate commerce) into retail bottles, the articles were held and repackaged under circumstances that failed to conform with current good manufacturing practice; and the repackaged tablets had been repacked in an establishment not duly registered and had not been included in a required drug list; 501(a)(2)(B), 502(o). Default decree ordered destruction. (F.D.C. No. 62337; S. No. 79-182-139; N.J. No. 22)

Phentermine hydrochloride capsules, at Northvale, Dist. N.J.

Charged 5-22-78: while held by Zenith Laboratories, Inc., Northvale, N.J., who was manufacturing the article using phentermine HCl shipped in interstate commerce, the article was a new drug without an effective approved New Drug Application; and the article's labeling lacked adequate directions for use and was not exempted due to the article's new drug status; 505(a), 502(f)(1). The article was claimed by the manufacturer, who denied the charges and moved to dismiss the complaint on the grounds that the complaint did not allege that the finished drug had traveled in interstate commerce. After a hearing, the court determined that the complaint stated a cause of action and denied the claimant's motion. The Government served requests for admissions upon the claimant and the claimant served written interrogatories on the Government. The claimant served requests for admissions and for documents upon the Government. Meanwhile, the claimant filed an Abbreviated New Drug Application and obtained a temporary stay of the action until advised of the outcome of such application. If the claimant's application was approved, the claimant would consent, without admission of any issue of fact, to a finding that the seized article was misbranded under 502(f)(1). The application was approved by FDA, and a consent decree of condemnation ordered the article destroyed. (F.D.C. No. 61769; S. No. 78-133-539; N.J. No. 23)

Spironolactone with hydrochlorothiazide tablets, at Cumberland, Dist. Md.

Charged 6-27-79: when shipped by Premo Pharmaceutical Laboratories, Inc., South Hackensack, N.J., the article lacked an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 62352; S. Nos. 79-207-065/6; N.J. No. 24)

Sodium para aminosalicilate powder, and dyphylline tablets, at Indianapolis, S. Dist. Ind.

Charged 4-14-77: while held by Century Pharmaceuticals, Inc., Indianapolis, Ind., who was processing the articles using interstate components, the articles had been packaged and held under circumstances lacking current good manufacturing practice—501(a)(2)(B); and the labeling of the dyphylline tablets lacked adequate directions for use and was not exempted since such article was a new drug without an effective approved New Drug Application—502(f)(1). The dealer claimed the articles and denied the charges. The Government served written interrogatories and requests for admissions on the claimant. The claimant served written interrogatories on the Government. The



Government moved for summary judgment. After considering all the pleadings, affidavits, and other submitted documents, the court found for the Government and granted summary judgment condemning the articles and ordering them destroyed. In finding for the Government, the court concluded in part, as follows:

"To prevail on a charge of adulteration for failure to conform to current good manufacturing practices [GMP's], the government need not establish that any article of drug actually was contaminated. The purpose of the GMP provisions is to give the FDA authority 'to attack commerce in unsafe and unreliable drugs in its incipency . . . regardless of whether the drug is deficient in some respect.'

"The P.A.S. [para aminosalicylate] Sodium powder and Circair Dyphylline tablets under seizure were not manufactured in conformity with current good manufacturing practice and they are adulterated drugs within the meaning of 21 U.S.C. 351(a)(2)(B).

"The article of Circair Dyphylline tablets is a 'new drug' within the meaning of 21 U.S.C. 321(p) and thus required premarketing approval of either a new drug application [NDA], or an abbreviated new drug application [ANDA], or a Notice of Claimed Investigational Exemption under 21 U.S.C. 355 in that NAS-NRC [National Academy of Sciences—National Research Council] and FDA have determined that its active ingredient, xanthine, is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

"This Court may properly rely on the Commissioner of Food and Drugs' determination that the article of Circair Dyphylline tablets lacks general recognition of effectiveness for its labeled uses and is thereby a new drug within the meaning [of] 21 U.S.C. 321(p).

"A drug will be deemed misbranded under the Federal Food, Drug, and Cosmetic Act if the labeling of said drug fails to bear 'adequate directions for use' (21 U.S.C. 351(f)). 'Adequate directions for use' means directions under which a layman can use a drug safely and for the purpose of which it is intended (21 CFR 201.5). Because the article of Circair Dyphylline tablets is a prescription drug within the meaning of 21 U.S.C. 353(b) it cannot be labeled in a manner suitable for lay use.

