

^{FDA} CONSUMER

September 1979



Say Cheese!



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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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Inside Front Cover: *Sleep aids have been controversially in the news recently. First, many over-the-counter sleep aids were recalled because they contained a cancer-inducing chemical. Then a report hit upon extended dependence on prescription sleep aids. But what can a person do to avoid sleeplessness? That question is addressed in the article On Making It Through the Night.*

Umbrella GMP's To Be Extended

Since 1969 FDA has had Good Manufacturing Practice (GMP) regulations in the food industry to assure that food is clean and safe to eat. The GMP's are intended to prevent the processing, packing, or holding of food under conditions that may permit it to become contaminated with filth or rendered harmful to health. There are GMP's for the food industry in general, called "umbrella" GMP's, and GMP's for specific foods or food industries. The purposes of and progress in development of food GMP's were described in A Greater Margin for Food Safety in the September 1974 FDA CONSUMER; FDA's set of GMP's for cocoa products and candy was the fourth specific category to be adopted, in June 1975. Others have been proposed. Here's an update.

FDA has decided its "umbrella" Good Manufacturing Practice regulations for food industry can be revised and extended to adequately cover essential concerns in all segments of the food industry, obviating the need for further GMP's for specific foods or industries.

The Agency's proposal to use "umbrella" GMP's instead of developing more new ones for specific foods follows its recently enunciated policy of keeping regulatory paperwork to a minimum.

The proposed regulations are thought to be so comprehensive and generally applicable that FDA plans to drop its GMP proposals for baked goods and tree nuts and peanuts and may even set aside GMP's adopted in 1975 for cocoa products and candy. Nevertheless, the Agency's detailed GMP's for low-acid canned foods, smoked fish, and frozen raw breaded shrimp—where processing is always critical because of the menace of foodborne pathogens—will remain in place under the latest proposal.

FDA plans to hold public hearings on the proposals in Chicago (September 11), San Francisco (October 3), and Atlanta (October 24) to receive information and views and to assess the possible impact on the food industry, especially small business. The final regulations would take effect 180 days after being published in the FEDERAL REGISTER.

Under the proposal, FDA plans to revise and update requirements for food plant personnel, plant design and construction, sanitary operations, facilities and controls, equipment and utensils, regulating and recording controls, processing operations, and coding and recordkeeping. The Agency

has received and incorporated some suggestions from the U.S. Department of Agriculture Food Safety and Quality Service and the U.S. Department of Commerce National Marine Fisheries Service.

Among the proposed changes FDA would:

- Recommend physical separation of the various steps in a food plant's operations to prevent contamination of one operation by another.

- Prohibit backflow or cross-contamination of piping systems carrying potable water and waste water or sewage.

- Require easy-to-clean food surfaces, accurate and effective thermometers, freezers and cold storage compartments fitted with thermometers, properly maintained equipment used to control microbial growth in foods, and restricted use of polychlorinated biphenyls (PCB's).

- Require adequate sanitation in all operations and better control over raw materials and several other sanitary practices to minimize risks from bacterial contamination. The GMP's would relax minimum temperature requirements for refrigeration from 40° Fahrenheit to 45° Fahrenheit to save energy.

- Require coding marks on all finished food packages for consumers, identifying the processing plant and the product or packaging lot to make it easier to locate products subject to recall. Coding is not mandatory at present.

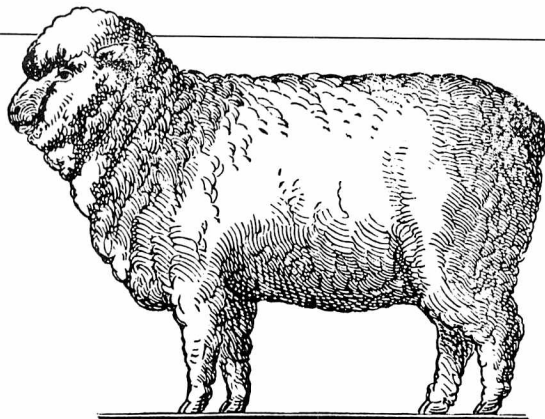
- Require records retention by the food processor for 2 years of all supply warranties of goods' compliance with the law, the plant's sterilization records for all lots, and distribution information for finished lots of food.

DES Banned in Cattle, Sheep

DES, a synthetic estrogen, has been used to promote growth of beef cattle and sheep since the 1950's. FDA's efforts to ban this use of the drug, because of its cancer-causing potential, were outlined in the story DES: The Drug With Unexpected Legacies, in the May 1979 issue of FDA CONSUMER. Here's an update.

FDA has banned the use of diethylstilbestrol (DES) for promoting growth in cattle and sheep. The ban on the manufacture and shipment of DES as an animal drug became effective July 13. Use of DES in livestock was to cease by November 1.

