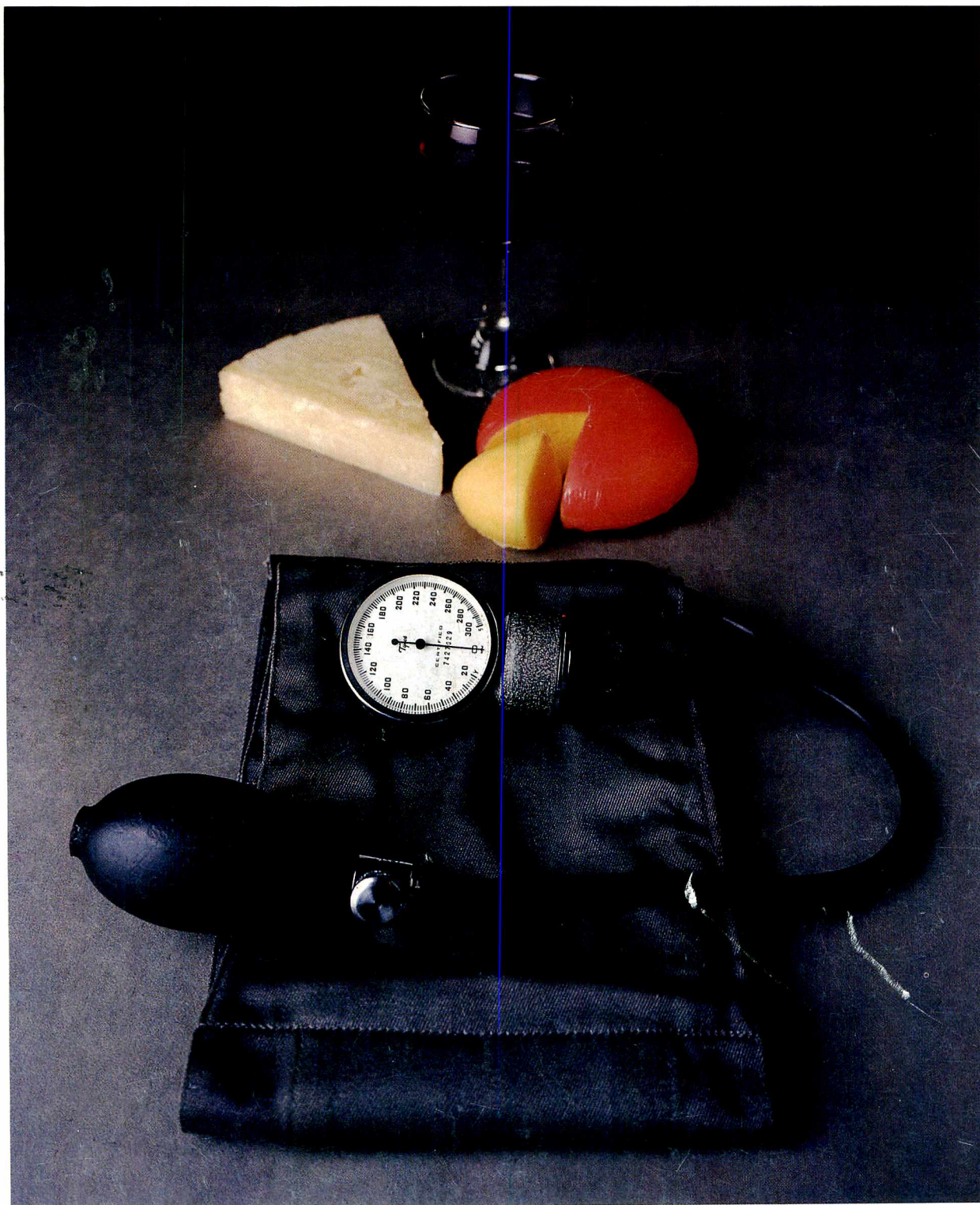


# <sup>FDA</sup> CONSUMER

March 1978



Food And Drug Interactions





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# This Month

Virtually since the beginning of recorded history philosophers, wits, and just plain folks have been talking about the weather. But Mark Twain's comment on the difference between talking and doing still sums up the dilemma of people who find the weather not to their liking. That being the case, some people who seek suntans but can't get the natural variety settle for an artificial substitute produced by sunlamps. Sunlamps do work; they can produce a "suntan." But, like the sun, they also can produce a painful burn and more hazardous effects. This month—in *Sunlamps: Putting Safety First*—we take a look at the different types of these devices, offer some tips on their use, and tell what FDA is doing to reduce the risks from them.

A sunburn or suntan can be described as the result of an interaction between the skin and ultraviolet radiation. Another kind of interaction that is of interest and concern to FDA involves food and drugs. The way a drug works—or, in some instances, the reason it doesn't work—can be related to the kind of food the person taking the drug eats. Sometimes food can make a drug work faster or better, but more often food slows down the body's absorption of medicine. There's more on *Food and Drug Interactions* beginning on page 20.

How protein from food acts in the body is an important question in assessing the effectiveness of very low-calorie protein diets. These diets are based in part on a belief that protein causes the body to use or "burn" excess fat. This theory has yet to be proved, but there is mounting evidence that these diets are potentially dangerous. For a report on what is known about these diets and what is being done to gather more facts about their benefits and risks, turn to page 6.

Chemical interactions are the concern of FDA scientists. Another group of FDA employees is interested in a different kind of interaction—that between the Agency and consumers. Explaining to the public what FDA does and why is the primary mission of 55 consumer affairs officers stationed throughout the country. Their work is the subject of *FDA's Show and Tell Squad*.

Also in this issue is an article on how a cooperative effort by FDA and New York State succeeded in reopening shellfishing waters that had been closed because of bacteriological contamination.

**Inside Front Cover:** *FDA Consumer Affairs Officer Kathy Jones (left) gets help from Joan Erwin, community relations coordinator for the Orlando Public Library, in setting up an FDA exhibit at the library. Exhibits are one of many ways FDA consumer specialists keep the public informed about the Agency's activities. There's more on this important group of communicators beginning on page 10.*

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Section 705 [375] of the Food, Drug, and Cosmetic Act:

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

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

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**Cover Photo:** Dan O'Toole



# Update

## 'Pill' Brochure Stresses Smoking Warning

*It has been estimated that as many as 10 million women in the United States take oral contraceptive pills. An FDA proposal calling for women who use The Pill to receive a brochure explaining the benefits and risks of this form of contraception was described in Informing Women About 'The Pill' in the February 1977 FDA CONSUMER. Here's an update.*

The Food and Drug Administration has established new patient information requirements for birth control pills, including a warning that women who take The Pill should not smoke.

Under the requirements, effective April 3, 1978, women will get a brochure explaining the benefits and risks associated with this form of contraception each time a prescription for The Pill is filled. Information in the brochure will be summarized in a separate, easy-to-read leaflet.

Both the brochure and the leaflet must be provided by the drug dispenser, usually the pharmacist.

The warning advising women who take The Pill not to smoke will appear in a box in both the brochure and leaflet.

This boxed warning says: "Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke."

The warning is based on two studies reported in 1977 which establish an increased risk of heart attack and other circulatory problems such as strokes for women who smoke while taking birth control pills.

The new requirements represent a major revision and expansion of the birth control pill labeling for patients that FDA first established in 1970. In that year FDA first required that specially written material about The Pill be available to women.

Under the 1970 labeling requirement, women have received with each pill packet a brief summary of benefits and risks. Manufacturers also have been required by FDA to supply physicians with brochures to give to their patients at their option.

A nationwide survey taken for FDA in 1975 showed that women read the information and found it useful and clear, but wanted more.

FDA also has ordered changes in the information physicians receive from manufacturers of The Pill to incorporate the smoking warning and other new information.

Major points made in the patient and physician labeling:

- The Pill that combines the two female hormones estrogen and progestogen is about 99 percent effective in preventing pregnancy when taken as directed. The "mini-pill," which contains only progestogen, is about 97 percent effective.

- Women who should not take The Pill, in addition to those who smoke, are those who have had blood clotting disorders, cancer of the breast or sex organs, unexplained vaginal bleeding, a stroke, a heart attack, or angina pectoris, or who suspect they may be pregnant.

- Women who are strongly advised not to take The Pill are those with scanty or irregular menstrual periods.

- Most side effects from The Pill are not serious, and include nausea, vomiting, bleeding between menstrual periods, weight gain, and breast tenderness.

- The more serious side effects, while less frequent, can be fatal and include blood clots in the legs, lungs, brain, heart, or other organs; hemorrhage into the brain due to bursting of a blood vessel; liver tumors that may rupture and cause severe bleeding; birth defects (if The Pill is taken while pregnant); high blood pressure; and gallbladder disease.

- The use of birth control pills by healthy women who do not smoke doubles the chances of heart attack. But the combination of birth control pills and smoking, especially heavy smoking, presents a far greater risk of heart attack and other circulatory diseases. Pill users who also smoke are three times more likely to die of a heart attack or other circulatory disease than women who take The Pill but do not smoke, and are ten times more likely to die of a heart attack or circulatory disease than women who do not use The Pill and do not smoke. The risk of heart attack for women taking The Pill

increases with the amount of smoking, with advancing age, and when other conditions exist, such as high blood pressure, obesity, or diabetes, that predispose people to heart attack.

- Since estrogen, an ingredient in most birth control pills, causes cancer in certain animals, these findings suggest that birth control pills containing estrogen may also cause cancer in people, though studies to date of women taking currently marketed pills have not confirmed that they cause cancer in people.

- Birth control pills are of no value in the prevention or treatment of venereal disease.

- Women who stop using The Pill should wait a few months before becoming pregnant.

The detailed brochure compares the effectiveness and risks of birth control pills with other forms of contraception. It says: "Other forms of contraception have lesser risks or none at all. They are also less effective than oral contraceptives, but, used properly, may be effective enough for many women."

The new labeling requirement appeared in the FEDERAL REGISTER January 31, 1978.

## Court Overturns Cosmetic Labeling Rule

*An FDA regulation requiring that cosmetic manufacturers who advertise their products as being "hypoallergenic" have scientific proof to back up such claims was explained in Cosmetics: The Substances Beneath the Form in the April 1977 FDA CONSUMER. Here's an update.*

The U.S. Court of Appeals for the District of Columbia has ruled that FDA's regulation defining "hypoallergenic" cosmetics is invalid.

FDA will petition the court to reconsider its decision.

The regulation was issued June 6, 1975. It said a cosmetic could be labeled "hypoallergenic" only if scientific studies showed that it caused fewer adverse reactions than a representative sampling of competing products.

Two makers of "hypoallergenic" cosmetics—Almay and Clinique—filed suit in U.S. District Court for the District of Columbia in July 1975. The court upheld the regulations, but the two companies appealed.

In its December 21, 1977 decision, the appeals court reversed the district court, maintaining that FDA's definition of the term "hypoallergenic" was unreasonable because FDA had not demonstrated that consumers perceive the term "hypoallergenic" in the way described in the regulation.

## Ice Cream Ingredient Change Revoked

*In April 1977 FDA issued a regulation giving ice cream manufacturers a wider choice in the ingredi-*

*ents they are permitted to use in their products and requiring that all the ingredients in ice cream be listed on the product label. The changes were explained in the July-August 1977 issue of FDA CONSUMER in an article entitled Inside Information on Ice Cream. Here's an update.*

FDA has revoked certain provisions of its revised frozen dessert standard because data indicate that they could have reduced the nutrient level of some ice cream.

On April 12, 1977, FDA published a revised frozen dessert standard. It would have provided more flexibility in the formulation of ice cream by replacing a requirement that the product contain a minimum amount of nonfat milk solids with a requirement for a minimum protein amount that could be derived from "safe and suitable" ingredients. The new standard also required, for the first time, that ingredients be listed on the labels of ice cream and other frozen desserts.

FDA's revised standard was to have gone into effect June 13, 1977. The National Milk Producers Federation (NMPF) and other members of the dairy industry filed objections to those parts of the new standard permitting "safe and suitable" ingredients. The industry said the new standard would downgrade the nutritional content of frozen desserts.

On July 8, 1977, FDA stayed the parts of the standard to which objections were raised. FDA concluded that there was not enough data to determine how the new standard would effect the physical characteristics and nutritional quality of frozen desserts, and allowed a 60-day period for submission of new data. In response, both opponents and proponents of the revised standard presented information.

FDA evaluated the information and conducted its own studies which indicated that the revised standard could have resulted in a reduction in nutrient levels in some frozen desserts. When it issued this standard, FDA did not anticipate there would be measurable differences between ice cream made under the new standard and that made under the one it was to replace. FDA's research found that under the new standard some ice cream formulations could have lesser amounts of some nutrients than under the old standard. For this reason, FDA revoked the parts of the new regulation that had been stayed, most importantly the part providing for the use of "safe and suitable" ingredients.

The section requiring ingredient labeling, beginning in July 1979, was not revoked, and will take effect. Under this provision all the ingredients in ice cream except added colorings will have to be listed on the product label. Dairy products are exempt under Federal law from any requirement that added colors be listed as ingredients.

FDA will examine the larger issues raised by the ice cream standard debate, such as the concept that manufacturers can use "safe and suitable" ingredi-

ents instead of a strict recipe approach. Commissioner of Food and Drugs Donald Kennedy plans to hold hearings to gather public comment on this and related food labeling issues. The information will help FDA decide on a new course of action, if needed, for the frozen dessert standard, particularly on the need to propose minimum nutrient requirements to assure that the use of "safe and suitable" ingredients would not reduce the nutrient levels of ice cream and related products.

The notice revoking the "safe and suitable" ingredients provision of the revised frozen dessert standard was published in the FEDERAL REGISTER February 3, 1977.

### Labeling of 'Paid' Blood Begins May 15

*The fact that blood from paid donors is much more likely to cause hepatitis was pointed out in Paid Blood: The Hepatitis Connection in the November 1977 FDA CONSUMER. The article also described an FDA proposal intended to reduce the hepatitis hazard by requiring that all whole blood and certain other blood products be labeled to indicate whether they come from a paid or volunteer donor. Here's an update.*

Beginning May 15, 1978, all whole blood intended for transfusion will be required to be labeled as coming from either a "paid" or "volunteer" donor.

The labeling regulation, published by the Food and Drug Administration in the January 13, 1978 FEDERAL REGISTER, is designed to reduce the risk of transmitting hepatitis through blood transfusions.

Blood from paid donors and commercial blood banks has been shown to be three to ten times more likely to cause hepatitis than blood from volunteer donors.

Hepatitis is a serious liver infection which is estimated to occur in 10,000 to 30,000 persons annually from infected blood following transfusions.

The new regulation requires that all containers of blood drawn after May 15 be prominently marked either "PAID DONOR" or "VOLUNTEER DONOR."

Donald Kennedy, Commissioner of Food and Drugs, said: "Hepatitis is a costly disease, not only in dollars, but in human lives. At least 400 people die of hepatitis each year, and the cost to treat a single case runs as high as \$30,000.

"Blood labels will now provide physicians and their patients with important safety information. This regulation is designed to reduce the life-threatening risks associated with blood transfusions and is consistent with the goal of the Government's National Blood Policy to move toward an all-volunteer blood donor system."

The regulation defines a "paid donor" as a person who receives monetary payment for donating blood. A "volunteer donor" is defined as a person who

receives no monetary payment. The regulation specifies that benefits such as time off from work or membership in blood assurance programs are not considered monetary payment.

Blood components, including red blood cells, antihemophilic factor, platelet concentrate, and single donor plasma, are also subject to the labeling regulation.

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## Consumer Forum

### Chiropractors and Health Care

The American Chiropractic Association feels most strongly that a direct attempt has been perpetuated to discredit the entire chiropractic profession through an article which appeared in the November 1977 issue of the FDA CONSUMER titled, *Health Frauds and Quackery*. Through the use of erroneous statements, unparallel comparisons, prejudiced opinions, illogical conclusions, and a complete disregard for the overwhelming evidence within public domain, Dr. Barrett has attempted to discredit the chiropractic profession.

Furthermore, Dr. Barrett has systematically set about to denounce acupuncture, Laetrile, weight reduction methods and antifluoridation proponents as useless or dangerous. It would seem to be intellectually superior to thoroughly investigate these so called "health frauds" and to utilize those positive benefits rather than discard everything as worthless.

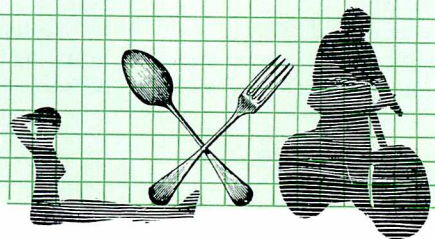
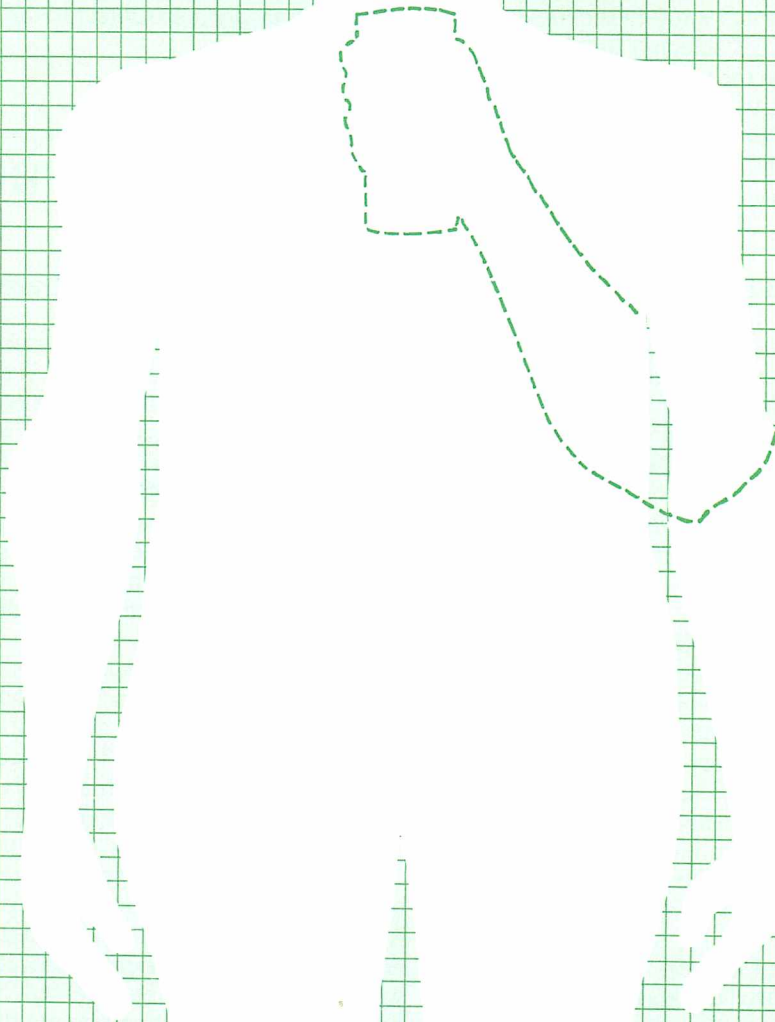
Bringing health frauds and quackery to the attention of the public is certainly in the public interest. It is also in the public interest that all the healing arts enter into a spirit of sincere cooperation when the welfare of the patient is concerned. Self-serving bigotry and zealot rantings are not the rational approach to solving the health problems of our nation.

Both medicine and chiropractic can record its accomplishments by working in isolation. But what would the accomplishments be when working together? Certainly it would be in the public's interest to explore the possibilities that this question poses.

The American Chiropractic Association is prepared to discuss the health care system with all interested parties. Through such dialogue, hopefully, an improved delivery system will evolve, thus affording the consumer the best possible care that presently exists.

Ralph L. Guenther  
Chiropractic Physician  
Chairman, Board of Governors  
American Chiropractic Association  
Des Moines, Iowa





# Low-Calorie Protein Diets

*Despite a tremendous boom in popularity of very low-calorie protein diets, many questions remain unanswered about their safety. The "modified fasting" these diets require puts considerable strain on the body and they should be used only under close medical supervision.*

by Nancy Glick

Going on a diet is one of the great American pastimes. It is estimated that each year over 70 million Americans spend upward of \$10 billion for anti-obesity prescriptions, over-the-counter appetite suppressants, reducing pills and diuretics, diet books, mechanical reducing devices, health spas, and special diets. According to one research firm over-the-counter weight-control products alone now account for \$110 million in sales annually and this figure is expected to reach \$194 million by 1985.

Why are American consumers spending so much of their time and money on weight reduction? Because a lot of us are overweight. According to national statistics, 13 percent of the men and 23 percent of the women between the ages of 20 and 74 are considered obese. (Generally, anyone who is more than 20 percent overweight is considered obese.) Statistics indicate that in addition to those who are obese, almost 25 percent of the women and 10 percent of the men between the ages of 40 and 59 are as much as 20 percent heavier than they were at 25, when their growth was completed.