"The article of Circair Dyphylline tablets therefore must be deemed misbranded as required by 21 U.S.C. 352(f)(1) unless it qualifies for an exemption from the 'adequate directions for use' requirement pursuant to regulations promulgated under the proviso clause in 21 U.S.C. 352(f). The article of Circair Dyphylline does not qualify for such an exemption since it is a new drug within the meaning of 21 U.S.C. 321(p) and no approvals of either an NDA, or an ANDA, or a Notice of Claimed Investigation[al] Exemption has been filed by Century Pharmaceuticals, Inc., with the FDA. Accordingly, the article of Circair Dyphylline tablets is misbranded within the meaning of 21 U.S.C. 352(f).

"Both articles of drug under seizure in this action are adulterated while held for sale after shipment in interstate commerce and are therefore condemned pursuant to 21 U.S.C. 334." (F.D.C. No. 61157; S. Nos. 77-68-575, 77-68-577; N.J. No. 25)

Zeet preparation for foot fungus, at Fort Lauderdale, S. Dist. Fla.

Charged 3-5-79: while held by McPhail Laboratories, Inc., Fort Lauderdale, Fla., who had manufactured the article using interstate benzoic acid, the article had been manufactured and processed under circumstances that failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 62086; S. No. 78-142-031; N.J. No. 26)

DRUGS/Veterinary

Diestrol-R repository diethylstilbestrol injectable, at Denver, Dist. Colo.

Charged 4-19-74 and amended 8-2-74: while held by Seney & Co., Inc., Denver, Colo., who had manufactured the article using interstate diethylstilbestrol, the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of such drug—501(a)(5). The article was claimed by the manufacturer. The parties served written interrogatories on each other. The claimant requested the production and the permission to copy a number of Government documents. The plaintiff moved for partial summary judgment on the issue of the claimant's article not being commercially used or sold in the United States on October 9, 1962, and that diethylstilbestrol repository was the subject of an approved New Drug Application on October 9, 1962. The Government also objected to a number of the claimant's written interrogatories.

The Government also served supplemental written interrogatories and moved for summary judgment condemning the article. A hearing on the Government's motion for summary judgment was set. However, the claimant advised that its management had been changed since the filing of the claim, and, because of the expense of litigation and questions concerning likelihood of success, the present management of Seney & Co., Inc., wished to withdraw its claim and to consent to a decree of condemnation. Accordingly, a consent decree of condemnation was entered which ordered the article destroyed. (F.D.C. No. 59742; S. No. 81-083 H; N.J. No. 27)

HiLo Dip Concentrated Rinse insecticide for eczema relief, HiLo ear mange remedy for cats, and HiLo ear mange remedy for dogs, at Glenford, E. Dist. N.Y.

Charged 1-18-78: while held by HiLo Products, Inc., division of Nip-Co Manufacturing, Inc., Glenford, N.Y., who had manufactured the articles using interstate components, the articles were new animal drugs and no approvals of New Animal Drug Applications were in effect with respect to the articles—501(a)(5); and the articles were also in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement on the principal display panel area of not more than 25 square inches of the dip was in a type size of less than 1/8 inch high—15 U.S.C. 1453(a)(3)(C)(i); the quantity of contents declaration in the principal display panel area of the ear remedy for cats was not placed within the bottom 30 percent of the principal display panel area—15 U.S.C. 1453(a)(3)(C)(i).

The articles were claimed by the manufacturer who denied the charges. The Government served written interrogatories on the claimant and a written request for the production of documents. The claimant filed a cross-motion for summary judgment in its favor. A partial consent decree as to the HiLo Dip Concentrated Rinse was entered into, which authorized release to the claimant for relabeling the article as an insecticide dip only. The claimant's and the Government's motions for summary judgment as to the remaining articles were denied. Upon consent of the parties, the action was tried solely upon the stipulations of the parties. The court found for the Government saying:

"By its verified complaint *in rem* filed January 18, 1978, the United States sought seizure and condemnation of certain articles of drug, more particularly described in the complaint and referred to below, in accordance with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, hereinafter 'FFDCA'. Two articles of drug were involved in this proceeding. One product, known as HiLo Dip Concentrated Rinse in liquid containers, was labeled in part 'Kills fleas, lice, ticks,' and was intended for use by the owners of dogs and cats. The second remedy [packaged in 1/2-oz bottles for cats and in 1-oz bottles for dogs] sought to be seized and condemned in the complaint was HiLo Ear Remedy for Cats and Dogs, labeled as 'effective in killing ear mites and dissolves ear wax and for the treatment of ear mange.'