The action by former FDA Commissioner Donald Kennedy upholds a decision made September 21, 1978, by FDA Administrative Law Judge Dan-



iel Davidson following a lengthy hearing.

Commissioner Kennedy concluded the following:

- DES causes cancer and it has not been shown that there is an amount below which it does not cause cancer.

- Residues of DES occur in food from animals which have been treated with it.

- There is no currently approved way to detect whether there are carcinogenic DES residues in the edible meat of animals.

- The law does not authorize FDA to consider the economic benefits of drugs such as DES; in any event, those opposing the ban have not demonstrated that it will have any significant adverse environmental or economic impact.

People who are adversely affected by the timetable may appeal to FDA for extensions.

DES was administered to animals in two ways: as an implant behind the ears, and as an additive to animal feed. Alternative growth promotants are available.

The drug also is used to treat certain cancers and other medical conditions in people. Today's action does not affect the uses of DES as a human drug.

FDA previously banned DES in August 1972 (in animal feed) and in April 1973 (as an implant), after the U.S. Department of Agriculture found DES residues in the edible tissue of food animals treated with the substance. However, the bans were overturned in January 1974 by the U.S. Court of Appeals for the District of Columbia Circuit because the Agency had not held a hearing.

In January 1976 FDA initiated new proceedings to ban DES. Four firms requested a hearing, which began in November 1976.

Levels of PCB's Lowered

Polychlorinated biphenyls (PCB's) are highly stable chemicals that have been used extensively for industrial purposes. Unfortunately, they have become unavoidable environmental contaminants. How they have been used in the past and what has happened to them in the present was the subject of an article, PCB's: Coping With the Indestructible Pollutant, in the December 1976-January 1977 issue of FDA CONSUMER. Here's an update.

The Food and Drug Administration has lowered the allowable levels of polychlorinated biphenyls (PCB's) that can be present in fish, poultry, and dairy products shipped in interstate commerce. Effective August 28, 1979, any food containing PCB's at levels above the new tolerances will be regarded as adulterated and subject to FDA regulatory action.

The new tolerance for PCB's in fish and shellfish is 2.0 parts per million (ppm). It had been 5.0 ppm. The tolerance for milk and dairy products will be reduced from 2.5 ppm to 1.5 ppm (fat basis); in poultry from 5.0 ppm to 3.0 ppm (fat basis); and in eggs from 0.5 ppm to 0.3 ppm.

Because of their presence in soil and water, some PCB contamination of food cannot be avoided; once present in food, PCB's cannot be eliminated by processing.

Under the law, FDA may set tolerances—permissible levels—for such unavoidable contaminants in food. FDA first set tolerances for PCB's in 1973. Since then the amount of PCB's in the diet has dropped significantly.

But new evidence indicates that these chemicals are more toxic than previously thought. Recent studies have linked PCB's to liver tumors and reproductive problems in test animals.

These new findings pointed to a need for lower tolerances, particularly for fish, the only food in which PCB levels routinely persist. The highest levels of PCB's are concentrated in certain freshwater fish, such as Coho and Chinook salmon from the Great Lakes, freshwater trout and catfish. With a few exceptions, saltwater species, which constitute most of the fish in the American diet, are rarely contaminated with PCB's.

The Agency has carefully evaluated the impact the new tolerance will have on commercial fishing and estimates that there could be a loss of about \$6 million worth of fish.

Announcement of the new tolerance levels was published in the June 29 FEDERAL REGISTER. Donald Kennedy, then Commissioner of Food and Drugs, sent letters to the governors of States where PCB contamination of waters persists, urging them to consider taking further action to protect consumers in those States from PCB-contaminated fish. Affected are Connecticut, Illinois, Indiana, Massachusetts, Michigan, Minnesota, New Jersey, New York, Ohio, Pennsylvania, and Wisconsin.

A large number of fish are caught and consumed by sport fishermen or by commercial fishermen whose catches do not enter interstate commerce. These fish are not subject to FDA tolerances, which apply only to food shipped in interstate commerce. State or local action may therefore be needed to protect consumers of these fish.

On Making It Through The Night

by Judith Willis

Sleeplessness was in the news when news was no more than gossip. Today is no different, except that nowadays drugs are often used to induce sleep. This article examines the safety of some of those drugs as well as coping with the problem without chemicals.

Insomnia is the triumph of mind over mattress, as one joke has it. But for many people insomnia is no laughing matter.

Americans spend approximately \$25 million a year on over-the-counter (OTC) sleep aids, and additional millions are spent by the approximately 8.5 million Americans who take prescription sleeping pills. In 1977, about two million of these insomniacs took prescription sleep medications every night for two consecutive months or longer.