Whether for reasons of health or appearance, the desire for thinness has led many to look for easy diets such as the "grapefruit diet," the low-calorie "drinking man's diet," and others that promise quick weight loss. The newest of these fad diets is the very low-calorie "protein diet," based especially on the use of liquid protein products but also including powdered protein that comes with instructions for mixing with a liquid and protein capsules and tablets. Promoters of very low-calorie protein diets flooded the market with advertisements of their products as the new way to reduce "without drugs." Millions of people have tried this diet, many of them without medical supervision.

The explanation offered in support of this dietary concept is that consumption of protein alone will induce the body to burn fat but spare the muscle tissue, minerals, and other materials referred to collectively as "lean body mass." Protein products now being sold vary in their directions for use. Some products contain virtually no directions; others

come with a plan suggesting that the product replace one or two meals a day. Some consumers have been using the protein products as the sole source of nourishment—a practice referred to as "modified fasting." If the protein product is consumed as the sole source of nourishment in the quantities usually recommended, the dieter gets about 300 to 500 calories a day, an amount that nutritionists consider insufficient to maintain good health.

Numerous very low-calorie protein diet products are marketed under a variety of trade names in health food stores, supermarkets, and drugstores. Terms commonly used to describe these products are "predigested" liquid protein (sometimes simply PDLP), "protein sparing fast," protein supplement, amino acids, collagen, and gelatin. Promotional materials for these products either directly or by inference indicate that they are useful for weight reduction by stressing such words as slim, slender, and lean.

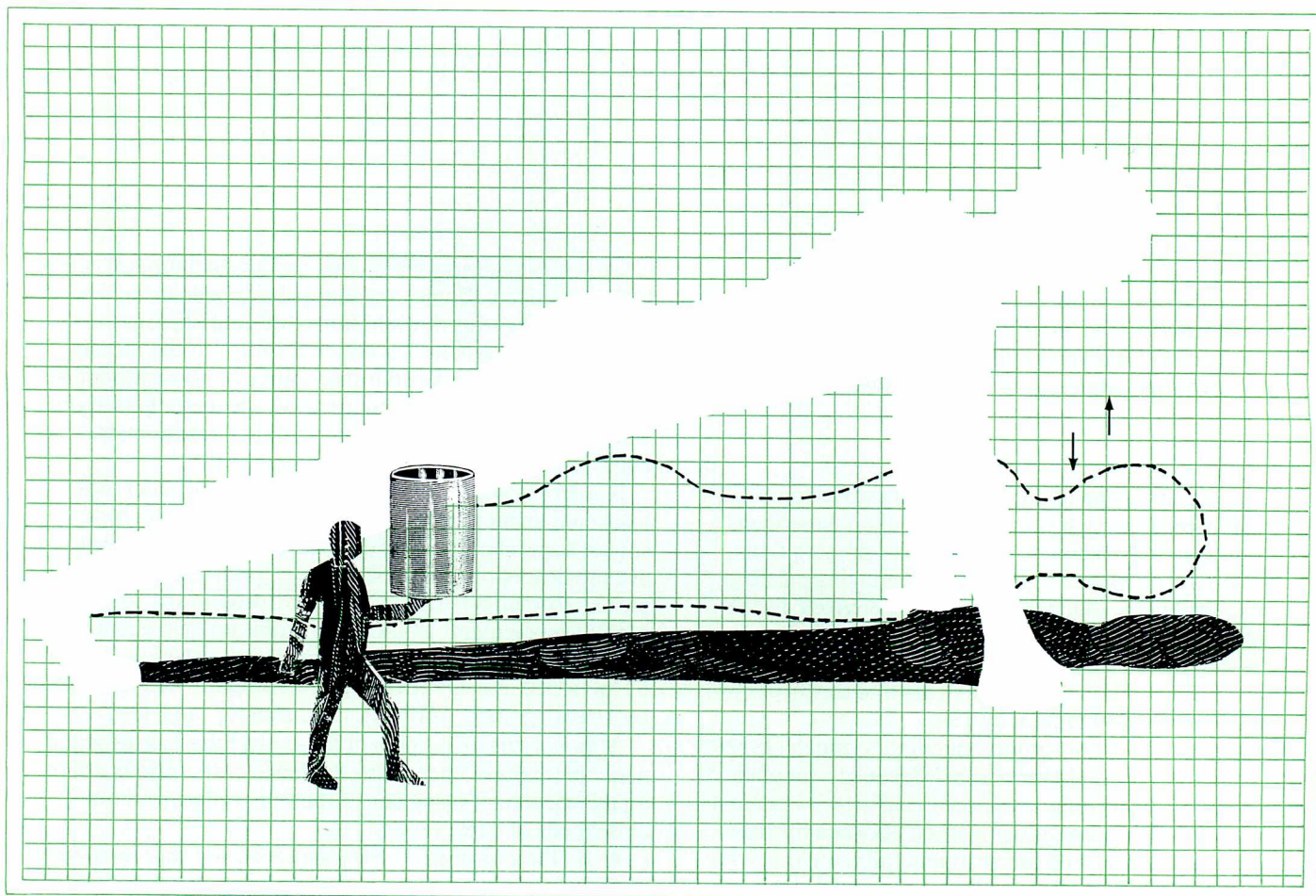
Although the promotion of these products has attracted many purchasers, increasing evidence casts serious doubt on the wisdom of using any of these diet plans without close medical supervision.

- By the end of 1977, FDA had received reports of more than 40 deaths associated with very low-calorie protein diets. The Center for Disease Control (CDC) found that in at least 15 the diet was highly suspect as a contributing factor in the deaths. In these 15 cases, the victims were obese women between the ages of 25 and 51 who lost an average of 83 pounds after being on low-calorie protein diets for two to eight months. None had a history of heart disease. All died suddenly, without previous symptoms, of heart irregularities—either while on the diet or shortly after going off it.

- In addition to the deaths, FDA has received reports of more than 100 people who said they became ill due to use of protein products that are promoted for weight control. Common complaints include nausea, vomiting, diarrhea (particularly with liquid products), constipation (particularly with the dry whole protein preparations), faintness, muscle cramps, weakness or fatigue, irritability, intolerance to cold weather, decreased sex drive, hair loss, and skin dryness. More serious medical problems associated with these diets include dehydration, gout recurrence, and hypokalemia, which is a potassium imbalance that can lead to death.

In October 1977, FDA convened a panel of medical experts to review the use of protein products in very low-calorie diets. The panel concluded that these products





should be used only under the careful supervision of medical personnel trained in their use. These diets are still experimental and are being developed for use by extremely obese people under the strict monitoring of a physician, the panel pointed out, but promotional material aimed at the public plays down the strain on the body caused by the restrictive nature of the diet.

In addition to discouraging general use of protein products in the very low-calorie diets, the panel said that the diets could be especially dangerous to certain groups of people. It recommended against use by individuals taking prescription medications (especially diuretics, oral hypoglycemic agents and insulin, or thyroid drugs); by individuals with kidney, liver, or heart disease or high blood pressure; by the elderly; by preschool-age children and adolescents; or by pregnant women or nursing mothers.

In addition to checking on illness associated with very low-calorie protein diets, FDA has been examining the general nutritional questions involved. FDA nutritionists have determined that most of these products are not

nutritionally complete and therefore are not advisable as the sole source of nourishment for extended periods of time.

Protein is made up of 22 amino acids, 14 of which can be manufactured within the body if there is a sufficient supply of nitrogen. Eight other amino acids are labeled "essential" because they are necessary for the normal maintenance and repair of body tissue in adults. These eight have to be provided by food; the body cannot make them. Most very low-calorie protein products are prepared from collagen or gelatin, both of which are made from animal hide, tendon, bone, and similar material. Neither collagen nor gelatin contain all of the eight "essential" amino acids. Some low-calorie protein products are fortified with some of the "essential" amino acids, as well as some vitamins and minerals, but most are nutritionally incomplete.

Research continues at several medical centers to assess the merit of these and related weight-reduction programs. The research is focused on extremely obese people who use the diet under strict medical supervision as part of a total program of weight reduction. If the protein diet regimen



proves of value, it most likely will be for some people who are extremely obese. For the general public, however, where the goal is to lose a relatively small amount of weight (less than 20 pounds), these types of diets are unnecessarily strenuous on the body's vital functions, and may not be worth the risk to health that can occur.

It is still hypothetical that protein causes the body to use or "burn" excess fat. A pound of fatty tissue equals 3,500 calories. Every time you consume 3,500 calories less than your body requires over a period of days, you should use (lose) a pound of fatty tissue. Eating fewer calories than the body consumes is the key to losing weight. It has not been shown that a low-calorie diet consisting almost solely of protein results in greater weight loss than other low-calorie diets.

Fat accumulation results from consumption of calories in excess of body needs. When burned for body energy, protein yields four calories per gram—exactly the same as starch and other kinds of carbohydrates. In contrast, fats contain nine calories per gram and alcohol contains seven.

Because of the evidence that very low-calorie protein diets are no more effective than other diets and may actually be hazardous when used improperly, FDA on December 2 proposed to require a mandatory warning label for all protein supplements intended for use in weight reduction or maintenance programs. The label would say:

"Warning: Very low-calorie protein diets may cause serious illness or death. Do not use for weight reduction or maintenance without medical supervision. Do not use for any purpose without medical advice if you are taking medication. Not for use by infants, children, or pregnant or nursing women."

FDA also proposed a warning label for protein supplements not intended for use in weight reduction or maintenance but nonetheless often used for this purpose by consumers. The label would say:

"Warning: Very low-calorie protein diets may cause serious illness or death. Do not use for weight reduction or maintenance."

FDA has asked the manufacturers of protein products to put these warnings on the labels of their products immediately, even while FDA is initiating the necessary legal steps to make these or similar warnings mandatory. At the same time, FDA is considering possible ways to remove some or all of these products from the market if the label warnings do not prove adequate to protect the public health.

Besides proposing the warning labels, FDA has taken a number of steps to assure that the manufacture and labeling of low-calorie protein diet products conform to Agency regulations. These include:

- Detailed inspections of producers, reproducers, and repackers of these products to determine how they are being manufactured and sold.
- Analysis of the products to determine their chemical and nutritional composition.

- Review of product labels to determine if they make misleading claims.

FDA also has begun animal studies to try to better understand the health hazards associated with indiscriminate use of very low-calorie diets.

In the meantime, for consumers who are using or considering using these products, FDA has these suggestions:

- Do not go on the diet without close medical supervision by a doctor skilled in the use of this kind of diet. People on this type of diet require vitamin and mineral supplements and detailed clinical monitoring by trained health professionals.
- Do not go on the diet if you are taking prescribed drugs; if you are elderly; if you have kidney, liver, or heart disease or high blood pressure; or if you are pregnant or a nursing mother.
- Be especially careful when coming off the diet and resuming consumption of solid food. Going back to a normal diet too suddenly can result in rapid changes in the body's metabolic state—particularly its potassium and fluid balances. It is best to consult a physician for advice on how to re-introduce your body to solid food.

In general, FDA believes that anyone who wants to lose less than 20–25 pounds should avoid any diet that involves a "modified fasting" regimen. Such diets put a considerable strain on the body and, until thoroughly tested, should be restricted to use by obese people under strict medical supervision. Most people can diet successfully by simply limiting their caloric intake. This can be done while maintaining good nutrition, which means balancing the diet with a variety of foods that include fruits, vegetables, milk or cheese, good sources of iron, and enriched or whole grain cereals.

Protein is important in good nutrition, but the average adult does not need large quantities of pure protein to be healthy. The Recommended Daily Allowances for protein set by the National Academy of Sciences are:

Children	1-10 years	25-40 grams
Boys	10-18 years	45-60 grams
Girls	10-18 years	50-55 grams
Adult men	18 and over	60-65 grams
Adult women	18 and over	55 grams

Consumers who are trying to keep tabs on their calorie intake can get some help from the nutrition labels that appear on many foods. The label tells how many calories are in each serving of the food. It also shows how much protein and vitamins and minerals are in each serving, so calorie counters can control the calorie and nutritional value of their diets on a daily basis.

*Nancy Glick is a staff writer with FDA's Office of Public Affairs.*

# FDA's Show And Tell Squad



*Telling consumers what FDA is doing and why—and keeping FDA up to date on consumer concerns—is what being a consumer affairs officer is all about. FDA now has some 55 CAO's stationed across the country to keep communication between the Agency and the public flowing in both directions.*

*by Harold Hopkins*

In upstate New York Lois Meyer is a popular television performer. Audiences watch her faithfully on highly rated daytime shows in Buffalo, Rochester, Syracuse, and in the Albany-Schenectady-Troy area. Viewers in the Elmira, Watertown, Plattsburgh, and Utica areas also are likely to see her several times a year.

Lois Meyer is not an entertainer; she's an FDA consumer affairs officer, and getting to the largest numbers of the public with FDA's messages and

other educational information for the consumer is what her job is all about. She appears weekly in Buffalo on WKBW-TV's "Dialing for Dollars," and as often as she is able on "A.M. Rochester" in that city, on "Woman of Today" in Syracuse, and on "Action News" over WTEN-TV which serves Albany, Schenectady, and Troy. The shows vary from interviews with the host plus answers to telephoned inquiries to "hard news" presentations on FDA activities of interest to consumers.

To get to the most people with the most usable information, Miss Meyer keeps an eye on the television ratings and also on radio programs and newspaper columns and sections which feature consumer news and information. The people responsible for filling these programs and columns with interesting and useful information have learned to rely on Miss Meyer because they know she knows what FDA is doing and

*FDA Consumer Affairs Officer Lois Meyer appears weekly on the "Dialing for Dollars" show on WKBW-TV in Buffalo. Here, she is interviewed by the show's host, Dave Thomas, on over-the-counter cough and cold remedies.*

what it means for consumers. They also know she usually finds a way to keep her commitments, even when the winter weather turns uncooperative.

In mid-January, when cancellation of plane flights from Buffalo to Albany were threatening her three days of closely scheduled appointments, she grabbed a bus the night before to make her next morning's appointment in Albany and spent most of the night on the way.

Over the next three days she appeared on WTEN-TV's "Action News at Noon" to discuss nonprescription

cough and cold remedies, taped two more three-minute segments on hair dyes and painkillers for future use on the noon news, and took part in a videotaped program for the Adult Consumer Homemaking Program (ACHP) to be shown on the Albany Board of Education's cable television network and by ACHP teachers in neighborhood storefront locations. She worked with State vocational rehabilitation hearing impairment specialists on adding written captions to a videotaped version of an FDA film on nutrition labeling and taped an interview on the same subject using both sound and split screen sign language.

She also met by invitation with the New York State Assembly's Task Force on Food, Farm, and Nutrition Policy, addressed 30 coordinators for the Adult Consumer Homemaking Program and distributed FDA educational materials to them, and was interviewed by the editor of the KNOCKERBOCKER NEWS women's section about FDA's recent actions on coal-tar hair dyes.

Lois Meyer has been explaining what FDA does and why since 1964 when she resigned as executive director of the National Dairy Council's Niagara affiliate to become one of FDA's consumer affairs officers or CAO's. The judgments and suggestions of these 55 or so specialists serving FDA around the country can and often do carry as much weight in the Agency's doings as anything a bureaucrat hands down from on high or a scientist turns up in the lab. When consumer affairs officers talk, it's good business for the rest of FDA to listen because more than any other group of employees at the Agency they speak from a firsthand knowledge of FDA's ultimate reason for existing—the consumer.

It was the lack of such knowledge that led to an unusual decision at FDA in November 1952. Charles W. Crawford, Commissioner of Food and Drugs, announced he was appointing a number of "consumer consultants," 16 in all, who would, he said, answer "a long felt need . . . to establish closer contact with the buying public." He couldn't have been righter, and his act was possibly one of the earliest recognitions of that public awakening which writers have called the consumer movement.

This 1952 cadre of part-time appointees consisted of women with diverse educational and social backgrounds.



*The controversial cancer drug Laetrile is discussed by Consumer Affairs Officer (CAO) Kathy Jones in a 30-minute interview on radio station WDIZ-FM in Orlando, Florida. She was interviewed by Randy Scott, the station's operations director.*

All had a grounding in home economics, some through formal education, others only through what they had learned in their own kitchens. A quarter of a century later none of the original 16 are left at FDA, but to them must go the credit for creating a service that has become indispensable to FDA's consumer protection functions.

Methods have changed but today's CAO's basically are carrying on the same work as their predecessors, and devoting full time to it. They have more than tripled in number. Collec-

tively they possess a broader background of education and work experience. Their specialties are no longer circumscribed by the home economics label and the inevitable association with kitchen and cradle. Today's CAO has a college degree and sometimes two. When the CAO comes to FDA she may be a dietitian, a teacher, a sociologist, a newspaperwoman, or a radio or television performer. And sometimes a he.

The gate is open to able talent and a few years ago, after a sizable expan-

*An audience at the Techwood Senior Citizens Center in Atlanta gets a lesson on adverse reactions to medicines from CAO Cynthia Leggett.*

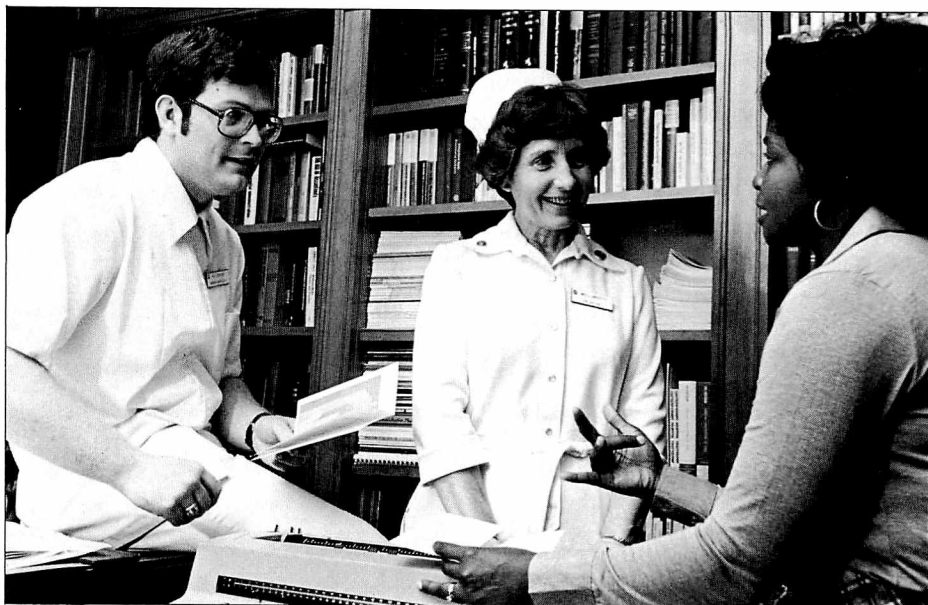




*FDA's functions and responsibilities are explained (top photo) by CAO Janice Moton to nurses Jim Dodds and Juanita Linkous at Atlanta's Crawford Long Hospital.*

*An FDA exhibit (middle photo) they created is set up by Kathy Jones (right) and Inspector's Aide Mike Freeman in a prominent spot at the Orlando Public Library. A variety of FDA consumer information leaflets are available at the exhibit, which was arranged in cooperation with Joan Erwin (center), the library's community relations coordinator.*

*The staff of Atlanta's Family Counseling Service is briefed (bottom photo) on proper use of medicines by CAO Ana Rivera. The counseling service works with Spanish-speaking residents in the Atlanta area.*



sion of the CAO squad, a few men entered the ranks and began doing the work some people had come to think was sacrosanct to women.

CAO's, originals or successors, can take part of the credit for FDA's reputation as one of the most consumer-conscious agencies in the Federal Government. They tell the public what's afoot at the Agency and how this translates to health protection and economic fair dealing in the purchase and use of foods and drugs and the other products FDA regulates. Just about every time they go out, CAO's come back to FDA management huddles bringing new slants on public reactions to the Agency's actions and what else consumers think ought to be occupying FDA's time and attention.

In the 20 FDA districts throughout the country where they are assigned, CAO's are indeed a rare breed, being the only Agency people in the field not involved in some way in the nuts and bolts of securing industry compliance with the Food, Drug, and Cosmetic Act. Their responsibility is not enforcing laws and regulations but explaining how they work or should work and how consumers can look out for their own end of the stick.

CAO's have the assignment of getting useful information to as many as possible of the millions of people in the areas they serve. For the most part, this can best be done by making effective use of printed and electronic information media, especially newspapers and magazines and television and radio. When a local newspaper or broadcast reporter or a talk show host wants to ask about some action FDA has taken it is often the CAO who gets the call. CAO's must know enough about any FDA activity or position to be able to discuss it and answer questions or know where and how to get the answers. Broadcast presentations featuring a CAO may include questions telephoned from the viewing or listening audience and a CAO must be nimble enough to deal with complex subjects without misstating the Agency's positions or functions.

It follows that CAO's have to keep track of what's happening both in the field and at FDA headquarters in Washington. Through daily conferences with FDA people involved in district activities and frequent consultations with program and bureau executives in Washington, the CAO is probably in a better position to explain



*CAO Julia Hewgley checks the stock of FDA consumer publications on display in the reception room of the Agency's Omaha Resident Inspection Post.*

these events to consumers than anybody else in the FDA district.