"The Court has subject matter jurisdiction under 28 U.S.C. §§ 1345, 1355 and 21 U.S.C. § 334.

"A warrant for the arrest of the *in rem* articles was issued January 18, 1978, and duly executed by the U.S. Marshal. HiLo Products, Inc., a corporation, intervened in the proceedings and filed a claim as owner of the product or goods.

"A partial consent decree of condemnation was filed November 21, 1978, which in effect disposed of the claims concerning the HiLo Dip Concentrated Rinse, as therein more particularly set forth. By that partial judgment, the Court expressly retained jurisdiction for purposes of disposing of the issues concerning the ear remedy.

"Thereafter, motions for summary judgment by the Government and claimant were denied by the Court, and the case set for trial. On the occasion for trial the parties agreed to and did execute a stipulation of all pertinent facts, and consented that the Court try the action solely upon the stipulation. Such trial was held December 18, 1978.

"The facts stipulated to and approved in the Court's order dated December 18, 1978, are hereby found. Stated briefly, the parties conceded that HiLo Products, Inc., the claimant here, manufactures the defendant articles of drug, consisting of 'HiLo Ear Remedy for Cats (Dogs)' and the same remedy also labeled as 'HiLo Ear Remedy for Dogs (Cats)' hereinafter referred to as the ear remedies, and that they were seized from its plant at Glenford, New York. The ear remedies were manufactured in part from sulfathiazole and sulfanilamide, shipped in interstate commerce, and were labeled in accordance with the exhibits attached to the stipulation and marked 'A'. No approval of a new animal drug application 'NADA' filed with the Secretary of Health, Education and Welfare, pursuant to 21 U.S.C.



§ 360b(b) with respect to the use or intended uses of the ear remedies is or has ever been in effect, and there are no toxicity or efficacy studies published or unpublished with respect to these remedies, which, in accordance with 21 U.S.C. § 321w(1) would warrant the conclusion that the ear remedies are generally recognized as safe and effective ('GRAS') for use under the conditions described in their labeling. No other products combining the same five ingredients satisfy that requirement, and at no time prior to June 25, 1938, were the ear remedies subject to the Food and Drug Act of June 30, 1906, as amended, which would give the product 'grandfather rights,' to be enjoyed along with aspirin and other toxic drugs which are GRAS.

"Annexed to the stipulation is an agreement dated December 9, 1971, between the Department of Health, Education and Welfare ('HEW') and the Environmental Protection Agency ('EPA') marked Exhibit B and referred to below, together with an amendment thereto dated August 28, 1973, marked as Exhibit C.

"The ear remedy for dogs was registered as an insecticide with the United States Department of Agriculture under registry No. 1452-17 on August 7, 1961, and on May 1, 1971, the registration was amended to include in the label a reference to cats as well as dogs. The product, HiLo Ear Remedy for Dogs and Cats, holds a currently effective registration under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 135, *et seq.* ('FIFRA'). There are other matters in the stipulation which may be regarded as attempts to prove a negative, and need not be recounted here.

"HiLo's position in this litigation can be summarized simply. While entitled to sympathetic consideration on our part, its contentions are insufficient to warrant judgment in its favor under the stipulated facts. Simply put, our Federal Government has become a Hydra-headed monster in its efforts to protect the interests of the people. Having made peace with one of Hydra's heads, the EPA bureaucracy administering FIFRA, claimant regards itself as thereby enfranchised to sell its 'insecticide' for use against insects found in the ears of cats and dogs, without having to come to terms with that other competing Hydra-head, the FDA. We share the sentiment expressed by George Whitney, D.V.M., in his letter of August 31, 1978, to FDA, read in support of claimant's motion for summary judgment docketed September 21, 1978, that 'It troubles me when Big Brother hurts the little businessman, and in this case sounds, at least on the surface, to be unreasonable.'