But the recent recall of OTC sleep aids containing methapyrilene and a previous FDA warning about the efficacy of OTC sleep aids, coupled with an Institute of Medicine report on prescription sedatives and hypnotics, has brought into question the wisdom of indiscriminate and widespread use of both OTC and prescription sleep medications.

In 1975, FDA's expert panel on sleep aids, daytime sedatives, and stimulants cautioned those with chronic sleep problems to seek medical help. It warned against using sleep aids containing bromides and scopolamine compounds, and found "irrational" the use of passion flower extract and vitamin B₁ (thiamine hydrochloride) in sleep aids. Although most sleep aids containing these ingredients were reformulated after the panel's report, some remain on the market.

More recently, OTC sleep aids containing the antihistamine methapyrilene, a carcinogen, were recalled down to the retail level in June (See FDA

CONSUMER, July-August 1979). Manufacturers again reformulated their products, mostly with a chemically similar antihistamine, pyrilamine, which has not yet been tested for carcinogenicity. This action leaves thousands of users of OTC sleep aids wondering if they should continue to take these drugs, see their doctor for a prescription medication, or possibly look for other ways to relieve insomnia.

Adding to the insomniac's quandary is the recent study on sedative-hypnotic drugs issued by the National Academy of Science's Institute of Medicine (IOM). IOM conducted the study at the request of the White House Office of Drug Policy and the National Institute on Drug Abuse. Of significance to insomniacs seeking prescription drugs was the IOM report's advice to physicians to restrict use of sedative-hypnotic drugs to short-term treatment of insomnia. IOM found little evidence that sedative hypnotics in general continue to be effective when used nightly over long periods. Indeed, sleep laboratory research on sleeping pills shows that practically all lose their sleep promoting effectiveness after 3 to 14 days of continuous use.

In addition to the time limitations on effectiveness, studies show that many of the prescription drugs interfere with various stages of sleep. The barbiturates suppress REM (Rapid Eye Movement) sleep during which persons dream. In the last several years, this knowledge, together with the association of barbiturates and drug abuse, has been responsible for a shift away from prescribing barbiturates in favor of the benzodiazepines, most notably Dalmane. However, there is now evidence that the benzodiazepines suppress sleep stages 3 and 4.

To better understand the significance of such suppression, we can look at an explanation of the various stages of sleep.

In their book, *INSOMNIA* (Double-day, N.Y., 1969), Gay Gaer Luce and Julius Segal describe what happens when a person falls asleep. At the threshold of sleep, body temperature goes down and what are known as "alpha rhythm" brain waves occur. At this point, after the alpha state is reached, many people experience a sudden jerking awake. This is technically known as the "Myclonic Jerk" and signals neural changes resulting from a sudden burst of activity in the brain. Typically, the sleeper jerks half awake, then quickly enters stage 1 of sleep. Muscles relax and the pulse slows. Sleepers awakened at this point often feel that they have not been asleep.

If unawakened, the sleeper now enters stage 2. At this time if an EEG (electroencephalograph) were being made the tracings would show a burst of activity as the brain waves grow larger. The sleeper's eyes roll from side to side. If the eyes open, they do not see. At this point, although asleep about 10 minutes, a person if awakened might wonder if he or she had been sleeping or might believe no sleep had occurred.

After about 30 minutes of sleep, stage 3 is reached. Brain waves are large and slow, rather like mountains. Muscles are relaxed and breathing even.

The sleeper then enters stage 4, or "delta" sleep. This is the deepest sleep of all and lasts longer in the first part of the night than toward morning. Initially, after about 20 minutes of delta sleep, the sleeper ascends near waking again, but does not awaken. Instead, the sleeper goes into REM sleep, so named for the rapid eye movements which occur during this phase. The sleeper dreams during 85 percent of REM. The heartbeats are irregular and blood pressure fluctuates; the brain waves resemble those of a waking per-

"When I lie down I say, when shall I arise and the night be gone? And I am full of tossings to and fro until the dawning of the day."