In organizing information campaigns, CAO's make full use of those institutions and organizations through which consumers can be reached. Besides information media, these include schools, hospitals, local and State consumer protection agencies, libraries, agriculture extension services, lay organizations interested in consumer protection, and organizations of professional persons such as educators, doctors, nurses, and dietitians.

CAO's spend a good deal of time on the road and a trip to a given city is the culmination of considerable thought about the information programs to be emphasized, places to be visited, and people and organizations to be seen. The agenda for such a trip might include a slide presentation—arranged by a consumer group and open to the public—on food additives, an appearance on a local television show to discuss the controversial cancer drug Laetrile, a meeting with school officials to show them lesson plans and materials FDA can provide, and a visit to a hospital to talk about a training program that will help its x-ray technicians reduce patient exposure to radiation.

The Atlanta Region of FDA (Region IV) presents practically all the challenges and problems CAO's confront in seeking to convey FDA's messages to the public. This eight-State area is one of 10 FDA regions, each containing one or more of FDA's 20 districts.

The region, with a population of 31 million people, includes three FDA districts: the Atlanta District—Georgia, Alabama, and South and North Carolina; the Nashville District—Tennessee, Kentucky, and Mississippi; and the Orlando District—the State of Florida.

The region has five working CAO's plus a consumer affairs program manager. Three of the CAO's are assigned to the Atlanta District: one serves North Carolina, another is assigned to South Carolina, and a third handles Alabama. The three share coverage of the State of Georgia. In the Nashville District one CAO covers all three States, and there is a CAO for the Orlando District, which means Florida. Although they report directly to their district directors, as do all CAO's, their overall efforts are planned and coordinated by Wilhelmina Lombardi, a veteran CAO who is consumer affairs program manager for Region IV in Atlanta. Not every FDA region has a consumer affairs program manager, a position usually assigned to regions with large populations and multiple districts.

The education and information programs these and other CAO's carry out cover a range of matters as broad as FDA's consumer protection responsibilities: food additives; nutrition labeling; cosmetics; food safety; prescription and nonprescription drugs; medical devices; veterinary drugs; and television sets, x-ray machines, micro-



wave ovens, and other ray-emitting products.

The ways in which CAO's reach consumers are almost as varied. In 1977, for example, the five CAO's in the Atlanta Region made 156 speeches to almost 40,000 persons; responded to some 600 requests for information from consumer and professional groups; put on 23 exhibits for viewing by more than 25,000 persons; participated in 220 radio and television interviews and furnished interviews to newspapers and to other print media in 170 instances; and took part in 7 seminars attended by 400 persons. They also handled more than 3,000 inquiries by

letter or telephone from consumers and professional people.

Once a month CAO's file reports to FDA headquarters on their activities for the past 30 days and on the concerns they have encountered among consumers and consumer groups. At least once a year they gather in Washington for briefings by headquarters people on various FDA programs. These meetings, which include question and answer sessions, enable both groups to update their information on the current objectives of each and to understand better how the many programs combine to make up the total consumer protection effort.

In their crusade to explain FDA to the consumer and the consumer to FDA, CAO's sometimes get the feeling that they're both insiders and outsiders. It's part of their concept of themselves to feel that they belong in the middle of every encounter between the consumer and FDA, hearing every inquiry or complaint and helping to come up with the answer or remedy. For most, the world is going right when the consumer is spang full of questions and the CAO is even fuller of answers.

*Harold Hopkins is editorial director of FDA CONSUMER.*

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# Sunlamps: Putting Safety First

*Thousands of people wind up in hospital emergency rooms each year because they fail to follow a few simple but important rules on the safe use of sunlamps. To reduce the risks from sunlamps, FDA has proposed safety performance standards for these devices, including a requirement that all lamps come with timers that will shut them off automatically.*

It isn't easy to get a golden natural tan in a Chicago apartment when a winter wind is whipping off Lake Michigan. So thousands of people, in Chicago or wherever else sunbathing is a sometime thing, do their basking under sunlamps. Others turn to the sunlamp to combat acne or other skin problems. The result may be a temporarily bronzed body or clearer skin. But it may also be a painful burn or, years later, prematurely wrinkled skin or even skin cancer.

Every year thousands of injuries from sunlamps are treated in hospital emergency rooms. The injuries usually occur when people don't follow the safety instructions that come with sunlamps. They fall asleep under the lamp, fail to use timers or goggles, or try to tan too quickly with long exposures.

But even people who follow the safety precautions are subjecting themselves to long term risks because repeated exposure to ultraviolet light—whether from a sunlamp or the sun itself—can result in premature aging of the skin and increase the risk of skin cancer.

When a sunlamp is prescribed to treat medical problems, your physician has determined that the benefits outweigh the long term risks. But when you decide on your own to use a sunlamp, you must decide whether the benefits outweigh the risks.

Sunlamps contain mercury gases. When electrical current excites the mercury, the lamp gives off ultraviolet radiation. This radiation is similar to that from the sun except that it can be more intense at the surface of the skin and thus can produce its effect in a much shorter time.

The most common type of sunlamp for home use has a "reflector" bulb which screws into a socket with a metal reflector. Another type, the fluorescent sunlamp, used primarily in health clubs, looks like a conventional fluorescent light. Both types of sunlamps have specially-treated glass enclosing the mercury, which filters out much of the more hazardous short wavelength ultraviolet radiation. This is similar to the filtering effect of the ozone layer of the earth's atmosphere which helps to block the harsher rays of the sun.

The third type of sunlamp has a bare mercury tube in a metal reflector. It often comes with a tabletop stand or an extendable tripod stand. This type of lamp sometimes includes an infrared light which gives off heat and an incandescent light which produces visible light. Because the glass on the mercury tube in this type of lamp does not filter out the short wavelength ultraviolet radiation, it gives off more of these harmful rays than other types of lamps. Some manufacturers of these lamps are working on new features so users will not be unnecessarily exposed to this hazardous radiation.

When you get a moderate, progressive tan over a period of time—from the sun or from a sunlamp—the ultraviolet radiation increases the production of melanin, the dark color pigment that lies beneath the surface of your skin. Many hours later, the melanin comes to the surface of the skin and darkens its overall color. This slow buildup of melanin helps to protect your skin since it acts to shield the cells beneath it.

When you get "sunburned" from too much ultraviolet radiation too quickly, your body increases the blood flow to the skin, carrying the healing components of blood and a redness to the burn. A severe burn can permanently destroy the cells which produce melanin, making you more sensitive to ultraviolet radiation for the rest of your life.

Long term or repeated exposure to ultraviolet radiation—even gradual tanning exposure which doesn't burn you—can make your skin age prematurely. Your skin may develop a leathery surface or become wrinkled, mottled, or discolored. When caused by ultraviolet radiation these kinds of changes can lead to skin cancer.

Your eyes also are very vulnerable to ultraviolet radiation. Acute exposure to ultraviolet light—which could result from looking directly at a sunlamp even for a few seconds—can cause a painful but temporary condition called photokeratitis. Photokeratitis causes the eyes to burn with a sandy, gritty sensation. A severe burn to the eyes can scar the cornea and permanently impair vision.

Some people should not use sun-







The three types of sunlamps an indoor "sunbather" is likely to encounter are the reflector bulb (right), most commonly used in the home; the fluorescent lamp (bottom), found most often in health spas; and the metal reflector lamp (left), most of which use a bare mercury tube that does not filter out the short wavelength radiation, thus making them more hazardous than the other lamps.

Protective goggles are a "must" for anyone using a sunlamp. Under FDA's proposed regulations, manufacturers would be required to provide such goggles, along with instructions for proper use of the lamp.





## Safety Standards Proposed for Sunlamps

The Food and Drug Administration has proposed a safety performance standard for sunlamps in an effort to reduce the number of injuries caused by these products.

The proposed standard would:

- Require that each lamp have a timer that will automatically shut it off in ten minutes or less. The timer could be reset if needed. Some manufacturers already sell sunlamps with such timers.
- Prohibit the sale of sunlamp bulbs that fit into conventional sockets, thus permitting their use in timers only. This would provide extra assurances that bulbs will be used only with timers.
- Prohibit the marketing of sunlamps which emit excessive short wavelengths of ultraviolet radiation that are particularly dangerous and not necessary for tanning.
- Require that sunlamps be sold with protective eyewear.
- Require better label warnings and instructions for use. A label warning that would have to be clearly visible during use would say that ultraviolet radiation can lead to premature aging of the skin and skin cancer. The instructions would urge people taking medications or with skin especially sensitive to light to see a doctor before using a sunlamp and would warn about the risk of eye injury or sunburn.

About a million sunlamps are sold each year in the United States. The proposed standard would apply to sunlamps used in health clubs and similar facilities, as well as those purchased for home use.

The proposal was published in the *FEDERAL REGISTER*, December 30, 1977, with 60 days from that date allowed for public comment. FDA now is reviewing the comments received and then will publish a final regulation.

lamps at all. People who have fair skin and freckle easily have little natural ability to build up melanin and thus are more likely to get burned by ultraviolet radiation. They also are more susceptible to the long term effects of this radiation. People who develop cold sores frequently also should avoid sunlamps.

Certain drugs can make people especially sensitive to sunlight and sunlamps. Among them are the sulfas and tetracyclines; high blood pressure drugs containing hydrochlorothiazide; tranquilizers containing phenothiazine derivatives; griseofulvin, a drug used to treat ringworm and similar infections; and sulfonyleurea-containing drugs used in the treatment of mature-onset diabetes. Some oils used in the manufacture of cosmetics, such as oil of bergamot, also may cause special sensitivity to light from the sun or sunlamps. Anyone using these products should avoid sunlamps and should be well protected from the sun when going outside.

As the Federal agency responsible for protecting the public from radia-

tion—including ultraviolet radiation—emitted by electronic products, FDA has proposed regulations to reduce the risk from sunlamps. These regulations would require manufacturers to keep the emission of short wavelength rays to a minimum and to include timers that automatically turn off the lamp, goggles, clear warnings, and instructions with all sunlamps. (See box accompanying this article.)

But FDA regulations can only reduce the risk. If you want to avoid the risks entirely, don't use sunlamps at all. If you do use them, you can reduce the hazards by taking these precautions:

- Don't use the bare mercury tube type of sunlamp, unless there is some indication that it was specially designed to limit the amount of short wavelength ultraviolet radiation.

- Don't use any lamp without a timer. Preferably use one which comes with an automatic timer that shuts off the lamp at a pre-set time. If the timer doesn't shut off the lamp it should have an alarm loud enough to awaken you if you fall asleep under the lamp.

If you already have a sunlamp without a timer, use a kitchen timer loud enough to awaken you at the end of the pre-set time if you fall asleep.

- Use a sunlamp which comes with clear instructions recommending the distance and exposure times—and follow the instructions carefully.

- Measure the distance between the closest part of the sunlamp bulb and your body. Make sure you are not any closer to the lamp than the recommended distance.

- Do not stay under the lamp beyond the recommended exposure time and don't use the lamp more frequently than recommended.

- Protect your eyes. A sunlamp should come with a set of goggles or other eye protection for each person who will be using it at the same time. If your lamp is not so equipped, be sure to buy and use these protective devices.

- Do not use a sunlamp if you are especially sensitive to the sun (have fair skin, freckle easily, often have cold sores) or if you are taking drugs or using other products that might make you more sensitive to the sun. If there is any question, discuss the situation with your doctor.

- Be especially careful after replacing an old sunlamp bulb with a new one. Sunlamp bulbs can wear out but they still may give off visible light. The new bulb may give off considerably more ultraviolet radiation than the old one. As you start out with a new bulb, you should take shorter exposure times than you would have with the old one.

- Avoid taking hot showers or saunas before using a sunlamp. When you dry off your body after a shower or sauna you will remove some of the natural body oils that would have absorbed some of the ultraviolet rays, thus leaving you more sensitive to the effects of radiation.

- If you see any tanning or reddening during the exposure turn the lamp off immediately. It should be at least several hours after exposure before any tanning effect is visible.

- If your lamp requires a warmup don't begin using it until it has warmed up. If you begin using it immediately count the warmup time as part of your exposure.

- If you use sunlamps at health clubs, the same precautions should be followed.

# Food And Drug Interactions

*If you're taking a drug, the food you eat could make it work faster or slower or even prevent it from working at all. Eating certain foods while taking certain drugs can be dangerous. And some drugs can affect the way your body uses food.*

by Phyllis Lehmann

Would it occur to you not to swallow a tetracycline capsule with a glass of milk? Or to avoid aged cheese and Chianti wine if you are taking a certain medicine to combat depression? Or to eat more green leafy vegetables if you are on The Pill? Probably not. Yet the effects foods and drugs have on each other can determine whether medications do their job and whether your body gets the nutrients it needs.

The extent of interaction between food and drugs depends on the drug dosage and on the individual's age, size, and specific medical condition. In general, though, the presence of food in the stomach and intestines can influence a drug's effectiveness by slowing down or speeding up the time it takes the medicine to go through the gastrointestinal tract to the site in the body where it is needed.

Food also contains natural and added chemicals that can react with certain drugs in ways that make the drugs virtually useless. Some reactions can be downright dangerous, triggering a medical crisis or, in rare instances, even death.

It is because of these interactions that your doctor tells you to take certain medications on an empty stomach, some just before meals, and some with meals.

A major way food affects drugs is by enhancing or impeding absorption of the drug into the bloodstream. There are a few cases in which foods speed up absorption. For example, blood levels of griseofulvin, a substance that combats fungus infections such as ringworm, rise markedly if the patient eats fatty foods before taking the drug.

More commonly, though, food and beverages interfere with absorption. A classic interaction is the one between tetracycline compounds and dairy products. The calcium in milk, cheese, and yogurt impairs absorption of tetracycline. On the other hand, taking some iron supplements with citrus fruits or juices which contain ascorbic acid enhances absorption of the iron.

In general, it is unwise to take drugs with soda pop or acid fruit or vegetable juices unless you check with your doctor first. These beverages can result in excess acidity that may cause some drugs to dissolve quickly in the stomach instead of in the intestines where they can be more readily absorbed into the bloodstream.

Some foods contain active substances which can cause a drug effect or which can interact with a drug to produce an unexpected or counter-effect. For example, licorice extracted from natural sources contains a substance which, when consumed regularly in excess amounts, may cause an elevation in blood pressure. Licorice is a favorite ingredient of candy and a flavoring for some pharmaceuticals. Most American manufacturers now use a synthetic flavoring but many imported products still contain licorice from natural sources. Continued regular use of products containing natural licorice extract could aggravate high

blood pressure or counteract the effect of medication for high blood pressure.

Excessive consumption of foods high in vitamin K such as liver and leafy green vegetables may hinder the effectiveness of anticoagulants. Vitamin K, which promotes clotting of the blood, works in direct opposition to these drugs which are intended to prevent clotting.

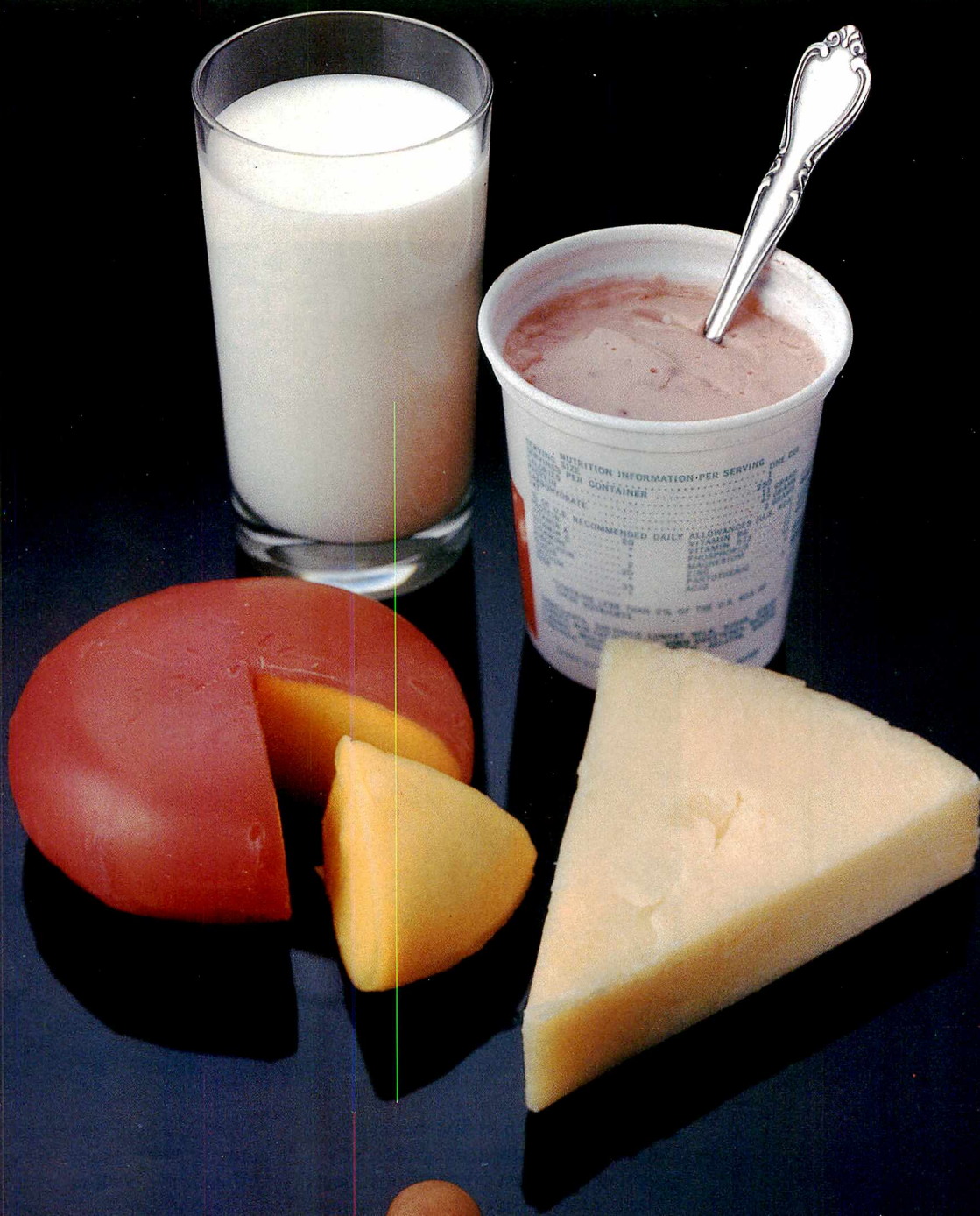
Some foods, such as soybeans, rutabagas, brussels sprouts, turnips, cabbage, and kale contain substances known as goitrogens which inhibit production of the thyroid hormone and thus can produce goiter. Scientists suggest caution in eating these foods when taking thyroid medications.

Perhaps the most hazardous food-drug interaction is the one between monoamine oxidase (MAO) inhibitors, drugs often prescribed for depression and high blood pressure, and such foods as aged cheese, Chianti wine, and chicken livers. MAO inhibitors can react with a substance called tyramine in these foods and force the blood pressure to dangerous levels, sometimes causing severe headaches, brain hemorrhage, and in extreme cases, death.

To prevent a possible reaction, anyone taking MAO inhibitor drugs should avoid aged and fermented foods, including pickled herring; fermented sausages, such as salami and pepperoni; sharp or aged cheeses; yogurt and sour cream; beef and chicken livers;

*If you take a glass of milk with your dose of tetracycline the medicine might not do you much good. Dairy products, such as milk, yogurt, or cheese, interfere with the body's ability to absorb this antibiotic.*







*Women who take The Pill should include dark green leafy vegetables in their diet. Oral contraceptives can cause a deficiency of folic acid and vitamin B<sub>6</sub>. Spinach, kale, and mustard greens, as well as asparagus, green beans, wheat bran, and wheat germ are good sources of folic acid. Vitamin B<sub>6</sub> can be found in beef and chicken liver, yeast, nuts, and whole grain cereals.*



broad beans, such as fava beans; canned figs; bananas; avocados; soy sauce; active yeast preparations; beer; Chianti wine; sherry; and other wines in large quantities. MAO inhibitors also are suspected of reacting adversely with cola beverages, coffee, chocolate, and raisins.

Alcohol, which is actually a drug itself, although not regulated as a drug under the Food, Drug, and Cosmetic Act, does not mix well with a wide variety of medications, such as antibiotics; anticoagulants; antidiabetic drugs, including insulin; antihistamines; high blood pressure drugs; MAO inhibitors; and sedatives. Alcohol combined with antihistamines, tranquilizers, or antidepressants causes excessive drowsiness that can be especially hazardous to someone driving a car, operating machinery, or performing some other task that requires mental alertness. A good rule of thumb is to

avoid alcoholic beverages when taking any type of prescription or over-the-counter medication.

Just as some foods can affect the way drugs behave in the body, so some drugs can affect the way the body uses food. Drugs may act in various ways to impair proper nutrition: by hastening excretion of certain nutrients, by hindering absorption of nutrients, or by interfering with the body's ability to convert nutrients into usable forms. Nutrient depletion of the body occurs gradually, but for those taking drugs over long periods of time these interactions can lead to deficiencies of certain vitamins and minerals, especially in children, the elderly, those with poor diets, and the chronically ill.