"Dr. Whitney advises that his late father passed the formula for this mighty mite killer on to the founder of the HiLo company, and that 'following my father's example [the product] has been my choice of treatment for ear mites in dogs and cats, since starting to practice in 1945.' Dr. Whitney also observes that in his opinion 'the HiLo product has been not only safe and efficacious all these years, but with such a short half life does not contaminate the environment as even some ingredients in approved newer products do.'

"Be that as it may, we agree with the Government in this action that there is no authority for the proposition that a valid registration of an insecticide under FIFRA exempts that product from registration as a new animal drug under the FFDCA.

"Recognizing that their vassals in commerce might have to atton to both regulatory barons, HEW and EPA, these regulators published an 'agreement' noted above, in Fed. Reg. Vol. 36, No. 246 on Wednesday December 22, 1971, annexed to the Stipulation of Fact, and later amended September 6, 1973. The stated purpose of this treaty between the regulators seems to be that they wish to eliminate 'confusion, misunderstanding and inconvenience' said to have arisen in the past from procedures followed in connection with the proposed marketing of products which by their nature or intended use, are subject to the requirements of both the FFDCA and FIFRA.

"The thrust of this baronial agreement is procedural in nature. Where a product comes under the purview of both statutes, the agreement governs the procedure for obtaining approval of both agencies. Depending upon the type of product, the treaty designates the agency of 'primary jurisdiction.' Even though the treaty may designate the agency of primary jurisdiction, it surrenders no turf, and in no way excuses a product from being subjected to the additional burdensome requirements of the act administered by the other agency.

"Paragraph (m) of the amendment to the aforementioned administrative agreement between EPA and FDA refers specifically to the situation where a 'new animal drug' is involved: 'If a product that is subject to joint jurisdiction is deemed to be either a new human or animal drug, prior to registration by EPA, it must be in full compliance with the requirements for FDA approval of a new drug application,

to include publication of its approval where required by the FFDCA, regardless of the agency of primary jurisdiction.' Since it has been stipulated that there has been no approval of a[n] NADA with respect to the use or intended uses of the insecticide as an ear remedy, claimant's contentions must depend on whether or not the ear remedies are a 'new animal drug,' as defined by 21 U.S.C. § 321(w), which provides in pertinent part: 'The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof ' It has been stipulated that there are no relevant toxicity or efficacy studies with respect to the ear remedies. Accordingly, the GRAS test, which would take the ear remedies out of the statutory definition has not been met in this case.

"Under 21 U.S.C. § 360b, the failure of HiLo to file a[n] NADA renders the ear remedies adulterated for the purposes of 21 U.S.C. § 351(a)(5). Any adulterated drug held for sale after shipment in interstate commerce is subject to condemnation pursuant to 21 U.S.C. § 334(a)(1).

"Claimant's second affirmative defense is completely without merit. There is not now, nor has there ever been a requirement of notice and hearing before enforcement proceedings under the FFDCA may be instituted. *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950).

"The seizure and condemnation of the ear remedies was in accordance with the FFDCA, and claimant's application for relief must be denied here. The Court believes claimant should address its complaints to Congress; probably any veterinarian reading the label would regard the product as useful and harmless, as Dr. Whitney's experience with it indicates. This is not, however, the statutory standard.

"The United States is entitled to judgment as prayed for in the complaint."

In accordance with the order of the court, the HiLo ear remedies were destroyed. (F.D.C. No. 61508; S. Nos. 77-95-111/3; N.J. No. 28)

Nitrofurazone solution, vitamin B₁₂ injection, Gwilate glyceryl gnaicolate combination expectorant, Triple sulfa solution, scour suspension, and udder ointment, at Kansas City, W. Dist. Mo.

Charged 2-7-79: while held by Chemvet Laboratories, Inc., Kansas City, Mo., who manufactured the articles using interstate components, the nitrofurazone solution, Gwilate expectorant, triple sulfa solution, udder ointment, and scour suspension were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to their use or intended use—501(a)(5); and the labeling of the vitamin B₁₂ injection lacked adequate directions for use, since it lacked the veterinary prescription legend and since a lay person could not be expected to diagnose vitamin B₁₂ deficiency in animals—502(f)(1). The articles were claimed by the manufacturer, who denied the charges. A partial consent decree of condemnation authorized release of the vitamin B₁₂ injection to the manufacturer for relabeling. A consent decree of condemnation ordered the destruction of the other articles. (F.D.C. No. 62078; S. No. 78-125-270 et al.; N.J. No. 29)

MEDICAL DEVICES

Diapulse electromagnetic energy generator, at Pensacola, N. Dist. Fla.