Some drugs inhibit nutrient absorption by their effect on the bowel wall. Among these are colchicine, a drug prescribed for gout, and mineral oil,

an ingredient used in some over-the-counter laxatives.

A number of drugs affect specific vitamins and minerals. The antihypertension drug hydralazine and the anti-tuberculosis drug INH can deplete the body's supply of vitamin B<sub>6</sub> by inhibiting production of the enzyme necessary to convert the vitamin into a form the body can use or by combining with the vitamin to form a compound that is excreted.

Similarly, anticonvulsant drugs that are used to control epilepsy can lead to deficiencies of vitamin D and folic acid because they increase the turnover rate of these vitamins in the body.

Quite a few drugs—for example, colchicine, oral antidiabetic agents, and the antibiotic neomycin—can impair absorption of vitamin B<sub>12</sub>. But because most Americans have good stores of B<sub>12</sub> in their livers, it takes prolonged ingestion of these drugs to cause a deficiency.

Long term use of diuretics, or "water pills," to treat such conditions as congestive heart failure, can lead to serious potassium depletion. If the potassium loss is not corrected in heart patients taking digitalis, the heart may become more sensitive to the effects of the drug. People taking diuretics regularly should eat foods which are good sources of potassium. These include tomatoes and tomato juice, oranges and orange juice, dried apricots, cantaloupes, figs, raisins, bananas, prunes, potatoes, sweet potatoes, and winter squash.

Modifying the diet to include more foods rich in the vitamins and minerals that may be depleted by certain drugs generally is preferable to taking vitamin or mineral supplements. In fact, supplements of some vitamins can counter the effectiveness of certain drugs.

Fortunately, the diets of most Americans are sufficiently well-balanced so that the threat of drug-related nutritional deficiencies can be easily overcome.

Because oral contraceptives are used so widely, their effect on nutrition has been getting increasing attention. The Pill is known to lower blood levels of certain vitamins, notably folic acid,

and vitamin B<sub>6</sub>, but usually the vitamin depletion is not serious enough to cause overt symptoms. In most healthy women with good diets, these vitamin levels do not go down to a point that is alarming, says Dr. Daphne Roe, a Cornell University nutritionist. "But in a poverty group of young women who are trying to make do with very little and who have limited nutritional knowledge, you may find a different situation," Dr. Roe says. "It is this group we are most concerned about."

Because her requirements for several vitamins may be increased, it is especially important for any woman on The Pill to eat a nutritionally balanced diet. In particular, if a woman on The Pill is living on snack foods, she is more likely to develop folate deficiency than her neighbor who every day eats green leafy vegetables, which are a good source of folic acid, according to Dr. Roe.

Drugs readily available without prescription also can lead to nutritional problems. The worst offenders are antacids, Dr. Roe says, because they are so widely abused by the public. Chronic use of these remedies without a doctor's supervision can cause phosphate depletion, a condition that in its milder form produces muscle weakness and in more severe form leads to a vitamin D deficiency. "Unfortunately," says Dr. Roe, "some people get into the habit of taking enormous amounts of these drugs to treat gastric upset that in itself is due to their abuse of some other substance, such as alcohol, coffee, or food."

Mineral oil, an old-fashioned laxative still widely used by elderly people and in nursing homes, can hinder absorption of vitamin D. Dr. Peter Lamy reports that as little as 20 milliliters (4 teaspoons) of mineral oil twice daily can interfere with absorption of vitamin D, vitamin K, and carotene, a substance the body converts to vitamin A.

Drug labels now give patients little direct information about possible reactions with foods and beverages. But under new FDA guidelines that will become official regulations in 1979, drug manufacturers will be required to spell out known adverse reactions—with other drugs or with foods—on

patient package inserts that accompany certain prescription drugs. More information on interactions also will be required on the physician labeling for drugs. Physician labeling is the information on their prescription drug products that manufacturers are required to supply to physicians. In anticipation of these regulations, some manufacturers have begun voluntarily including such information with their products.

FDA also is seeking to make the labeling of over-the-counter drugs more informative. All over-the-counter drugs are being reviewed for safety, effectiveness, and labeling claims by FDA advisory panels. The recommendations of these panels may result in FDA requiring that manufacturers provide consumers with more detailed information about how certain non-prescription medicines interact with other drugs and with foods.

What can consumers do to prevent undesirable food-drug interactions? Here are a few suggestions:

- Read the labels on over-the-counter remedies and the package inserts that come with prescription drugs.
- Follow your doctor's orders about when to take drugs and what foods or beverages to avoid while taking medications.
- Don't be afraid to ask how drugs might interact with your favorite edibles, especially if you consume large amounts of certain foods and beverages. While taking drugs, be sure to tell your doctor about any unusual symptoms that follow eating particular foods.
- Eat a nutritionally well-balanced diet from a wide variety of foods. Use of a needed drug, even on a long term basis, is less likely to cause depletion of vitamins and minerals if your overall nutritional status is good.

Drug labeling and informed health professionals can be helpful to you, but your doctor and pharmacist cannot follow you to the dinner table or the snack bar. Remember that warnings about food-drug interactions are only as good as the patient's willingness to heed them.

*Phyllis Lehmann is a freelance writer.*

# Helping Ducks And Clams Coexist

*Nearly 1,500 acres of Long Island waters have been reopened for shellfishing because Federal, State, and local agencies worked together to solve an unusual environmental pollution problem.*

*by James Greene*

**"State Closes Long Island Shellfish Waters"**

**"Judge OKs Closing of Clam Beds"**

**"Clammers to Harass Patrols at Closed Beds"**

**"The Sea of Confusion on Clam Bed Closings"**

**B**ad news travels fast. That axiom applies to many stories reported in the news. The above headlines, which appeared in several New York City and Long Island newspapers last spring and summer, were quick to announce the closing of polluted shellfishing waters in the Great South Bay, near Long Island, New York. There were no such headlines, however, during the same period when the State announced the reopening of other shellfish waters in two smaller bays on the south shore of Long Island.

The reopening of nearly 1,500 acres in Moriches Bay and Bellport Bay illustrates how Federal, State, and local governments can pool their resources and manpower to combat environmental pollution. In this instance the cooperative effort reclaimed important shellfish growing waters and thus helped maintain the livelihood of many watermen in the surrounding towns. The two bays, which total about 16,000 acres, had been closed for shellfishing in 1972 because of a growing problem peculiar to these areas. Large commercial duck farms with minimal sewage treatment facilities were emptying increasing amounts of sludge containing duck excreta into the two bays, causing bacteriological pollution.

The sludge accumulated in the bot-

tom of ponds and streams where the ducks are raised. Some bottomland areas contained up to 15 feet of compacted duck sludge. Water from heavy rains would carry the sludge through streams and tributaries into the bays.

Clams feed by pumping large quantities of water through their bodies and retaining nutrients from sediments in the water. If the clams live in water that contains large numbers of harmful bacteria or large deposits of industrial chemicals they may become contaminated. These contaminated clams, in turn, can cause serious illness in people who eat them. Outbreaks of hepatitis and typhoid fever have been traced to sewage-contaminated shellfish.

To prevent possible serious health hazards, the New York State Department of Environmental Conservation found it necessary to prohibit commercial shellfishing in Moriches and Bellport Bays. The action was based on the requirements of the National Shellfish Sanitation Program, which is administered by the Food and Drug Administration and enforced by State and local health authorities. The program requires States to classify waters that may be used to harvest shellfish for human consumption. It also requires States to perform sanitary surveys in shellfish growing waters to determine if they are polluted and, if so, with what and to what degree.

To reclaim parts of the closed bays, the State Department of Environmental Conservation, under the supervision of Robert B. MacMillan, supervisor of marine and environmental control, worked with Suffolk County health sanitarians to make sure that local duck farms improved their sewage treatment facilities as required by updated sanitation regulations. These State regulations and related enforcement activities, including duck farm inspections, caused a number of farms to close or consolidate. The number of

operating farms dropped from about 25 to 12 and this cutback, coupled with improved sewage treatment facilities and strict enforcement of sanitation regulations, greatly reduced the amount of contaminating sludge which found its way into the bays.

While the source of the pollution was being corrected on land, the State Bureau of Shellfisheries was routinely collecting water samples to determine the progress being made to clean up the waters in question.

As administrator of the National Shellfish Sanitation program, FDA monitored the clean-up campaign. FDA shellfish sanitation specialists stationed in New York reviewed water sample data and accompanied State conservation officials to check on the progress of upgrading the sewage treatment facilities at the duck farms.

In addition, FDA and State inspectors periodically check shellfish processing and packing plants to make sure they meet sanitation requirements. FDA also routinely reviews other shellfish activities conducted by the States, including the training and equipping of State inspectors and enforcement personnel, policing of closed shellfish harvesting waters, and the relocation of clams from contaminated to clean waters where after a period of time they cleanse themselves.

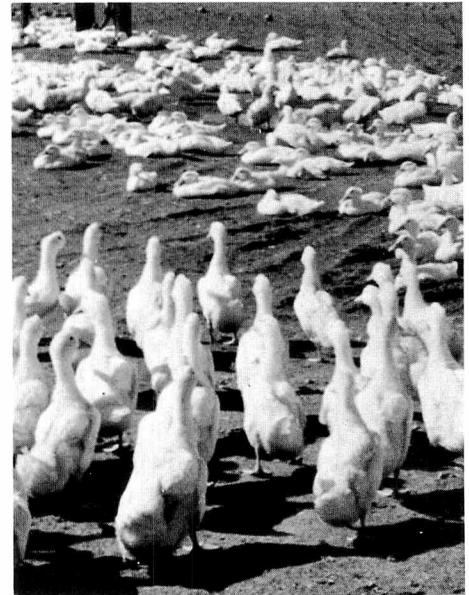
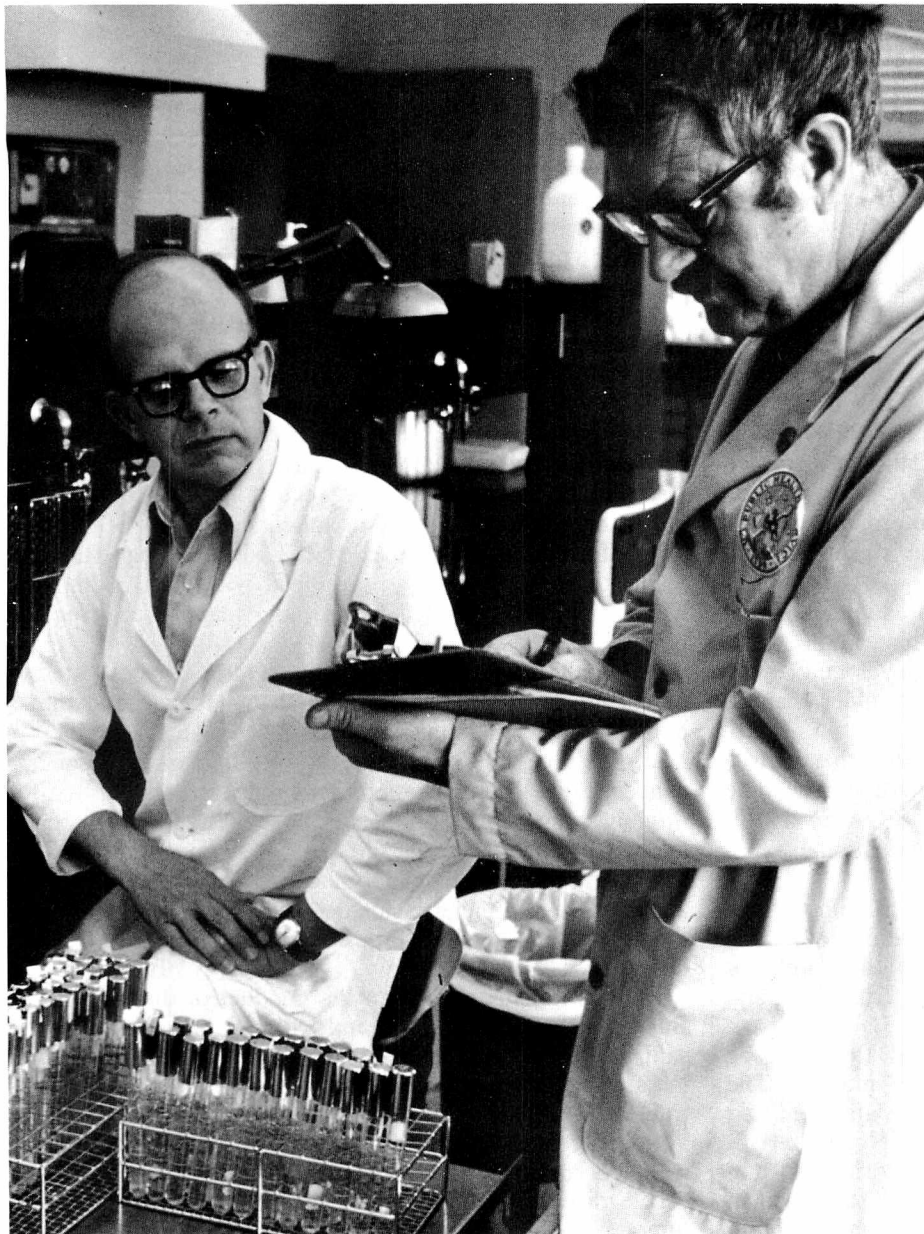
The reopening for shellfishing of less than one-tenth of the total waters in two bays may not be the kind of achievement that makes headlines. But it was an important first step in the continuing revitalization of these waters for shellfishing. And it was more than a footnote for the duck farmers and watermen whose livelihoods were threatened—as well as an encouraging development for consumers whose tastes run to Long Island duckling and clams.

*James Greene is a staff writer with FDA's Office of Public Affairs.*





*Even ice-covered waters don't deter some Long Island clammers. They cut a hole in the ice and, using clam rakes with extension handles, scrape the bottom for clams.*



*Water contaminated by Long Island duck farms such as this was a major factor in the closing of nearby shell-fishing waters.*

*FDA Microbiologist Willard Adams (right) evaluates the techniques used by New York State Aquatic Biologist James Redman in analyzing shellfish samples for possible microbiological contamination. FDA periodically evaluates the State microbiological laboratory at Stoney Brook for proficiency as part of its responsibilities under the National Shellfish Sanitation Program.*

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# News Highlights

## Saccharin Link to Bladder Cancer Studied

The Food and Drug Administration (FDA) and the National Cancer Institute (NCI) have begun a nationwide study on the possible role of saccharin in causing bladder cancer in humans.

The study will cost \$1.375 million and require about 18 months to complete. It is being conducted in five States—New Jersey, Connecticut, Iowa, New Mexico, Utah—and four metropolitan areas—Detroit, San Francisco-Oakland, New Orleans, and Atlanta.

All but New Jersey are part of the nationwide Surveillance, Epidemiology, and End Results (SEER) network of population-based cancer registries established by NCI to monitor patterns of cancer occurrence, treatment, and survival in the United States. The New Jersey study is being coordinated by the State Health Department of New Jersey.

The study will include about 3,000 people with bladder cancer diagnosed during 1978 and 6,000 randomly chosen healthy individuals living in the same areas. All 9,000 people will be interviewed. NCI will analyze the data and compare the saccharin consumption patterns of the cancer patients with those of the healthy individuals to determine whether there may be an association between the sweetener and bladder cancer.

Of the 3,000 bladder cancer patients, an estimated three-fifths will be 65 or older and three-fourths will be male, according to past bladder cancer statistics developed by the SEER network. Patients younger than 21 or older than 85 will not be eligible.

The study also will develop information on other factors that may play a role in bladder cancer, including cyclamate (another artificial sweetener, banned by FDA in 1970), drinking water, cigarette smoking, and occupational exposures.

FDA is providing \$750,000 for the initial funding of the study out of a special \$1 million appropriation to FDA's budget voted by Congress for studies on the safety of saccharin. The remaining funding will come from NCI and other agencies.

The FDA-NCI study is one of several that will be conducted on saccharin during the coming months. The studies are being conducted as a result of legislation enacted by the Congress and signed by the President November 23, 1977. The legislation put an 18-month moratorium on any regulatory action by FDA against the use of saccharin in foods. FDA in April 1977 proposed a ban on saccharin

following receipt of a Canadian study which, along with other evidence, showed saccharin could cause bladder cancer in test animals.

FDA also is negotiating with the National Academy of Sciences for a number of studies specifically required by the legislation to assess the health benefits and risks of the artificial sweetener.

The NCI-FDA study is not specifically required by law. It stems from a recommendation by a special task force of FDA and NCI scientists, which recently urged that a large, population-based study be conducted to determine whether the proven association between saccharin and bladder cancer in animals also applies to humans.

## Cancer Institute Seeks Laetrile Patients

In an effort to determine whether there is sufficient evidence to justify testing Laetrile in human volunteers, the National Cancer Institute (NCI) has begun a study of cancer patients who have used the controversial drug.

The Institute is asking physicians to submit names of consenting patients who may have shown a response to Laetrile. NCI will review the records of these patients to see if there is any evidence of anticancer effects of Laetrile. This information will be used by NCI in deciding whether it wants to seek approval to go ahead with tests in humans. FDA approval is needed before any unapproved drug can be tested in people.

Normally FDA does not allow a drug to be tested in people unless animal tests show that it is safe and that it holds promise of being effective. Many animal studies of Laetrile have been carried out by the Nation's leading cancer research organizations, but none has shown that the drug has any effect on cancer. When Laetrile advocates applied for permission to do human testing in 1970, FDA asked an independent panel of cancer experts to study the application. The panel concluded that there was not enough evidence of Laetrile's effectiveness to justify tests in humans.

FDA is not taking part in the conduct of the NCI study. But Commissioner of Food and Drugs Donald Kennedy has said information gathered in the study will not be used to initiate legal action against doctors or patients using Laetrile.

In order for a case to be included in the NCI study there must be confirmed pathological diagnosis of cancer; measurable disease (defined as a palpable or other measurable tumor, or objective radiological evidence of tumor); ade-



quate documentation of case history; and documented evidence that Laetrile was the only anticancer treatment used for at least 30 days. Case records will be reviewed by a group of experts in the analysis of anticancer drug activity.

Physicians who know of patients who might qualify for the review should write to Laetrile Review Office, c/o Office of Cancer Communications, National Cancer Institute, Bethesda, Md. 20014. The consent of all participating patients or surviving next-of-kin (for deceased patients) is required to obtain pertinent medical records and to publish the results of the study.

## Liquor Label Pregnancy Warning Studied

The Bureau of Alcohol, Tobacco and Firearms (BATF) in the Treasury Department has issued a call for information to determine whether a warning is needed on the labels of alcoholic beverages to alert expectant mothers that alcohol consumption may harm their unborn children.

BATF published a notice in the *FEDERAL REGISTER* January 16 soliciting information on the subject.

BATF Director Rex Davis said: "Our objective is to find the best way to make information (about fetal alcohol syndrome) available to those who need it. A label warning is one way, and we will examine any alternatives offered."

BATF allowed 60 days from the January 16 *FEDERAL REGISTER* notice for public comment on the types of warnings, likely impact on women, and possible alternative ways of getting the warning to expectant mothers.

Commissioner of Food and Drugs Donald Kennedy, who in a November letter to BATF had urged the Bureau to require a fetal alcohol syndrome warning on alcoholic beverage labels, praised the BATF action and said FDA will help in any way it can.

"The evidence is clear that excessive alcohol use by pregnant women can cause birth defects in the children they bear," Kennedy said. "Even pregnant women who drink moderately may be inflicting some risk on their babies if they occasionally have more than two drinks a day. I applaud Director Davis and BATF for taking the first step toward warning women about the possible risks of drinking during pregnancy."

## Proposal Asks Safety Caps on Acetaminophen

The U.S. Consumer Product Safety Commission has announced that it will propose that child-resistant packaging be required for the drug acetaminophen. Acetaminophen is a pain reliever widely used as a substitute for aspirin.

The Commission believes that special packaging is necessary to protect children under 5 years of age from serious illness and injury resulting from accidental ingestion of excessive amounts of acetaminophen.

Although acetaminophen is effective when taken in its proper dosage, and is also valuable for those who are sensitive or allergic to aspirin, many persons apparently believe acetaminophen is safer than aspirin in overdose situations. However, ingestion of excessive amounts of acetaminophen can cause health problems, possibly serious liver damage.

The National Clearinghouse for Poison Control Centers for the period 1969 to 1975 reported 4,819 ingestions of acetaminophen-containing products by children under 5. Of



these, 102 cases required hospitalization and two of the children died. Statistics are not currently available for 1976 and 1977.

In view of medical reports and the significant number of ingestions by young children, the Commission proposes that those preparations containing more than one gram of acetaminophen in a single package be packaged with child-resistant closures. Tablets of acetaminophen are usually 325 mg or 500 mg.

## Ginseng Approved Only for Use in Tea

FDA has advised consumers that the only approved use for the herb ginseng is for making tea. Any product containing whole, ground, or powdered ginseng must state on the label that it is for use only in tea.

Ginseng may not be used for any other food purpose, FDA said, and food products containing ginseng that are not intended for tea use are considered adulterated and subject to FDA regulatory action.

FDA also said that ginseng has not been approved for any drug use.

## Better Drug Monitoring System Sought

The Food and Drug Administration, National Bureau of Standards, and Joint Commission on Prescription Drug Use have announced the award of a contract for the first stage of a program to develop better systems for monitoring unexpected effects from newly approved drugs.

The \$356,618 contract was awarded on a competitive basis to IMS America, Ltd., Ambler, Pa. Funds are part of \$1.1 million provided by the Bureau of Standards to FDA for the design and testing of better drug monitoring systems.

FDA Commissioner Donald Kennedy said: "During the coming months the Congress will be considering a major overhaul of the present drug law. One goal is to enable FDA to approve useful new drugs more quickly, provided we also can remove them quickly if necessary. If we are to meet this goal a dependable post-approval drug monitoring system is essential. This contract is intended to help us develop such a system."

Under the 18-month contract, IMS will review drug surveillance systems here and in other countries and develop new methods for possible use in the United States.



Additional contracts will be awarded on a competitive basis to evaluate the systems developed under this contract.

The Joint Commission on Prescription Drug Use, an independent group created in 1976 to recommend systems for postmarketing surveillance and monitoring of prescription drug use, participated in developing the contract. The funding by the Commerce Department's Bureau of Standards came from its Experimental Technology Incentives Program, which funds projects to develop technological innovations.

## Change Ordered in Antianxiety Drug Labels

FDA has ordered that the manufacturers of antianxiety prescription drugs change their labeling to say that the drugs have not been demonstrated effective when taken by patients consistently for extended periods.

In an order published in the *FEDERAL REGISTER* January 10, 1978, FDA gave manufacturers 60 days to add the following paragraph to the indications section of the labeling:

"The effectiveness of (drug name) in long term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient."

This statement will be added to the labeling of all antianxiety drugs, including chlorthalidopoxide (Librium), meprobamate (Equanil), and diazepam (Valium).

The requirement grew out of a recommendation made by FDA's Psychopharmacological Agents Advisory Committee. The committee said that the long term use of antianxiety drugs, in the absence of other measures designed to combat or alter the situation causing the distress or the individual's response to it, is unwise.

## No Hazard Seen in Coffee Pesticides

FDA has completed a survey of pesticide levels in imported coffee beans which concludes that current levels of residues do not pose a hazard to the consumer.

Coffee is imported into the United States as green (unroasted) beans. Approximately 2.75 billion pounds of coffee were imported into the United States in 1976.

In 1977, FDA received reports that some pesticides illegal for use on food crops in this country were being used on coffee beans in South American countries. To determine if residues of these pesticides were present in imported coffee, FDA conducted a survey of imported coffee beans between August and October 1977. The survey involved seven FDA districts—New York, New Orleans, San Francisco, Houston, Dallas, Orlando, and Baltimore—which encompass the principal ports of entry for coffee beans.

FDA analyzed 55 samples of coffee beans from 19 countries. The analysis found that 45 percent of the beans contained detectable residues of one or more of the following pesticides: DDT, BHC, DDE, lindane, diazinon, malathion, dieldrin, and heptachlor (in decreasing order of detection frequency). Of these residues, however, 60 percent were at trace levels. The highest levels were for malathion (0.2 parts per million) and diazinon (0.13 ppm). Diazinon may be legally present up to 0.2 ppm in green coffee beans.

FDA also performed experiments to determine the extent to which pesticides in green coffee beans survive the

roasting process. All pesticide residues were significantly lower after roasting. In the case of DDT, which had the highest survival rate, more than 90 percent of the residue was removed by roasting. Also, FDA expects that there will be a further reduction of the pesticide residues when the coffee is brewed because it is anticipated that not all residues in the beans will transfer to the brew.

FDA considers the small amounts of pesticides in green coffee beans as probably unavoidable at the levels reported in this survey because of the past worldwide use of pesticides. The Agency will continue to monitor pesticide levels in coffee and other foods to insure that residues continue at safe levels.

## 'Pop Rocks' and 'Space Dust' Found Safe

FDA's Bureau of Foods has tested "Pop Rocks" and "Space Dust," two candies sold nationwide, to determine if there is any danger to the stomach from eating them and found both products safe and acceptable.

Both products are made of sugar, lactose, and artificial color and flavorings. They are processed with carbon dioxide to provide a crackling sensation in the mouth. "Space Dust" is a powdered form; "Pop Rocks" is the granular form. FDA found the amount of carbon dioxide used in a package of the candy is about one-tenth the amount in a 12-ounce can of carbonated soda.

FDA has received ten complaints of illness or injury associated with "Pop Rocks" and "Space Dust." FDA has investigated these cases but has not been able to confirm that the candy caused illness or injury.

## Budget of \$306 Million Asked for FDA

An FDA budget of \$306 million and 7,563 positions has been proposed by the President for fiscal year 1979. This is an increase of \$19 million and 100 positions over the current budget.

Of this increase, \$12 million is in the buildings and facilities appropriation and will go for renovation or replacement of existing FDA facilities.

Medical device regulation will get \$5 million of the total increase and will also get 159 additional positions, 79 of them shifted from programs involving food economics and cosmetics. This will permit orderly expansion of new medical device regulatory programs implemented by FDA to carry out the requirements of the Medical Device Amendments of 1976.

Programs involving the regulation of human and veterinary drugs will get an increase of about \$1.9 million.

The budget calls for a cut of \$2.6 million in funding for food economics and cosmetics programs. Food safety and radiological health activities will continue at their current level.

The budget request for fiscal 1979 was prepared using for the first time a "zero-base" budget process adopted throughout the Public Health Service.

This process requires an agency to justify its entire budget in detail each year, as though it were being funded for the first time. This is a change from past incremental procedures, which assume that an agency receives the prior year's level of funding and must justify only its increases.

"Zero-base" calls for systematic evaluation of an agency's basic program elements, using a priority ranking

system. This process applied to the 1979 budget caused FDA to move positions to medical devices, whose responsibilities continue to increase.

### **Restrictions Proposed on Medicated Feed**

The Food and Drug Administration has proposed restrictions on the distribution and use of animal feeds containing the antibiotics penicillin, chlortetracycline, or oxytetracycline.

The proposal is FDA's third step in its effort to halt the routine addition of small quantities of these antibiotics to animal feed to prevent disease and make animals grow faster. FDA is concerned because this practice is known to cause bacteria to become more resistant to the drugs. This resistance can then be transferred to bacteria in people and as a consequence antibiotics may be less effective in therapy because the bacteria have increased immunity to the drugs.

The latest proposed restrictions would limit distribution of the three antibiotics, when intended to be used in animal feed, to manufacturers licensed to produce medicated feed containing these antibiotics.

They also would prohibit livestock and poultry producers from purchasing and using medicated feeds containing these antibiotics without an order from a licensed veterinarian.

In effect, the proposed restrictions set up a new category of medicated feeds—restricted medicated animal feeds. The labels would have to say "For use only on the order of a licensed veterinarian."

Currently, livestock and poultry producers do not need an order from a veterinarian to purchase any medicated feed for their animals.

The first action toward limiting use of antibiotics in feed was taken August 30, 1977, when FDA proposed to prohibit routine addition of penicillin to animal feed.

The second step was on October 21, 1977, with a similar proposal to eliminate most uses of chlortetracycline and oxytetracycline in animal feeds. Under the October 21 proposal, the tetracyclines could be used in animal feeds to treat specific disease outbreaks, and could also be used to prevent diseases in certain cases where effective alternative drugs are not available.

The proposed new regulation appeared in the *FEDERAL REGISTER* January 20, 1978. Comments will be accepted for 90 days from that date and may be sent to the Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

### **Four Agencies Seek Uniform Health Tests**

Four Federal agencies that prescribe numerous health and safety tests for consumer goods and industrial operations are striving to eliminate confusion and duplication from their requirements.

The Food and Drug Administration, Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), and Environmental Protection Agency (EPA) are developing uniform standards and guidelines for industry to follow in measuring the human and environmental consequences of their products and manufacturing processes.

The agencies want to eliminate, as much as possible, the current situation in which a particular company may be

required to test for a health hazard one way for FDA, another way for EPA, and still two other ways for CPSC and OSHA.

Under a uniform guidelines approach, one test rather than four would suffice for all the agencies. Considerable time and money would be saved by both industry and Government.

The chemical industry is likely to benefit most from this reform since it must often answer to all four regulators because of the mix of products it manufactures, such as basic industrial chemicals, drugs, pesticides, and household cleaning items.

A work group of the four agencies is now drafting consistent guidelines for a variety of human and environmental effects tests. These toxicity tests include inhalation, skin exposure, ingestion, eye irritation, reproductive effects, birth defects measurements, vapor pressure, water solubility, soil impacts, and acute toxicity to birds, fish, and plants. Persons knowledgeable in these areas have been asked to submit written materials that would aid in creating compatible requirements.

It may be this summer before the first uniform testing guideline will be completed. It will cover tests designed to measure eye irritation from products.

The testing work group is also investigating the use of identical formats for reporting toxicity research results and standards methods for Government review of this information.

Standards and guidelines for toxicity tests are one of eight areas for cooperative action mapped out by the four regulatory agencies last summer. The other areas are risk assessment, epidemiology information exchange, research planning, compliance and enforcement, regulatory development, and education and communications. The staffs working on these issues are known as the "Interagency Regulatory Liaison Group."

Notices on the activities of the testing standards work group appeared in the *FEDERAL REGISTER* on January 10 and 13.

### **Committee Seeking Veterinary Bureau Chief**

Commissioner of Food and Drugs Donald Kennedy has formed a committee to undertake a nationwide search to fill the position of director of FDA's Bureau of Veterinary Medicine. The present director, Dr. C. D. Van Houweling, has announced his intention to leave the position no later than July 1978.

The Search Committee will be chaired by Dr. Ruth Kirschstein of the National Institutes of Health (NIH) and will include Dr. Fred Davison of the University of Georgia, Dr. George Poppensiek of Cornell University, Ms. Camille Haney of Consumer Concepts and a former member of the National Advisory Food and Drug Committee, Dr. Walter Bowie of Tuskegee Institute, Dr. Allen Edgar of Auburn University, Dr. Bennett Cohen of the University of Michigan, Dr. David Hoel of NIH, and Dr. Rosa Gryder of FDA.

Target date for choosing a new director is the summer of 1978. Dr. Van Houweling has agreed to continue in the position until a new director can be named.

The Bureau of Veterinary Medicine's primary responsibility is approving and regulating the use of drugs for veterinary purposes. This includes regulating the use of drugs in feed given to food-producing animals.

# Regional Reports

*"Regional Reports" consists of important 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. "State Actions," the section immediately following "Regional Reports," consists of similar information about the consumer protection activities of State and local governments.*

## REGION I

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

A U.S. marshal supervised the destruction of 36 cases of frozen egg rolls seized by the Federal Government at a warehouse in Milton, Massachusetts. The egg rolls were manufactured by Hung's Food Products, Brighton, Massachusetts, and were short in weight. The seizure and subsequent destruction occurred after investigators from FDA's **Boston District** collected samples of the egg rolls during a routine inspection of the manufacturer and laboratory analysis revealed the product was short in weight.

A deputy U.S. marshal seized 219 hundred-pound bags of a product labeled Wingold Pure Wheat Bran at Port Terminals, Inc., a public storage warehouse in Boston, because of insect contamination. The seizure resulted from a routine surveillance inspection of the warehouse by investigators from the Boston District who discovered the bran was contaminated with insect larvae and excreta. The product was valued at approximately \$2,000.

Investigators from FDA's Boston District and a deputy U.S. marshal supervised the destruction of an esti-

mated \$300,000 worth of foodstuffs including mung beans, tea, monosodium glutamate, cookies, and candy because of insect and rodent contamination. The foodstuffs, manufactured by Eastern Enterprises, Inc., Boston, had been seized at the firm following an inspection by the Boston District which revealed the contamination. Destruction was accomplished by burial in a local landfill.

## REGION II

*New Jersey, New York, Puerto Rico, Virgin Islands*

Gro-Pak Co-op, Inc., Eden, New York, a cannery specializing in green and wax beans, voluntarily destroyed more than 22 tons of beans including raw, in-process, and canned beans awaiting retort processing. The action came after inspectors from FDA's **Buffalo District** noted defects in the beans during a routine inspection. The defects included field rot caused by recent record rainfalls, discoloration from windburn, and insect damage. The beans, valued at \$2,000, were converted to animal feed.

FDA issued a warning letter to the Lutz Feed Co., Roxbury, New York, after investigators from FDA's **Albany Resident Post** determined that the firm had been repacking molasses for use in animal feed in 55-gallon drums which had not been sufficiently cleaned. The problem was discovered after a dairy farmer complained that his herd became ill after eating feed containing molasses from the company. Laboratory analysis of the molasses by the Buffalo District revealed the presence of Varsol, a chemical used in dry cleaning, and in paint thinning.

Metzendorf Bros., Inc., Perth Amboy, New Jersey, a bakery supply warehouse, has agreed to stop distrib-

uting foodstuffs until it eliminates rodent infestation of its premises and brings its operation into compliance with the Food, Drug, and Cosmetic Act. The firm entered into a consent decree of permanent injunction in the U.S. District Court for the State of New Jersey, after a routine inspection of the warehouse by FDA's **Newark District** revealed the rodent infestation. Investigators discovered extensive rodent defilement of the firm's flour, sugar, and donut mix. FDA reported its findings to the New Jersey State Health Department, which placed an embargo on the entire contents of the building. The firm then voluntarily destroyed more than 60,000 pounds of foodstuffs, and reopened for business, while it was conducting a bag-by-bag examination of susceptible containers under State supervision. This effort resulted in the destruction of an additional 14,000 pounds of food. A follow-up inspection by FDA found continuing infestation however, and resulted in a mass seizure of all foodstuffs and the court action.

The Federal Government seized over 300,000 exercise devices, valued at \$700,000, at General Home Products Corp., Burlington, New Jersey, because of mislabeling violations. Labeling for the plastic pulley-and-rope devices, sold under the names of Torso Trimmer and Wonder Body Exercisers, claimed that they would keep the user alert and dynamic, build energy, slim fatty deposits everywhere, and make the user look and feel young. The label also suggested that the devices could be used helpfully and effectively by everyone, yielding worthwhile dividends almost at once. The seizure resulted from a routine inspection at the firm by the Newark District. Investigators found the labels were false and misleading and lacked adequate warning that the use of these



devices by people suffering from certain pathological conditions might be dangerous to their health. The seized lot will be destroyed after FDA determines a method of destruction that conforms to environmental impact restrictions regarding the destruction of plastics.

### REGION III

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

A lot of 45 cases of insect-infested Larosa elbow macaroni, valued at \$400, was seized by the Federal Government at Springfield Sugar and Products Co., Suffield, Connecticut. Each case contained 20 one-pound boxes of macaroni. The seizure resulted from findings made in an inspection of the manufacturer, Victor Larosa & Sons, Inc., Warminster, Pennsylvania, by FDA's **Philadelphia District**.

The Federal Government seized nearly 1,400 pounds of sunflower seeds for use as bird feed at McCracken's Feed Mill, Inc., Manheim, Pennsylvania, because of rodent contamination. The seizure resulted from an inspection by the Philadelphia District of the New Holland Supply Co., New Holland, Pennsylvania, where the bags of sunflower seeds were found rodent gnawed and contaminated with rodent and bird excreta. Investigators traced the subsequent shipment to the Manheim firm where the seizure was made. The sunflower seeds were valued at \$300.

### REGION IV

*Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee*

Sophie Mae Candy Corp., Atlanta, converted over 15,000 pounds of peanut brittle into hog feed after an inspection of the firm by FDA's **Atlanta District** revealed live insect infestations in the peanut brittle handling equipment and in cardboard bulk containers used to store bulk peanut brittle. The peanut brittle was valued at about \$7,000. Following the inspection the firm voluntarily suspended operations and conducted a general cleanup of the plant, which included destruction of the storage containers and other related equipment. The inspection and

subsequent actions were based on a consumer complaint to the Atlanta District about peanut brittle infested with insects.

An investigator from FDA's **Memphis Resident Post** witnessed the destruction of about 27 tons of dog and fish feed, valued at over \$6,200, at a sanitary landfill at Tupelo, Mississippi. The feed had been damaged by an explosion at Sunshine Mills, Inc., Tupelo. The investigator assisted in the salvage operation to assure that damaged or unfit feed or raw materials would be properly destroyed or diverted to nonfeed uses. He also witnessed the removal of about 220,000 pounds of apparently undamaged feed material including ground corn, wheat, and soybean and fishmeal from damaged storage tanks to another location for storage. An additional five tons of undamaged materials were converted to hog feed for local use.

### REGION V

*Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin*

Westerville Creamery, a Division of Beatrice Foods, Covington, Ohio, voluntarily recalled over 700,000 pounds of *Salmonella*-contaminated nonfat dry milk, sweet buttermilk, and whey following cooperative action by the U.S. Department of Agriculture and FDA's **Cincinnati District**. The Department of Agriculture notified the Cincinnati District after finding the *Salmonella* contamination during its routine surveillance. The recall was initiated after investigators from the Cincinnati District visited the firm. The products, with an estimated value of nearly \$530,000, were packed in 50-pound bags and sold to bakeries, dairies, and other food manufacturers for use in a variety of retail food items.

Piqua Milling Co., Piqua, Ohio, has resumed production after temporarily shutting down to clean up its operations, including the fumigation of equipment, following an inspection of the firm by FDA's Cincinnati District. Investigators found a continuing problem of insect infestation of conveyors, packing bins, and other equipment. In addition, the firm also voluntarily recalled several thousand dollars worth of flour contaminated by beetles. Most of the flour had been sold to a fast-

food service franchise and some to bakeries. The Ohio Department of Agriculture assisted in the final disposition of the recalled flour.

U.S. marshals seized \$50,000 worth of new animal drugs in the possession of Wendt Laboratories at Belle Plaine and Blakely, Minnesota, because they had not been approved by FDA. The seizure was made after repeated warnings to the firm by FDA's **Minneapolis District** regarding the illegal status of these veterinary preparations, most of which are antibiotic products. The materials, seized at the two locations simultaneously, consisted of bulk raw, in-process, and finished products.

### REGION VI

*Arkansas, Louisiana, New Mexico, Oklahoma, Texas*

U.S. marshals seized nearly 12,500 boxes of contaminated chili peppers at Martin Bouvet & Sons, a freeze processor of green chilies at Garfield, New Mexico. The seizure resulted from a routine inspection of the firm by FDA's **Dallas District** which revealed manufacturing practices conducive to bacterial adulteration. Laboratory examinations of samples collected confirmed the presence of microbiological contamination. Each of the boxes contained 25 pounds of chili peppers. Total value of the peppers amounted to \$126,000.

The Strachan Shipping Co., New Orleans, pleaded guilty in the U.S. District Court for the Eastern District of Louisiana to three counts of storing food under insanitary conditions at two locations at the Port of New Orleans. Judge Morey Sear accepted the guilty plea and fined the corporation a total of \$1,500. The court action resulted from two inspections on the wharf by FDA's **New Orleans District** which revealed two lots of green coffee beans and one lot of cornmeal were contaminated with rodent and bird excreta. In addition, investigators observed bird and insect activity, including bird nests and live rats in the storage areas.

### REGION VIII

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

The U.S. District Court in Denver, Colorado, ordered Tutag Pharmaceuti-

cals, Broomfield, Colorado, to cease manufacturing and shipping the drug X-Otag Plus, because it has not been approved by FDA. The drug contains an analgesic and a muscle relaxant for use in the treatment of musculo-skeletal disorders. Tutag Pharmaceuticals has filed an appeal of the court decision. The legal action resulted from an FDA program which reviews drugs for safety and effectiveness.

Six 240-millimeter plastic bags containing human blood derivative used to treat hemophiliacs were seized by the Federal Government at the Liberty County Hospital in Chester, Montana, after a routine inspection of the hospital's blood bank system by the **Denver District**. The derivative was Cyro-precipitated Antihemophilic Factor and had not been stored at freezer temperatures low enough to ensure stability and safety.

A shipment of ground buffalo meat patties valued at \$320, and labeled Wyoming Buffalo Chips, was seized by the Federal Government at Gorham Distributing, Loveland, Colorado, because the product contained sodium nitrite and nitrate, which FDA has

never approved for use in buffalo meat. In addition, the product was mislabeled in that the name Buffalo Chips was not a common or usual name for the product. The patties, packed 40 to a jar, were manufactured by Pat's Meat Discounter, Casper, Wyoming. The seizure resulted from information supplied to the Denver District from FDA's Kansas City District, which initiated similar seizures in its area.

## REGION X

*Alaska, Idaho, Oregon, Washington*

A lot of over 3,800 pounds of canned salmon, valued at approximately \$6,700, was seized by a U.S. marshal at a public storage warehouse in Seattle because of decomposition. The salmon was shipped by St. Elias Ocean Products, Cordova, Alaska, to the Seattle warehouse where samples were collected by FDA's **Seattle District**. Organoleptic examination by FDA laboratory personnel revealed the product contained decomposed salmon.