Charged 9-12-78: the article (which had been shipped by Diapulse Corp. of America, New Hyde Park, N.Y., and which was labeled in part "PEMF Model . . . DCA Leasing Corp.") lacked adequate directions for lay use and lacked adequate information for use by licensed practitioners; 502(f)(1). The article was claimed by Frederick D. Yost, D.C., Pensacola, Fla., who denied the charge. The Government served written interrogatories on the claimant. Subsequently, pursuant to stipulation, the court ordered the article destroyed. (F.D.C. No. 61884; S. No. 78-141-555; N.J. No. 30)

Hair fibers of polyacrylic for implanting in human scalp, at Bellevue, W. Dist. Wash.

Charged 6-15-79: the labeling of the article, which was labeled in part "United Laboratories of America, Inc. . . . Maple Heights Ohio . . . Blended Fiber Device . . . Non-Sterile," lacked adequate directions for use, and was not exempted, since neither adequate information for use by licensed practitioners was provided, nor was such



information commonly known to such practitioners; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 62351; S. No. 79-176-584; N.J. No. 31)

Urinometer, diagnostic sugar tester, at Livonia, E. Dist. Mich.

Charged 11-17-78: the labeling of the article (which was promoted, by Brothers Scientific Products, Inc., Chicago, Ill., to diabetic patients as a test for high or low sugar) contained false and misleading claims to test sugar levels in the urine of diabetics and false and misleading claims of acceptance by FDA and of approval by the medical profession—502(a); the labeling of the article lacked adequate directions for use and such directions could not be written for the article's intended use—502(f)(1); and the article was dangerous to health when used as directed—502(j). Default decree ordered destruction. (F.D.C. No. 61968; S. No. 79-182-053; N.J. No. 32)

NOTICES OF JUDGMENT on Criminal Actions

Puryear Grocer Co., and Clifford G. Bishop, president, Jonesboro, E. Dist. Ark.

Charged 9-12-78 by grand jury: flour was held under insanitary conditions in a building accessible to insects and rodents and was contaminated with insects; 402(a)(3), 402(a)(4). The defendants moved to suppress FDA's inspectional evidence and to suppress their oral and written statements. However, the defendant corporation pleaded guilty and the individual entered into a pretrial diversion agreement conditioned, in part, upon making all reasonable efforts to liquidate the holdings of the corporation. The corporation proceeded to liquidation, its doors were closed, and the sale and purchase of merchandise was discontinued. Upon motion of the Government, the indictment was dismissed as to the individual. The corporation was fined \$2,000. (F.D.C. No. 61519; S. No. 78-136-088; N.J. No. 33)

Albert C. Iwen and Douglas Evers, managers of a pharmaceutical plant, Manitowoc, E. Dist. Wis.

Charged 5-18-77: that the defendants refused to permit entry and inspection by an authorized FDA employee acting pursuant to Section 374, U.S. Code, of the premises of a Manitowoc, Wis., pharmaceutical establishment (in which drugs were being processed and held for introduction into interstate commerce and after introduction into interstate commerce), when a valid inspection warrant for the premises had been obtained from a U.S. magistrate and the defendants had been advised of the inspection warrant; 704. The defendants moved to dismiss the information, moved for a bill of particulars, and filed a demand for discovery. The motion for a bill of particulars and the discovery demand were rendered moot because the court granted the motion for dismissal. In dismissing the action, the court said:

"The defendants are charged in an information with violating 21 U.S.C. §§ 331(f) and 333(a) and 18 U.S.C. § 2 by refusing to permit the entry upon the premises of Mosinee Research Corporation by a duly designated employee of the Secretary of Health, Education and Welfare, acting pursuant to 21 U.S.C. § 374, for the purpose of conducting an inspection of said premises despite the fact that the employee displayed to the defendants a valid inspection warrant. The defendants have moved the court for an order dismissing the information, for a bill of particulars, and have filed a demand for discovery. For the reasons hereinafter stated, the motion for dismissal is granted, thus rendering the motion for a bill of particulars and the discovery demand moot.