The Federal Government seized approximately 900 pounds of cashew kernels, valued at about \$1,300, in the

possession of C. C. Grains, Seattle, after an inspection by the Seattle District revealed the product was contaminated with insects. Investigators collected samples at the firm and subsequent analysis showed the product was contaminated with live insects in various stages of development. The cashews were imported from Mozambique by J. F. Braun & Sons, Inc., Lake Success, New York, and had been shipped from a warehouse in San Francisco, California, to the Seattle firm.

A U.S. marshal in Seattle seized nearly 8,500 pounds of canned salmon at a local public storage warehouse because of decomposition. The seizure resulted from organoleptic examination of samples collected at the warehouse by FDA's Seattle District, which revealed the presence of decomposed salmon. The raw fish was shipped by the Yakutat Fishermen's Cooperative in Yakutat, Alaska, to Dressel-Collins Fish Co., Seattle, where it was canned, and then delivered to the warehouse for storage. The salmon was valued at approximately \$18,500 and was stored to the account of John J. Ehlinger Co., Seattle.

## State Actions

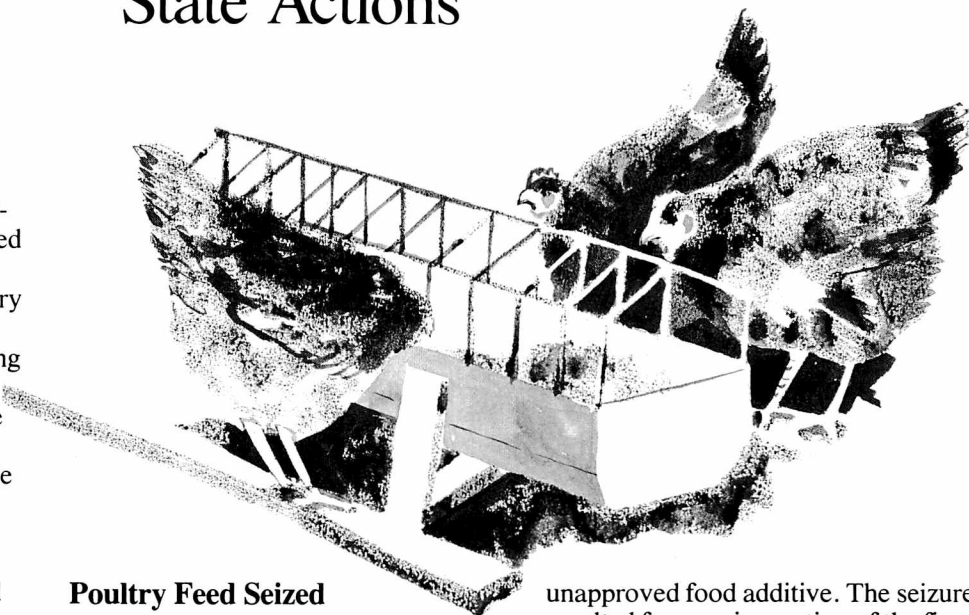
### Substandard Cheese Seized

A shipment of 3,600 pounds of low-moisture mozzarella cheese was seized by U.S. marshals at a warehouse in Rochester, New York, after laboratory analysis by FDA's Buffalo District confirmed an earlier State test showing that the product did not meet FDA standards for fat content. The seizure resulted from a routine inspection of the warehouse by the New York State Department of Agriculture and Markets in which samples of the cheese were analyzed and found low in fat content. The deficiency was reported to the Buffalo District by the State, which then placed an embargo on the shipment pending FDA analysis. The cheese, valued at \$2,000, was manufactured by Farmer's Cheese Co., New Wilmington, Pennsylvania.

### Poultry Feed Seized

A lot of 346 fifty-pound bags of premix for poultry feed was seized in the possession of Johnston Feed Mill of Mena, Inc., Mena, Arkansas, because the bags contained gentian violet, an

unapproved food additive. The seizure resulted from an inspection of the firm by the Arkansas State Plant Board under an FDA contract. The State inspector placed the lot under a "stop use" order until a sample of the premix was examined to verify its contents.



# Seizures

## SEIZURE ACTIONS

charging violation of the Federal Food, Drug, and Cosmetic Act are published when they are reported by the FDA District Office.

A total of 35 actions to remove from the consumer market products charged to be violative was reported in December. These included 19 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 12 involved charges concerning contamination, and 4 involved charges concerning economic and labeling violations. Other seizures included 6 of food additives, 6 of drugs (including 2 of veterinary), and 4 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substances</b>		
Dog food, Iams Plus/Riverside, Calif. 8/18/77	Ross Well/Serlin, Md. (M); Iams Food Co./Dayton, Ohio (S)	Contains the added poisonous and deleterious substance <i>Salmonella</i> microorganisms.
Swordfish/Washington, D.C. 9/2/77	Emerald Bay Inc./Needham Heights, Mass. (S)	Contains the added poisonous and deleterious substance mercury.
Swordfish steaks, frozen/Peoria, Ill. 10/26 & 27/77	Prelude Foods International/South Boston, Mass. (S)	
<b>Contamination, Spoilage, Insanitary Handling</b>		
Azuki beans, dried shrimp, sesame seed, orange peel, dried codfish, chinese almonds, and rice cakes/San Francisco, Calif. 7/21/77	Wing Sing Chong Co./San Francisco, Calif. (D)	Held under insanitary conditions; some articles rodent contaminated.
Barley, pearled/Grove, Okla. 10/28/77	F. L. Wilson Co./Grove, Okla. (D)	Held under insanitary conditions; contains insects; contains the nonconforming food additive chlor-dane.
Chamomile/Boulder, Colo. 8/30/77	Celestial Seasoning, Inc./Boulder, Colo. (D)	Held under insanitary conditions; contains insect larvae.
Chilies, green, frozen/El Paso, Tex. 10/27/77	D.C.B. Enterprises, Inc./La Union, N. Mex. (M,S)	Prepared, packed, and held under insanitary conditions; contains <i>E. coli</i> and bacterial filth.
Cornhusks/Modesto, Calif. 10/31/77	Eduardo Serrano Valdez/Tijuana, Mexico (S)	Contains insect infestation and mold.
Cottonseed oil/Lincoln, Nebr. 8/16/77	Riverland Oil Co., Inc./Bossier City, La. (M,S)	Prepared under insanitary conditions.
Mung beans, sweet rice, and glutinous rice flour/Kansas City, Mo. 8/18/77	King's Trading, Inc./Kansas City, Mo. (D)	Held under insanitary conditions; rodent contaminated.
Popcorn, yellow/Laredo, Tex. 9/20/77	David M. Slaughter & Son, Inc./Laredo, Tex. (D)	Held under insanitary conditions; contains insects.
Potato flakes/Milwaukee, Wis. 8/17/77	Minit Foods, Inc./Milwaukee, Wis. (D)	Held under insanitary conditions.
Rice/Aguada, P. R. 10/26/77	Irma Hernandez, Inc./Aguada, P.R. (D)	
Rice; breading; corn syrup solids; and powdered dextrose/Union City, Calif. 9/15/77	MJB Co./Union City, Calif. (D)	
Salmon, canned/Seattle, Wash. 10/6 & 14/77	St. Elias Ocean Products/Cordova, Alaska (M,S)	Contains decomposed salmon.
<b>Economic and Labeling Violations</b>		
Dairy powder, chocolate-flavored/Dubuque, Iowa 9/28/77	Consolidated Flavor Corp./Bridgeton, Mo. (M,S)	Chocolate-flavored dairy powder made with cocoa and carob was substituted for chocolate-flavored dairy powder made with cocoa; name of food not followed by words "with other natural flavor"; article is short weight; lacks names of each ingredient, since carob is not declared.
"Flounder" fillets/Monmouth Beach, N.J. 8/3/77	Massachusetts Coastal Seafoods, Inc./Magnolia, Mass. (P,S)	Turbot had been substituted for flounder.
Seabrook, N.J. 8/4/77	"	
Mozzarella cheese, "low moisture"/Rochester, N.Y. 10/5/77	Farmers Cheese Coop. Association/New Wilmington, Pa. (M); Lisanti Foods, Inc./West Paterson, N.J. (S)	Fails standard of identity for low moisture mozzarella cheese.



PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD ADDITIVES</b>		
Buffalo jerky patties/York, Nebr. 10/5/77	Grumpy's Buffalo Jerky Co./York, Nebr. (D); Smokey's Smokehouse/Spanish Fork, Utah (M,S)	Contains unsafe food additives sodium nitrate and sodium nitrite; plant proteins as well as water and monosodium glutamate have been substituted for buffalo meat; and the article lacks common or usual name for a product composed of buffalo meat, water, plant proteins, and other ingredients, all of which were ground and shaped into patties.
Chromium and amino acid combination tablets/Burbank, Calif. 7/12/77	Daly Laboratories, Inc./Burbank, Calif. (D,M)	Contains nonconforming food additives, chromium, and an unidentified amino acid.
Chromium and yeast combination tablets/Concord, Calif. 10/12/77	Natural Formulas, Inc./Hayward, Calif. (M); Seroyal Brands, Inc./Concord, Calif. (P)	Contains nonconforming food additives, chromium, and a yeast chelate.
Ginseng capsules, Korean/Minneapolis, Minn. 8/24/77	Pavo Co., Inc./Minneapolis, Minn. (D,P); Encapsulations, Inc./Newark, N.J. (M,S)	Contains the nonconforming food additive ginseng.
Ginseng powder capsules/South El Monte, Calif. 9/8/77	Pharmacaps, Inc./Elizabeth, N.J. (M,S)	
Lemon flavoring with egg white, Cramores Sweet-Sour Mix/Watertown, N.Y. 8/4/77	A-W Brands, Inc. (Cramore Products, Inc.)/Carteret, N.J. (M,S)	Contains the nonconforming food additive saccharin since the saccharin is not for a valid special dietary purpose.
<b>DRUGS/Human Use</b>		
Cod liver oil and creosote capsules/North Bergen, N.J. 10/6/77	Metro International Distributors, Inc./North Bergen, N.J. (P,D)	Circumstances used for its processing, packing, and holding are not in conformity with current good manufacturing practice.
Chlordiazepoxide HCl & clidinium bromide capsules/Hollywood, Fla. 9/19/77	Premo Pharmaceutical Labs/South Hackensack, N.J. (M,S)	New drug without an effective approved New Drug Application.
Ergonovine maleate/Marietta, Pa. 10/3/77	C. H. Boehringer Sohn/Ingelheim, Germany (M); Henley & Sons, Inc./New York, N.Y. (S)	Quality and purity of article fall below N.F. standards; and label statement "Ergonovine Maleate (U.S.P. XVIII)" is false and misleading since article's quality and purity fall below the standards of that compendium.
Ophthalmic zinc sulfate ophthalmic solution, and 0.5% tetracaine hydrochloride/Fort Worth, Tex. 10/17/77	Alcon Laboratories/Fort Worth, Tex. (D,M)	Ophthalmic solution's quality and purity fall below the official compendium standards; tetracaine hydrochloride is not packaged as prescribed in the official compendium.
<b>DRUGS/Veterinary</b>		
Calphosan calcium glycerophosphate & calcium lactate suspension/Tenafly, N.J. 8/5/77	Torigian Labs/New York, N.Y. (M,S)	Circumstances used for article's manufacture, processing, and packing are not in conformity with current good manufacturing practice; no approval of New Drug Application is in effect with respect to article's use and intended use.
Tranquapet methapyrilene HCl, scopolamine aminoxide, valerian extract & passiflora extract tablets/Cranbury, N.J. 6/24/77	Lambert Kay, Div. of Carter-Wallace/Cranbury, N.J. (M,D)	New animal drug and no New Animal Drug Application is in effect with respect to the use of such drug.
<b>MEDICAL DEVICES</b>		
Electrometer devices, Acuther devices, accessories, and components/Albuquerque, N. Mex. 9/8/77	Brummett Electronics, t/a Acutronics, Ltd./Albuquerque, N. Mex. (D,M)	False and misleading labeling; inadequate directions for use.
Hair removal devices/Dallas, Tex. 10/25/77	Bio 2000, Inc./Irving, Tex. (M); Bea Cranford, Inc./Dallas, Tex. (D)	False and misleading claims about removing unwanted hair, dehydrating the papilla, coagulating the papilla, destroying the root hair, eliminating the hair cell from the skin, breaking down the hair cell, being more effective than electrolysis, removing hair in seconds without tissue damage, and being painless and permanent.
Pillows "therapeutic"/Bethany, Okla. 10/20/77	Mid America Sales & Marketing Inc./Bethany, Okla. (D)	False and misleading claims for prevention of chin and neck wrinkles, for treatment of cardiac cases, and for prickling sensations with fingers; lacks adequate directions for such uses.
Wuf-E-Nuf electric shock collars for dogs/Tucson, Ariz. 7/6/77	Tri-Tronics/Tucson, Ariz. (D,M)	Inadequate directions for use; inadequate warnings against unsafe use; dangerous to health when used as directed.

# Notices of Judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD/Poisonous and Deleterious Substances

#### **Dog food, Iams Plus**, at Riverside, C. Dist. Calif.

Charged 7-21-77: when shipped by Iams Food Co., Dayton, Ohio, the article contained the poisonous and deleterious substance *Salmonella* microorganisms; 402(a)(1). Default decree ordered destruction. (F.D.C. No. 61346; S. No. 77-10-867; N.J. No. 1)

#### **Mahi mahi fillets, frozen**, at Boston, Dist. Mass.

Charged 5-3-77: when shipped by Beaver Street Fisheries, Inc., Jacksonville, Fla., the article, labeled in part "Mahi Mahi Fillet . . . Product of Ecuador . . . Sociedad Nacional De Galapagos . . . Perlita Brand," contained added poisonous and deleterious histamine-like substances which might render the article injurious to health; and contained decomposed fish; 402(a)(1), 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61211; S. No. 77-91-236; N.J. No. 2)

### FOOD/Contamination, Spoilage, Insanitary Handling

#### **Beans, dried, and other warehouse stocks**, at St. Albans, E. Dist. N.Y.

Charged 6-9-77: while held by Economy Restaurant Supply, Inc., St. Albans, N.Y., a number of the articles contained rodent and/or insect filth; and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61264; S. No. 77-14-607 et al.; N.J. No. 3)

#### **Caramel coloring syrups**, at New Orleans, E. Dist. La.

Charged 4-15-77: while held by Thompson Hayward Chemical Co., New Orleans, La., the articles had been held under insanitary conditions whereby they might have been rendered injurious to health, since analysis of dust on the drums of the articles revealed the presence of the pesticide leptophos; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 61186; S. No. 77-38-591; N.J. No. 4)

#### **Coffee beans**, at Knoxville, E. Dist. Tenn.

Charged 12-13-76: while held by JFG Coffee Co., Knoxville, Tenn., the article had been held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61025; S. Nos. 77-32-698, 77-32-700; N.J. No. 5)

#### **Flour**, at Abilene, N. Dist. Tex.

Charged on or about 9-8-76: while held by Independent Grocers, Inc., Abilene, Tex., the article contained insect filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60878; S. No. 77-64-826; N.J. No. 6)

#### **Flour**, at North Little Rock, E. Dist. Ark.

Charged 3-25-77: while held for sale in a railcar, the article contained rodent filth, and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Missouri Pacific Railroad, Little Rock, Ark., for salvaging. (F.D.C. No. 61139; S. No. 77-78-459; N.J. No. 7)

#### **Flour for donuts, Gilt-Edge**, at London, E. Dist. Ky.

Charged 11-5-76: when shipped by Henry Nagel & Son, Cincinnati, Ohio, the article had been prepared and packed under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 60949; S. No. 77-81-914; N.J. No. 8)

#### **Kelp blend seasoning**, at Valley Stream, E. Dist. N.Y.

Charged 6-4-76: while held for sale after packaging by Lan-O-Tone Products, New York, N.Y., the article contained insect and rodent filth and had been packed and held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 60736; S. No. 76-41-305; N.J. No. 9)

#### **Mushroom pieces and stems**, at Hollywood, S. Dist. Fla.

Charged 1-14-77: while held for sale, the article contained decomposed mushrooms and was unfit for food due to an offensive hydrogen sulfide-like odor; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61005; S. No. 77-43-446; N.J. No. 10)

#### **Peanuts, unshelled, W Brand**, at Forest Park, N. Dist. Ga.

Charged 4-29-77: when shipped by Williams Peanut, Inc., Portales, N. Mex., the article contained rodent filth; 402(a)(3). Consent decree authorized release to Portales Valley Mills, Inc., Portales, N. Mex., for conversion into feed stock. (F.D.C. No. 61200; S. No. 77-62-960; N.J. No. 11)

#### **Pepper, allspice, cloves, sage, cassia, and hazel nut kernels**, at Brooklyn, E. Dist. N.Y.

Charged 12-12-75: while held for sale, the hazel nut kernels

contained insect filth, and all of the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decrees authorized destruction of the hazel nut kernels; and authorized the release for salvaging of the pepper, allspice, cloves, sage, and cassia to Malagasy Agencies, Inc., New York, N.Y.; Archibald & Kendall, New York, N.Y.; Internatio, Inc., New York, N.Y.; Overseas Produce Corp., Mamaroneck, N.Y.; and Carter Macy Co., Inc., New York, N.Y., respectively. (F.D.C. No. 60568; S. Nos. 76-40-744/6, 76-40-748/51; N.J. No. 12)

#### **Poppyseed**, at Berkeley, N. Dist. Calif.

Charged 1-6-77: while held by Brothers' Bagel Factory, Berkeley, Calif., the article had been held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61041; S. No. 77-50-301; N.J. No. 13)

#### **Raisins and dried currants**, at Buffalo, W. Dist. N.Y.

Charged 12-15-76: while held for sale after storage by William Simon Brewery Corp., Buffalo, N.Y., the articles contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). The articles were claimed by Federal Bakers Supply Corp., Buffalo, N.Y. Consent decree authorized: release of the articles to the claimant for FDA's reinspection to determine if a reconditioning on December 13-14, 1976, had resulted in compliance; release of those lots of the articles in compliance; and destruction of remaining lots of the articles. Subsequently, a supplemental consent decree was entered in which one lot of fancy, golden seedless raisins were released from the action, and in which shipment of the remaining lots of the articles to California for reconditioning under bond was authorized. (F.D.C. No. 60881; S. No. 77-94-541; N.J. No. 14)

#### **Rice**, at Caguas, Dist. P.R.

Charged 7-15-77: while held by Celestino Perez & Co., Inc., Caguas, P.R., the article was held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 61323; S. No. 77-83-953 et al.; N.J. No. 15)

#### **Rice, pancake mixes, and other warehouse food stocks**, at Denver, Dist. Colo.

Charged 7-22-77: while held by Shetakis Wholesalers of Colorado, Inc., Denver, Colo., some articles contained insect filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61355; S. No. 77-79-625 et al.; N.J. No. 16)

#### **Tomato juice, canned**, at Davenport, S. Dist. Iowa.

Charged 3-25-77: while held for sale, the article was unfit for food due to loose pieces of can liner; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61131; S. No. 77-25-113; N.J. No. 17)

#### **Tomatoes, peeled, canned**, at Albany, N. Dist. N.Y.

Charged 3-8-77: while held for sale, the article contained a decomposed substance, and was unfit for food due to swollen cans, leaking cans, and cans having corroding interiors; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61100; S. Nos. 77-58-715/6; N.J. No. 18)

#### **Wheys and nonfat dry milk**, at New Iberia, W. Dist. La.

Charged 3-24-77: while held by J. J. Meinerz Distributors, New Iberia, La., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61133; S. Nos. 77-78-981/5; N.J. No. 19)

## FOOD/Economic and Labeling Violations

#### **Chocolate-flavored dairy powder, Gold Standard**, at Greenville, Dist. S.C.

Charged 6-13-77: when shipped by Consolidated Flavor Corp., St. Louis, Mo., the article had had a chocolate-flavored dairy powder made with cocoa and carob substituted for chocolate-flavored dairy powder made with cocoa; 402(b)(2). Default decree authorized donation to a charitable institution. (F.D.C. No. 61259; S. Nos. 77-63-086/7; N.J. No. 20)

#### **Macaroni products**, 2 seizure actions, at North Bergen, Dist. N.J.

Charged 1-30-73 (C.A. No. 124-73) and 1-17-77 (C.A. No. 77-108): when the articles in the earlier action (C.A. No. 124-73) were shipped by Florence Macaroni Manufacturing Co., Inc., Los Angeles, Calif., the articles, labeled in part "Balanced . . . Artichoke Spaghettini [or "Artichoke Ribbons"] . . . Packed for Balanced Foods, Inc., Dist. . . No. Bergen, N.J.," and "Old Stone Mill . . . Soya Long Spaghetti [or "Whole Wheat Cut Macaroni," "Soya Macaroni," "Soya Ribbons," or "Sea Shells"] . . . Packed for Balanced Foods, Inc., . . . N. Bergen, N.J.," had



been prepared, packed, and held under insanitary conditions—402(a)(4); some of such articles bore the statements “No coloring no preservative” and “no coloring or preservatives used [or “added”]” which were misleading in suggesting that macaroni products generally contained added coloring and preservatives, when added coloring and preservatives were not permitted by the definition and standard of identity for macaroni products—403(a); some of such articles, purported to be “wheat and soya macaroni products,” failed to bear the required name “Wheat and Soya Macaroni Product”; some of the articles were represented as foods for special dietary use for regulating the intake of salt, and their labels failed to bear the number of milligrams of sodium in 100 grams of the food and the number of milligrams of sodium in an average serving—403(j).