"Section 374 [Section 704 of the Food, Drug, & Cosmetic Act] provides in pertinent part as follows: '(a) *** [O]fficers or employees duly designated by the secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any *** establishment in which *** drugs *** are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction ***; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such *** establishment *** and all pertinent equipment, finished and unfinished materials; containers, and labeling therein ***.' Section 331(f) makes it a prohibited act for an individual to refuse to permit an entry or inspection authorized by § 374, and § 333(a) makes such refusal punishable by imprisonment of one year, or a \$1,000 fine, or both.

"The defendants have moved to dismiss the information on the grounds that it fails to allege facts demonstrating that the employees complied with the procedures set forth in § 374. The Court agrees that such failure is fatal to the information.

"Section 374 establishes a procedure for warrantless administrative inspections. Congress has broad power to design the powers of inspection, and such power applies to the regulation of the food and

drug industry. *Colonnade Catering Corp. v. United States*, 397 U.S. 72 (1970); *United States v. Business Builders, Inc.*, 354 F.Supp. 141 (N.D. Okla. 1973); *United States v. Litvin*, 353 F.Supp. 1333 (D.C. Cir. 1973). In passing § 374, the Congress adopted a warrantless inspection procedure for the food and drug industry. Having done that, the Congress was then faced with the issue of how to insure that needed inspections which might not be consented to could be conducted. As the Court said in *United States v. Litvin*, supra, at 1337: 'In *Colonnade* [supra], the Court suppressed the evidence saying that although the search was reasonable, under the existing statutes, Congress selected a standard that did not include forcible entry without a warrant. Instead, Congress resolved the issue not by authorizing forcible, warrantless entries, but by making it an offense for a licensee to refuse entry to the inspector. [Citation omitted.]' Although *Colonnade* did not deal with § 374, *Litvin* did and adopted the reasoning in *Colonnade*.

"It is apparent from the statute and the case law that § 374 authorizes warrantless inspections and that §§ 331(f) and 333(a) were designed to assist in obtaining the consent of the owner or operator to warrantless inspections. The information establishes that the employees of the Secretary attempted to conduct an inspection of the Mosinee Research Corporation, not pursuant to § 374, as alleged, but pursuant to an inspection warrant. The information must therefore be dismissed, for the defendants cannot be prosecuted for refusing to consent to a § 374 inspection when a § 374 inspection was not attempted.

"For the foregoing reasons, it is ordered that the information charging the defendants Albert C. Iwen and Douglas Evers with violations of 21 U.S.C. §§ 331(f) and 333(a) and 18 U.S.C. § 2 is dismissed." (F.D.C. No. 61319; S. No. 77-98-701 et al.; N.J. No. 34)

NOTICE OF JUDGMENT on Injunction Action

Garcia Brothers Seafood, Inc., Arsenio Garcia, president, **Juan Garcia**, vice president, **Esteban Garcia**, secretary-treasurer, and **Ramon R. Cora**, salesman responsible for swordfish distribution, Miami, S. Dist. Fla.

Charged 10-21-76 in a complaint for injunction: that the defendants were engaged in Miami, Fla., at various specified locations, in receiving, storing, and delivering swordfish which contained the added poisonous and deleterious substance mercury in excess of the 0.5 ppm FDA action level; that FDA examination of swordfish samples established 0.8 to 1.55 ppm of mercury in the defendants' swordfish; that the defendants violated the law by shipping in interstate commerce such swordfish, by receiving them in interstate commerce, and by delivering and proffering delivery of such swordfish; that, despite discussions, seizures, and a written warning, the defendants had continued to distribute swordfish containing excessive amounts of mercury which might render the food injurious to health and had failed to withhold from distribution mercury-contaminated swordfish pending FDA testing; 402(a)(1).

A consent decree of permanent injunction enjoined the complained of violations and enjoined the interstate shipment of swordfish and the receipt and proffer of delivery of interstate swordfish, as follows: unless and until procedures, methods, and controls were established for sampling and testing each lot of swordfish and for the nonfood disposition of each lot containing mercury in excess of 0.5 ppm; unless and until a system for coding each lot to correlate the analytical results of the samples was established; and unless and until all swordfish stocks on hand which were adulterated with mercury in excess of 0.5 ppm were disposed of under FDA supervision. (Inj. No. 747; S. No. 77-43-414 et al.; N.J. No. 35)

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.

Jere E. Goyan, Ph.D., *Commissioner of Food and Drugs*
Washington, D.C., March 1, 1980

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