While the sesame, small elbow macaroni of the subsequent action (C.A. No. 77-108) was held for sale, the article, labeled in part “Old Stone Mill . . . Sesame Small Elbows A Macaroni Product Made with Hygluten Flour . . . Packed for Balanced Foods, Inc., N. Bergen, N.J.,” bore the label statements “Sodium . . . 0.148%” and “50 Mg of Sodium to 100 grams of Product,” which contradicted one another—403(a); the article’s labeling was also misleading because of nutritional claims and information other than sodium content, while failing to reveal the required list of all nutrients contained in the article—403(a); the article’s labeling was further misleading due to the designation of the food (containing more than two ingredients) by a name which included and suggested the name of one rather than all such ingredients—403(a); the article failed to meet the definition and standard of identity for macaroni products, since it contained sesame flour, which was not prescribed by regulation—403(g)(1); the article’s label lacked the common or usual name of each ingredient, since “hygluten flour” and “germ” were not common or usual names of ingredients and since the ingredient, water, was not declared—403(i)(2); and, in the declaration of percent sodium, the article was represented as a food for special dietary use for regulating the intake of sodium, and the label lacked required information, since it failed to bear a statement of the number of milligrams of sodium in a specified serving—403(j).

A default decree ordered the sesame, small elbow macaroni (C.A. No. 77-108) destroyed. In the earlier action (C.A. No. 124-73), the articles were claimed by Balanced Foods, Inc., North Bergen, N.J. The parties discussed revised labels for the articles. Subsequently, a consent decree of condemnation authorized release of the articles for conversion into animal feed. Meanwhile, however, those articles had been destroyed. (F.D.C. Nos. 58821, 61097; S. Nos. 48-143/50 F, 77-87-496; N.J. No. 21)

#### **Mixed nuts, at Grand Rapids, W. Dist. Mich.**

Charged 1-26-77: while held for sale after packaging by B&S Produce Co., Inc., Detroit, Mich., the article was short weight (approximately 10.88 percent)—403(e)(2); the bag label lacked the common or usual name of the food—403(i)(1); the label lacked the common or usual name of each ingredient—403(i)(2); and the article was also in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement was expressed as “3 LBS. (48 OZ.)” instead of “Net Wt. 48 Oz. (3 Lbs.),” and the quantity of contents statement appearing on the principal display panel area of more than 100 square inches was in a type size less than 1/4 inch high—15 U.S.C. 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 61095; S. No. 77-68-473; N.J. No. 22)

#### **Pepperoncini, pickled, at Northboro, Dist. Mass.**

Charged 6-7-77: while held for sale after packaging by Gloria Packing Corp., Boston, Mass., the article was short in volume; 403(e)(2). Consent decree authorized release to packager for bringing into compliance. (F.D.C. No. 61226; S. No. 77-71-941; N.J. No. 23)

### **FOOD ADDITIVES**

#### **Chromium & amino acid combination tablets, at Burbank, C. Dist. Calif.**

Charged 6-22-77: while held by Daly Laboratories, Inc., Burbank, Calif., who manufactured the article using chromium nitrate powder shipped in interstate commerce, the article, labeled in part “Daly Laboratories, Inc., . . . Chelated Chromium,” contained the nonconforming food additive chromium, for which there was no regulation prescribing conditions for safe use, and contained the nonconforming food additive, unidentified amino acid, whose use and intended use did not improve the biological quality of food; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61298; S. No. 77-12-566; N.J. No. 24)

#### **Lemon flavoring with egg white, Cramores Crystals, at Watertown, N. Dist. N.Y.**

Charged 6-8-77: [when shipped by Cramore Products, Inc., (A. W.

Brands, Inc.), Carteret, N.J., and] while held for sale, the article contained the nonconforming food additive saccharin, since the article was not for a valid special dietary use; 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61253; S. No. 77-82-468; N.J. No. 25)

### **DRUGS/Human Use**

#### **Digitoxin tablets, U.S.P., at Valley Stream, E. Dist. N.Y.**

Charged 9-24-76: when shipped by Marshall Pharmacal Corp., South Hackensack, N.J., the strength and quality of the article differed from U.S.P. standards, since the article contained less than 90 percent of the labeled amount of digitoxin and failed the tablet content uniformity requirements; 501(b). Default decree ordered destruction. (F.D.C. No. 60917; S. No. 77-42-520; N.J. No. 26)

#### **Ephedrine tablets, unlabeled, at Denver, Dist. Colo.**

Charged 7-14-77: while held for sale, the article’s label lacked the name and place of business of the manufacturer, packer, or distributor, lacked a quantity of contents statement, and lacked the established name of the drug; and the article’s labeling lacked adequate directions for use; 502(b)(1), 502(b)(2), 502(f)(1), 502(e)(1)(A)(i). Default decree ordered destruction. (F.D.C. No. 61341; S. Nos. 77-79-318/9; N.J. No. 27)

#### **Uninatal sodium fluoride and folic acid combination tablets, at Springfield, W. Dist. Mo.**

Charged 4-26-77: while held for sale after manufacture by Alpha Pharmacal Co., St. Louis, Mo., using interstate folic acid, the circumstances used for the manufacture and processing of the article failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61156; S. No. 77-84-830; N.J. No. 28)

#### **Various finished drugs, in-process drugs, and drug components, at Minneapolis, Dist. Minn.**

Charged 7-6-76: while held by Universal Drug Co., Inc., Minneapolis, Minn., the circumstances used for the manufacture, processing, packing, and holding of the articles failed to conform with current good manufacturing practice; 501(a)(2)(B). Consent decree authorized release to manufacturer for bringing into compliance with the law. (F.D.C. No. 60788; S. No. 76-30-765; N.J. No. 29)

### **DRUGS/Veterinary**

#### **Pet-Tabs Gee diethylstilbestrol and vitamin-mineral supplement tablets, at Northport, E. Dist. N.Y.**

Charged 3-24-77: when shipped by Beecham Laboratories, Div. of Beecham, Inc., Piscataway, N.J., the article was a new animal drug and no approval of a New Animal Drug Application was in effect with respect to the article’s use and intended use; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61116; S. No. 77-15-145; N.J. No. 30)

#### **NF-180 Concentrate furazolidone premixes, at Modesto, E. Dist. Calif.**

Charged 6-21-77 and amended 7-8-77: when shipped by Rhodia, Inc., Hess & Clark Div., Ashland, Ohio, the articles were nonconforming new animal drugs, since they contained furazolidone from a source which had not been approved in their New Animal Drug Applications; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61285; S. Nos. 77-75-726/7; N.J. No. 31)

### **MEDICAL DEVICES**

#### **Acu-Aid Ion steel spheres affixed to adhesive patches, at Van Nuys, C. Dist. Calif.**

Charged 4-9-76: when shipped by Tama Enterprises, Inc., Tokyo, Japan, and while held by IonLab, Inc., Van Nuys, Calif., the shipper’s and dealer’s accompanying labeling contained false and misleading claims for “pain ailments,” “specific ailments,” stiff shoulders, stiff shoulders due to tonsillitis, coughing, stiff chest, slight cold, headache, stiff occipital region, dizziness, insomnia, toothache, low back pain, knee joint pain, allergies, immediate relief from muscular pain, contusion, sprain, and inflammation of joint and tendons; and the labeling lacked adequate directions for use for the article’s intended purposes; 502(a), 502(f)(1). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 60687; S. No. 76-26-840; N.J. No. 32)

#### **Diapulse electromagnetic energy generator, at Kernersville, M. Dist. N.C.**

Charged 9-9-77: the labeling of the article (which had been manufactured by Diapulse Corp. of America, New York, N.Y.) failed to bear adequate directions for use, since adequate directions for use by laymen could not be written, and the article was not exempted therefrom, since adequate information for use by licensed





practitioners could not be furnished; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61409; S. No. 77-62-337; N.J. No. 33)

**Replacement spheres of medical oxygen, Vital Air, at Cambridge, Dist. Mass.**

Charged 8-4-77; the article (which had been shipped by Vital Air Oxygen Co., Cleveland, Ohio) was a device, and its label lacked an accurate quantity of contents statement in terms of measure of oxygen; the labeling lacked adequate directions for its intended purposes; and the article was dangerous to health when used as directed, since it was intended for emergency use and failed to maintain a sufficient supply of oxygen for emergency medical purposes for the period of time claimed in its labeling; 502(b)(2), 502(f)(1), 502(j). Default decree ordered destruction. (F.D.C. No. 61297; S. No. 77-91-607; N.J. No. 34)

**Vibrator & heating pad cushions and components, at Fort Worth, N. Dist. Tex.**

Charged 4-22-77: the completed cushions (which were labeled in part "Arthritis—Massager Co. [some devices with label partially blocked out] . . . 'All-Purpose Massagers' . . . Ft. Worth Tex."), and the other articles were accompanied by labeling, prepared by the dealer Ed I. Carruth (All Purpose Massager Co.), Fort Worth, Tex., that contained false and misleading claims as follows: for relief of pain associated with spurs on the spine, dislocated disks, and arthritis; for traffic accident-caused pain in the limbs and everywhere in the body, arthritis-like pains of the body and limbs when they occur, shoulder and spine pain, and wheelchair arthritic pains; that the devices will return semi-invalids to work in days or weeks; that the motor-driven vibrator is an ultrahigh frequency medical device; that the device can massage completely from end to end and side to side at one time, doing all the body; and that the devices will tighten teeth; 502(a). Consent decree authorized release to dealer for bringing into compliance. The claimant, however, was unable to post the required bond, and the articles were ordered destroyed. (F.D.C. No. 61080; S. No. 77-15-102; N.J. No. 35)

**NOTICES OF JUDGMENT on Criminal Actions  
FOOD**

**B. C. Tanner & Son Pecan Co., Inc., and Bergia C. Tanner, Jr.,** president, Mobile, S. Dist. Ala.  
Charged on or about 2-25-77 by grand jury: when shipped, Shamrock Brand fancy shelled pecans contained *E. coli* and had been prepared and packed under insanitary conditions; 402(a)(3), 402(a)(4). Guilty pleas; fines. (F.D.C. No. 60905; S. Nos. 76-00-470, 76-18-250; N.J. No. 36)

**Sea Frost Fish Co., Inc., and Morris M. Entis,** president, Boston, Dist. Mass.

Charged 4-29-77: when shipped, swordfish portions contained the added poisonous or deleterious substance mercury; 402(a)(1). The individuals moved to suppress all statements made by them on the grounds that no Miranda warning had been given. The defendants also moved for a written bill of particulars, moved to dismiss because of delay in the filing of the criminal information, and made a number of other motions. There was a hearing. After the hearing, the court took the following action on some of the pretrial motions:

"1. **MOTION TO INSPECT EVIDENCE:** Upon representation of counsel for the defendant that he intends to comply with the provisions of Rule 16(b)(1)(A), F. R. Crim. P., motion allowed.

"2. **MOTION FOR EXCULPATORY EVIDENCE:** Motion allowed, except to the extent that *pre-trial* disclosure would be inconsistent with the provisions of the Jencks Act, 18 U.S.C. 3500.

"3. **MOTION FOR STATEMENTS:** Motion denied.

"4. **MOTION TO PRODUCE STATEMENTS OF THE DEFENDANTS:** Motion allowed to the extent required by Rule 16(a)(1)(A), F. R. Crim. P.

"5. **MOTION FOR DISCOVERY OF RECORDS RELATING TO INTERCEPTED COMMUNICATIONS:** Upon the representation of the government that there are no interceptions, no further action is warranted.

"6. **MOTION TO BE FURNISHED WITH TAPE RECORDINGS:** Upon the representation of the government that there are no tape recordings, no further action is warranted.

"7. **MOTION TO MAKE SAMPLES AVAILABLE FOR TESTING:** Motion allowed.

"8. **MOTION FOR DESCRIPTION OF TESTING PROCEDURE:** Motion allowed.

"9. **MOTION TO INSPECT STATEMENTS OF PROSECUTION WITNESSES:** Motion denied.

"10. **MOTION FOR NAMES AND REPORTS OF EXPERT WITNESSES:** Motion allowed.

"11. **MOTION FOR LIST OF PROSPECTIVE WITNESSES:**

Motion denied.

"12. **MOTION TO COMPEL PRODUCTION:** Motion denied.

"13. **MOTION FOR BILL OF PARTICULARS:** The motion is allowed as to Requests Nos. 3 [date and time of day of alleged offense], 4 [precise place], and 16 [exact quantity of swordfish].

"With respect to Requests Nos. 7 [exact description of adulterated substance], and 8 [exact description of mercury], the motion is allowed, provided, however, that the government may, in lieu of a bill of particulars, provide such information by way of documents and/or laboratory reports.

"With respect to Requests Nos. 9 and 10 [concerning how mercury is poisonous and deleterious and renders swordfish injurious to health], the motion is allowed to the following extent: The government shall state in what manner it contends that the presence of mercury in swordfish is so poisonous or deleterious that it may render said swordfish injurious to health.

"With respect to Requests Nos. 11, 12, and 13 [concerning regulations relied upon by the government], the government having represented that it will provide such information by way of discovery, those requests are denied.

"With respect to Request No. 18 [concerning kinds of mercury in the swordfish], the government shall state the kinds of mercury—if there be more than one kind—which the government intends to prove were present in the swordfish alleged to have been adulterated.

"In all other respects, the motion for a bill of particulars is denied."

Thereafter, prior to trial, the Government moved for dismissal of the action on the grounds that further prosecution would not be in the interest of justice. Upon such motion, the court dismissed the action. The defendants subsequently requested that the record show that the dismissal was without the consent of the defendants. (F.D.C. No. 62021; S. No. 76-06-981 et al.; N.J. No. 37)

**NOTICES OF JUDGMENT on Injunction Actions**

**Hathaway Allied Products, and Maynard C. Hathaway, Jr.,** president, **James R. Moss,** vice president & general manager, and **Bill Nagy,** plant manager, Harbor City, C. Dist. Calif.

Charged 11-20-75 in a complaint for injunction: that the defendants were engaged at their plant at Harbor City, Calif., in preparing, packing, and holding for sale after interstate shipment and in distributing in interstate commerce, herbs for food and drug use, such as thyme, peppermint leaves, poppyseeds, sweet basil, and red clover tops, and drugs such as burdock root and mullein leaves; which foods and drugs contained insect filth and were prepared, packed, and held under insanitary conditions; that FDA inspections had disclosed a number of specified, continuing, insanitary conditions and practices; that FDA investigators sampled poppyseed, agrimony herb, and mullein leaves which had been repacked and shipped in interstate commerce by the defendants, and FDA analyses revealed that they contained insect filth; that by shipping such articles of food and drug and by preparing, packing, and holding them in their plant, the defendants were violating the law; and that the defendants had been repeatedly warned concerning the insanitary conditions and practices; 402(a)(3), 402(a)(4), 501(a)(1), 501(a)(2)(A).

The defendants entered into a consent decree of permanent injunction which enjoined the complained of violations, and enjoined the preparation, packing, and interstate distributions of any food or drug unless and until: the plant's methods, facilities, and controls were such as to assure that foods and drugs would not be adulterated, and all foods and drugs of plant origin subject to insect infestation (as illustrated in an attached list of 185 products which were prepared, packed, and held by the defendants) were examined for filth and were destroyed or otherwise brought into compliance. (Inj. No. 717; S. No. 76-27-395 et al.; N.J. No. 38)

**Officials having duties & responsibilities in connection with Clifton Terrace Treatment Center** (sued in their official capacities: Dept. of Human Resources Director Joseph P. Yeldell; Acting Narcotics Treatment Administration Administrator Fred R. West, M.D.; and Acting Chief of Clinic Operations Division Joseph P. Savoy); Washington, Dist. Columbia.

Charged 5-5-76 in complaint for injunction: that the Narcotics Treatment Administration was a component of the Department of Human Resources of the government of the District of Columbia whose mission was to assist drug-dependent residents of the District of Columbia in becoming drug free by providing adequate treatment, education, and supportive services; that the Clifton Terrace Treatment Center, Narcotics Treatment Administration Center #28, was an approved "methadone treatment program" in Washington, D.C.; that the defendants were operating under an interim approval to receive shipments of the new drug methadone



for the treatment of narcotic dependence; that FDA inspections revealed a number of specified significant deviations from the conditions for use of methadone prescribed by regulation; that the defendants were in violation of the law in causing the Vitarine Co., Inc., Springfield Gardens, N.Y., to ship methadone hydrochloride in interstate commerce in violation of the new drug provisions of the law (21 U.S.C. 355(a)), because the drug was not used in accordance with the conditions prescribed for use of methadone and because of their failure to establish and maintain proper records; and that the defendants were well aware that their activities were in violation of the law; 505(a).

In their answer to the complaint, the defendants denied that the court necessarily had jurisdiction, denied that the FDA inspections had revealed "significant" deviations from the prescribed conditions for use of methadone, and denied that the defendants failed to take corrective action in major areas. The defendants stated that they had continuously made good faith efforts to comply with all Federal statutes and regulations governing the operation of the D.C. Narcotics Treatment Administration Program; that the program at the Clifton Terrace Clinic was then in compliance with all applicable Federal statutes and regulations; that any past deviations from the letter of FDA regulations were not significant; that an injunction was not in the public interest, not required by law, and not necessary to accomplish compliance; and that, compliance having been achieved through the good faith efforts of the defendants, there was no reason to believe that the defendants would not continue to be in compliance. The Government moved for a temporary restraining order; but, after a brief hearing, the court denied such motion. The Federal Government moved for a preliminary injunction; and a combined hearing on a preliminary injunction, as well as on a permanent injunction, was held.

After the hearing, the court found that the record established that injunctive relief was appropriate because "there exists some cognizable danger of recurrent violations" of 21 U.S.C. 331(e) and 21 CFR 310.505, *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953), and that an injunction pursuant to 21 U.S.C. 332(a) was necessary to prevent the continued violation of Federal law and was in the public interest. (Inj. No. 722; S. No. 76-03-590; N.J. No. 39)

#### NOTICE OF JUDGMENT on Miscellaneous Action

##### Cardiovascular hazard warning, and access to University Group Diabetes Program's underlying data, Ardsley, S. Dist. N.Y.

Charged 10-14-75 by CIBA-GEIGY Corp., Ardsley, N.Y., against HEW Secretary David Mathews, the Dept. of Health, Education, & Welfare, the National Institutes of Health, FDA Commissioner Alexander M. Schmidt, the Food & Drug Administration, University Group Diabetes Program Coordinator Christian Klimt, and the University of Maryland, in complaint for production of data for inspection and copying: that plaintiff manufactured and sold phenformin (DBI and DBI-TD), an oral hypoglycemic drug used to lower the blood glucose level in patients with maturity-onset diabetes mellitus, that plaintiff's sales of phenformin were over \$24 million in 1974; that oral hypoglycemic drugs were widely prescribed and preferred by many physicians for selected patients because they are ingested orally and as such are easier for the patient to accept than other more discomforting and inconvenient forms of treatment; that the University Group Diabetes Program (UGDP) conducted a study in 12 university medical clinics throughout the United States in order to evaluate the efficacy of various hypoglycemic treatments in the prevention of vascular complications in patients with mild diabetes; that data from each clinic was sent to the UGDP Coordinating Center at the University of Maryland where the data was collected and recorded; that, pursuant to FDA regulations under which UGDP filed with FDA a New Drug for Investigational Use Notice, UGDP expressly agreed to have records maintained by UGDP investigators subject to inspection and copying "upon the request of a scientifically trained and properly authorized employee of the Department"; that the records, subject to copying and inspection at any time by FDA, constituted "agency records" within the meaning of the Freedom of Information Act; that FDA proposed a regulation that the labeling of oral hypoglycemic drugs contain a warning of associated cardiovascular hazard; that proposed labeling would warn that oral hypoglycemic drugs should only be used in the treatment of patients with maturity-onset nonketotic diabetes whose symptoms or glucose elevation could not be controlled by diet alone and in whom insulin could not be used because of such hazard; that the proposed warning was based on the published results of the UGDP study which reported results suggesting that maturity-onset diabetic patients treated with oral hypoglycemic drugs experienced a greater

incidence of deaths due to cardiovascular causes than those patients treated with insulin or diet alone; that, of the numerous long term, prospective controlled studies, UGDP was the only study which reported such conclusions; that the UGDP study had been widely criticized; that the defendant had consistently failed to make the data available to the plaintiff or other interested parties; that two investigators had resigned from the UGDP study due to their doubts as to the reliability of data handling at the UGDP Coordinating Center in Maryland; that plaintiff had formally requested production and the right to inspect the UGDP basic data; that continued denial of access to the basic data of the UGDP study (past the date on which the regulation would be finalized) would irreparably injure the plaintiff; and that the plaintiff had no adequate remedy at law.

The Government moved to dismiss, or, in the alternative, for summary judgment. The research defendants also moved to dismiss the complaint and to quash the service of process. In denying the plaintiff's motion, in denying the research defendants' motion as moot, and in granting the Federal defendants' motions (to the extent set forth in the court's memorandum), the court said:

"An explanation of the underlying factual circumstances is necessary. In mid-1959 scientists at various university medical research clinics throughout the United States conceived a study which had as one of its objectives the evaluation of the efficacy of various hypoglycemic treatments in the prevention of vascular complications in patients with mild diabetes. To finance their research, these private parties applied for federal grants from the National Institute of Arthritis, Metabolism and Digestive Diseases ('NIAMDD'), one of the institutes of NIH. Grants were awarded to six university clinics in addition to the coordinating center at the University of Maryland, where Dr. Klimt was the principal investigator. Each submitted a separate grant application. Subsequently, six additional universities became involved in the study, and each also received an individual grant. The clinics involved in the UGDP study began their research in 1961. Test results from each medical clinic were sent to the UGDP coordinating center where all the data was collected and recorded. . . .

"The study focused on the relationship between the control of blood sugar in patients suffering from maturity-onset diabetes and the development of complications from that disease. Defendants contend that the UGDP's goal was a general expansion of knowledge and not the testing of a hypothesis that one form of treatment caused greater cardiovascular complications than another, and that the UGDP did not have a particular regulatory impact in mind. . . . It appears that the raw data assembled from the study consists of millions of documents involving over 1,000 patients examined since the study commenced in 1961. . . .

"The terms of the grant applications provided that the 'raw data generated by the UGDP study at the 12 clinics are the property of the individual investigators and the coordinating center.' . . . Although NIH has access to the raw data generated by funded projects under 45 C.F.R. § 74.23, it customarily relies solely upon the interim and final reports which must be submitted to it. . . .

"The FDA was not initially involved in the UGDP study. However, when the UGDP reported results indicating a significantly higher mortality apparently due to cardiovascular causes for patients being treated with oral hypoglycemic drugs, and in 1967 voluntarily submitted these findings in report form to the FDA, the FDA decided to become involved. In 1970, the FDA convened an ad hoc expert committee to consider the UGDP findings and their possible regulatory significance. It reviewed the results of the UGDP study and in addition obtained the opinions of other experts in the fields of diabetes treatment and pharmacology as well as the assessment of the Biometrics Society, an organization of biostatisticians independently retained by the FDA to review the UGDP study. On these bases, the FDA concluded that a warning in the labeling of oral hypoglycemic drugs was necessary to inform physicians of the ostensibly increased risk of cardiovascular complications arising from treatment with such drugs as compared to treatment with diet alone or diet plus insulin. . . .

"In July 1975 the FDA proposed revised labeling requirements and at the same time solicited comments from interested persons. An announcement was printed in the FEDERAL REGISTER that an informal public hearing would be held to receive additional data and information on the proposed labeling requirement. . . .

"Plaintiff challenges the manner in which the UGDP raw data was handled the UGDP coordinating center and consequently questions the accuracy of the results reported. Accordingly plaintiff instituted this action pursuant to the FOIA [Freedom of Information Act] to obtain access to the data underlying the UGDP reports, claiming that such data constitutes agency records within the purview of the Administrative Procedure Act. . . . Plaintiff con-



tends that the UGDP is de facto a federal agency and that its records are therefore agency records. Plaintiff further contends that even if the UGDP is not a federal agency in itself, it nevertheless served as an extension of a federal agency. Plaintiff also justifies its action against the University of Maryland on the theory that the university, acting as the UGDP coordinating center, maintains custody of the above mentioned Government records. All defendants refute that the UGDP is a federal agency and that its underlying records are Government or agency records.

"The FOIA grants a district court jurisdiction to 'enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.' 5 U.S.C. § 552(a)(4)(B). The Act is directed at Government agencies and enables the court to compel an agency to release its records. *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971) ('*Soucie*'). If the UGDP is such an agency, then it is obligated to release any non-exempt records requested by plaintiff. If the UGDP is not a federal agency, plaintiff contends that disclosure of its records may still be compelled if those records can be characterized as Government agency records. *Cf. Nichols v. United States*, 325 F. Supp. 130, 137 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir. 1972), *cert. denied*, 409 U.S. 966 (1972) ('*Nichols*'). If the Court neither finds that the UGDP is a Government agency nor accepts plaintiff's construction of the UGDP records as Government agency records, then it is without power to grant plaintiff's request under the FOIA for relief in this action.

#### The UGDP is Not an 'Agency'

"Courts analyzing the 'agency' status of various organizational entities under the FOIA have not applied a precise standard but have adopted a functional analysis, examining numerous factors including whether the organization has the authority in law to perform the decision-making functions of a federal agency and whether its organizational structure and daily operations are subject to substantial federal control.

"In *Soucie*, *supra*, the United States Court of Appeals for the District of Columbia Circuit examined a congressionally created executive office which, in addition to advising the President, performed the legislatively delegated investigatory function of 'evaluating federal programs.' . . . Unlike the entity in *Soucie*, the UGDP has no independent authority to perform specific Governmental functions.

"In *Washington Research Project, Inc., v. HEW*, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975) ('*Washington Research*'), the court considered the nature of outside private consultants appointed by the National Institute for Mental Health ('NIMH'), a subdivision of HEW, to independently review applications for NIMH grants. The consultants did extensive evaluations and reported their findings and recommendations to the federal agency. . . . Only if the agency automatically adopts the organization's decision as its own can it be considered a functional equivalent of the agency and achieve for itself the status of a federal agency under the FOIA. . . . Like the review group of *cc. Itants* in *Washington Research*, the UGDP researchers and the coordinating center in this case have no independent legal authority to make decisions for the FDA or HEW.

"In *Rocap v. Indiek*, 539 F.2d 174 (D.C. Cir. 1976), the court considered whether the Federal Home Loan Mortgage Corporation ('FHLMC') would be deemed an agency for purposes of the FOIA. . . . Plaintiff argued that the FHLMC was a 'government controlled corporation,' subject to the reporting and disclosure requirements of the FOIA. The court reiterated its earlier theme that there was no one determinative characteristic. It observed that the corporation was 'subject to . . . substantial federal control over its day-to-day operations,' . . . and concluded that it was an agency. . . . Unlike the FHLMC, the UGDP project was privately conceived and organized, and its regular operations were not subject to substantial federal supervision.

"Finally, in *Wolfe v. Weinberger*, 403 F. Supp. 238 (D.D.C. 1975) ('*Wolfe*'), the district court was called upon to determine whether transcripts of an FDA advisory review panel, turned over to HEW, had to be released to the public under the FOIA. The defendants contended that the transcripts fell within exemption five of the Act, 5 U.S.C. § 552(b)(5), which protects 'inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency.' The court first considered whether the panel constituted an agency within the Act, and then examined its role in relation to general FDA regulatory functions. FDA panels are commonly appointed to receive and evaluate information, and to solicit submissions of the views of all interested parties. Private discussions about the information are recorded in transcripts. The panel then submits its conclusions and recommendations to the Commis-

sioner of the FDA, who reviews the report and formulates proposed regulations, sometimes merely adopting the report *in toto*. . . . The court recognized that the panel in this case performed a crucial role in the decisionmaking process but nevertheless concluded that it was not an agency since it was authorized only to make recommendations and not decisions. Since the ultimate decisionmaking authority lay with the FDA, the degree of scrutiny given the report was held irrelevant to determining whether the panel served as an agency. . . . Like the panel in *Wolfe*, the UGDP is empowered only to make recommendations. . . .

"This court finds that the degree of Government involvement and control in the operations of the UGDP was insufficient as a matter of law to hold that the UGDP constituted an agency for purposes of the FOIA. The university researchers were private parties and individual recipients of NIH grants. Although publicly funded, their coordinated project originated privately as a scientific venture and did not perform a regular federal function, such as that delegated by Congress to an administrative agency. It was subject to federal audit but not to federal supervision of its daily operations. It voluntarily presented its conclusions and findings to the FDA but had no 'authority in law' to make the decisions for the agency. In other words, the UGDP did not substitute in form or in authority for an administrative agency.

#### The Underlying Data of the UGDP Study Does Not Constitute 'Agency Records'

"Plaintiff contends that even if the UGDP is not an agent its records and compilation of data are tantamount to agency records subject to disclosure since the UGDP served as an extension of a Government agency. In support of this contention plaintiff focuses on three attributes of the UGDP study which allegedly vest it with federal Governmental character—federal funding of the research, federal access to its data and federal reliance upon its results. Since the UGDP study was funded by an arm of NIH, which is itself a division of HEW, plaintiff posits a principle that 'ownership of work performed at Government expense lies with the Government,' and therefore that all papers and materials relating to the federally financed research project should be deemed agency records. . . . Plaintiff further contends that because HEW, NIH and the FDA have access to the data by virtue of HEW regulations, the data is under the control of those agencies. . . . Finally, plaintiff urges that since the FDA relied upon the UGDP reports in proposing labeling regulations, it necessarily relied upon the data underlying the reports and therefore that such data constitutes records of the FDA. . . .

"There is little official authority to aid the Court in discerning whether documents are agency records. . . . The statutory scheme does not define the essential attributes of agency records, but merely enumerates examples of the type of information to be made available to the public. These include, *inter alia*, descriptions of agency organization and procedure, substantive policy statements, final opinions and orders along with official agency interpretations. . . .

"In this context it is helpful to remember that purposes and policies sought to be effectuated by the FOIA. Congress intended the FOIA to provide public access to information dealing with the structure, operation and decisionmaking functions of Government agencies and to prevent these agencies from cloaking their actions in secrecy. Implicitly, the FOIA's purpose of disclosing Government agency records reaches only those records which are owned or controlled by the Government agency and thus used in the performance of its public business.

"In evaluating whether these records are agency records, this Court holds that the goals and purposes of the Act would be served best by imposing a standard which calls for proof that the records were either Government-owned or subject to substantial Government control or use. In other words, it must appear that there was significant Government involvement with the records themselves in order to deem them agency records.

"Absent the guidance of direct legislative or judicial authority, the Court will focus its evaluation of Government involvement with the UGDP data on the elements noted by plaintiff. Plaintiff suggests that the existence of Government funding, access and reliance is strongly indicative of the federal character of the data. To the extent that these factors are present in this case, they are insufficient to meet this Court's standard of substantial Government control, use or involvement with the UGDP records.

"The UGDP research project was funded by a grant from NIH's NIAMDD, which operates under congressional authority to support private research efforts as well as to conduct its own research in specific fields. . . . Despite the existence of federal funding, the Court finds that the UGDP was not doing the research of NIH in this instance, but, as a recipient of statutory grants from NIH, was





conducting its own private scientific studies. . . .

"Nor will the amount of federal funding of a research project determine the character of the work produced. In *Lombardo v. Handler*, . . . 397 F. Supp. 792, the court held that substantial federal funding failed to make the National Academy of Sciences ('Academy') subject to the strictures of the FOIA. The Academy, a congressionally created entity, was in regular receipt of federal appropriations. It generally served to compile information with respect to scientific studies conducted pursuant to contracts with federal agencies. The court concluded that the Academy, despite its numerous federal connections and large amounts of federal appropriations, was not 'controlled' by the Government and that its information-gathering research was 'not comparable to the assembling and maintenance of information as an adjunct to performing specific governmental (administrative) functions. Upon transmittal to the agency for which an investigation or study is conducted the reports of the Academy are available under the provisions of the F.O.I.A. . . . The strength of the F.O.I.A. is the concept of public accountability for the operation of federal agencies. It was not intended to be applied directly to private entities which merely contract with the government to conduct studies.' . . .

"This Court agrees that federal funding, regardless of amount, is not sufficient to vest the underlying raw data of the UGDP research with a public character. To hold otherwise at a time when public monies flow to numerous private endeavors would surely have a chilling effect on independent efforts at research and development by all but those institutions able to survive without Government support.

"The second and third factors raised by plaintiff—Government access to and reliance upon information—likewise will not signify Government ownership or control of such information. The Court is convinced that the data in question was intended to be and is essentially *private* material. Although the federal defendants have access to the underlying data, there is no evidence that they have used it to exercise regular dominion and control over the raw data. The documentation has remained primarily in the custody of the UGDP group and its coordinating center, and although it was transmitted temporarily to the Government for limited auditing purposes, ownership and control were not conveyed along with it.

"Mere access without ownership and mere reliance without control will not suffice to convert the UGDP data into agency data. Here, the FDA, as a Government agency, referred to reports submitted by the UGDP grantees. It maintained, studied and directly utilized those reports and not their underlying documentation. Just as the Government cannot be compelled to obtain possession of documents not under its control or furnish an opinion when none is written, . . . it should not be compelled to acquire data it neither referred to directly nor relied upon in making decisions. Hence, this Court agrees with the opinion in *Nichols*, *supra*, that 'the Court may not require production of records not in the custody or control of an agency.' . . .

"The difference between the FDA's control and use of final reports and its alleged dependence upon underlying documentation may seem slight, but it is a valid distinction in this Court's opinion. First, the Government neither obtained nor needed significant authority over the underlying raw data since it had no plans to conduct its own independent scientific assessment. The data was compiled and assembled according to the methodology of the private research grantees. The FDA neither controlled this aspect of the study nor became officially aware of, its work until 1967. . . . In short, the FDA, which considered the results of the UGDP research, exerted no control or impact on the conduct of that research.

"It has been held that 'any report prepared by the agency or its consultants in fulfillment of that [agency's] function must be regarded as a record of the agency.' *Soucie*, *supra*, 448 F.2d at 1076. This holding was relied upon in *Wolfe*, *supra*, in which the district court ruled that transcripts of a private advisory committee meeting submitted to the FDA along with the committee's report should be disclosed as agency records. Although the transcripts did not constitute a final report, they were in the possession of the agency and used in its deliberations, thereby qualifying as an agency record.

"In the instant case, the underlying data from the UGDP research has not been officially surrendered to the FDA, and although the FDA may have access, it does not own the documents. Whether or not the FDA obtained possession of the documents at some particular point in time, it is clear that the FDA did not receive them permanently. This Court cannot rule that mere possession at a particular point in time transforms the nature of the documents. Insofar as *Wolfe* interprets the *Soucie* opinion to the contrary, this Court must disagree. In *Soucie* the court merely held that a report expressly *prepared for* and finally *submitted to* an agency for use in decisionmaking should be disclosed as an agency record within the FOIA.

"The proprietary interest of the agency in such a report, as in the *Wolfe* transcripts submitted to the agency for the purpose of aiding its deliberations, is clearly distinguishable from the data in question here which is permanently held by private parties and not directly utilized in agency decisionmaking.

"The Court finds that the FDA, in formulating proposed regulations, did not rely directly upon the raw data of the UGDP research. The principle is now established that documents directly relied upon or memoranda expressly adopted by an agency in its rule making proceedings must be available for public inspection even if the materials in question were prepared by non-agencies. . . . Given this rule, it is obvious that by this lawsuit compelling the FDA to include as part of its administrative record the UGDP raw data, plaintiff hopes to improve its efficacy as a participant in the rulemaking proceedings. However, since the Court has not found that the documents were used or relied upon in a direct manner such as would permit their characterization as agency records, there is no basis for requiring the FDA to obtain and disclose the underlying UGDP data as part of its administrative record. The distinction between direct reliance, in whole or in part, upon a summary report, and direct reliance (via usage or control) on supporting documentation is necessary to preserve a salutary balance between the public's right to be informed of the grounds for Government decisionmaking and the protection of private interests. . . .

"Nor can plaintiff show control by NIH over the daily activities of the UGDP grantees in order to infer that their records became official records of NIH. . . . Furthermore, the FDA's indirect connection with the raw data is unrelated to the NIH's sponsorship of the UGDP study. Even a count of cumulative Government contacts (albeit by different Government organizations) will not suffice to prove an unequivocal identification of the UGDP raw data as Government records or property.

#### Conclusions

"In sum, the Court finds that the UGDP functioned as a private organization. The raw data of the research organization's study was its own private property and not Government property. Because there has not been an adequate showing that the underlying data of the researchers was directly controlled or substantially utilized by a Government agency in the performance of governmental operations, the records cannot be deemed 'agency records' for the purposes of disclosure under the FOIA." (Misc. No. 314; N.J. No. 40)

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, DHEW.

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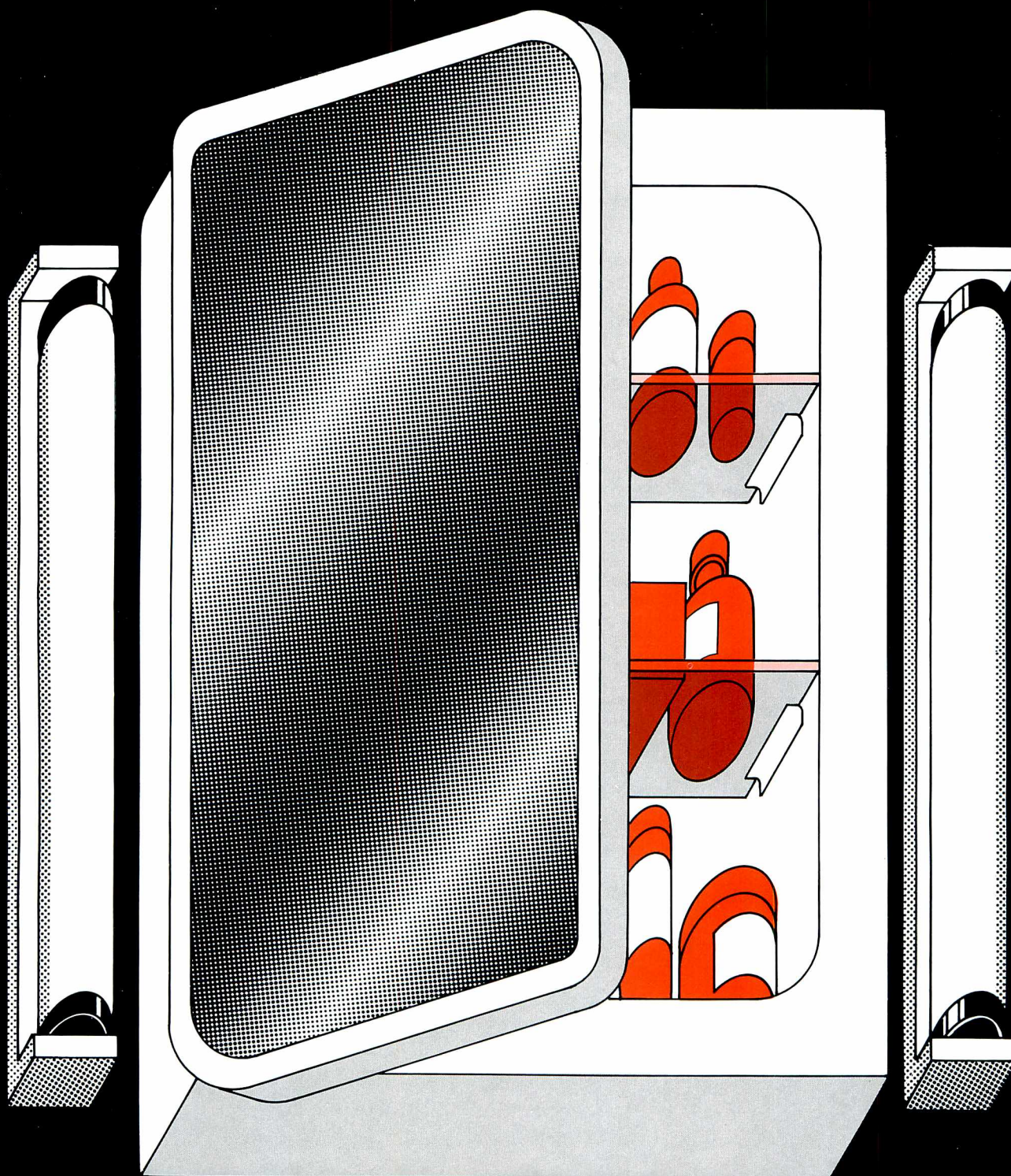
Donald Kennedy, *Commissioner of Food and Drugs*  
Washington, D.C., March 1, 1978

# A Child's World Is Full of Pretty Poisons

There are pink pills and yellow pills that look like candy. There are cleaning fluids just the color of soft drinks.

And a child can't tell the difference.

But we adults can. So we have to see that medicine is locked in cabinets and kept in containers with safety closures. We have to refrain from teaching kids that medicines "taste like candy." We have to keep household chemicals out of children's reach. And we have to keep the telephone number of the nearest Poison Control Center handy—just in case.

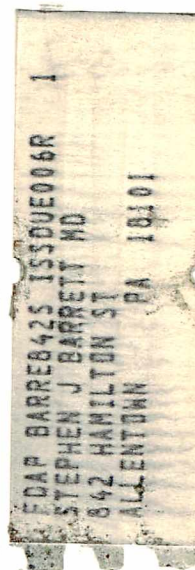




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