Job 7:4

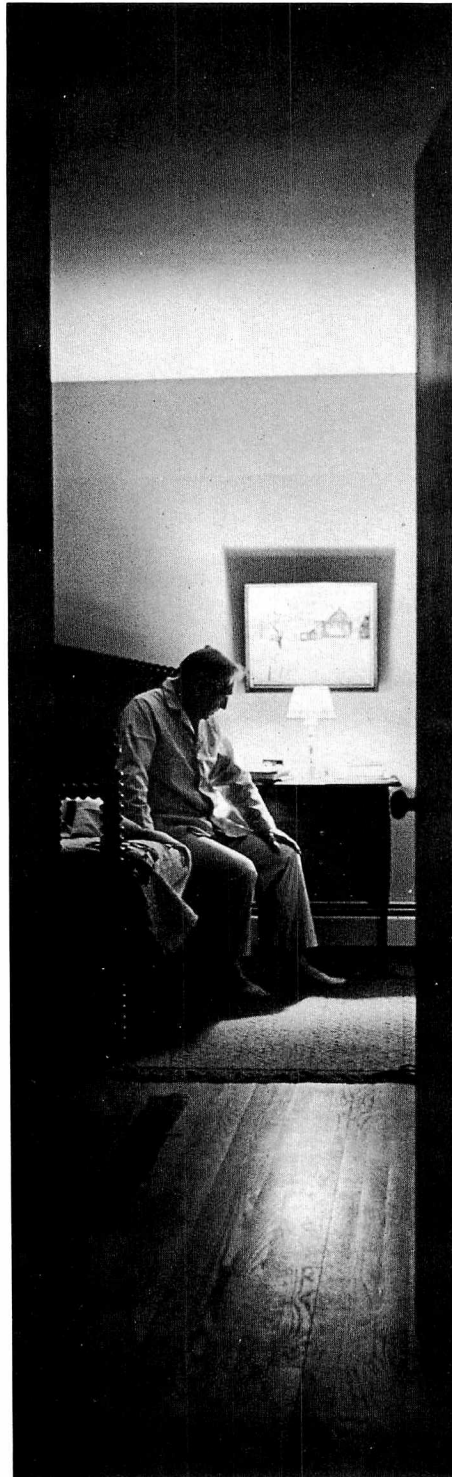
son. The first REM period lasts about 10 minutes, and then the cycle begins again with the sleeper entering sleep stage 2. This cycle repeats itself about once every 90 minutes. Toward morning there is less delta sleep and more REM.

The orders of the sleep cycle and each of its stages seem to be biologically essential. Studies of people deprived of REM show that they become hostile, irritable, and anxious. Those deprived of delta sleep seem to become depressed and apathetic. Both the REM- and the delta-deprived make up the missed stages as soon as possible when allowed to return to normal sleep.

Given this knowledge, it is understandable that medical authorities are questioning the use, especially over extended periods, of sleeping pills that may suppress these important phases of sleep.

What, then, do you do if you don't want to take pills but you can't get a good night's sleep? Just such a question was recently addressed in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA, Nov. 17, 1978, Vol. 240, No. 21). In an article entitled "What to Use Instead of Sleeping Pills," Thomas J. Coates, Ph.D., and Carl E. Thoresen, Ph.D., point out that the insomniac should be given a thorough physical examination to make sure that the insomnia is not related to liver, kidney, or heart disease, a metabolism problem, or some other physical ailment. With these problems ruled out, the authors then suggest that physicians advise insomniac patients to look to their eating, drinking, exercise, and relaxation habits to see if these might be preventing good sleep.

In another article along the same lines in Harvard University's MEDICAL FORUM (Vol. IV No. 7, May 1979), Dr. Quentin R. Regestein, director of the Sleep Clinic at Peter Bent Brigham



Hospital, Boston, observes that most insomnia cases are related to lifestyle problems such as irregular times of going to bed and arising, night work, daytime naps, completely sedentary daytime routine, overuse of caffeine or other stimulants, and chronic abuse of tranquilizers, sleeping pills, or alcohol.

Luce and Segal point out that there are a number of types of insomnia and a variety of reasons a person may be having sleeping problems.

A major problem for many is not inability to sleep but fear they will not sleep. The Greeks had a word for it: *agrypniaphobia*, fear of not being able to sleep. Then there are people who dwell on their sleeplessness, constantly pointing to it as the insurmountable problem in their lives, as a way of avoiding confrontation with more threatening problems.

Others believe mistakenly that they have insomnia. These persons may actually be getting adequate sleep for their needs, but because they have not had a full 8 hours of sleep, believe they have a problem. In fact, 8 hours may be too much sleep for some people and not enough for others. There is no statistical evidence that everyone needs 8 hours of sleep a night. Average amounts of habitual sleep can vary from 5 to 10 hours a night. There are even a few persons who habitually get as little as 2 or 3 hours sleep a night and awake feeling refreshed.

There is a type of insomnia in which persons believe they have not been asleep when they actually were. This occurs, Luce and Segal theorize, because periods of light sleeping and wakefulness are often fused and the insomniac believes he or she has not slept at all. In addition, some persons have more difficulty judging time at night than in daytime and therefore are likely to overestimate wakeful hours.

Another type of insomnia occurs when something upsetting or exciting

"It covers a man all over, thoughts and all, like a cloak; 'tis meat for the hungry, drink for the thirsty, heat for the cold, and cold for the hot. 'Tis the current coin that purchases all the pleasures of the world cheap; and the balance that sets the king and shepherd, the fool and wise man even."

From DON QUIXOTE by Cervantes

happens in a person's life. This type disappears by itself when the crisis is over.

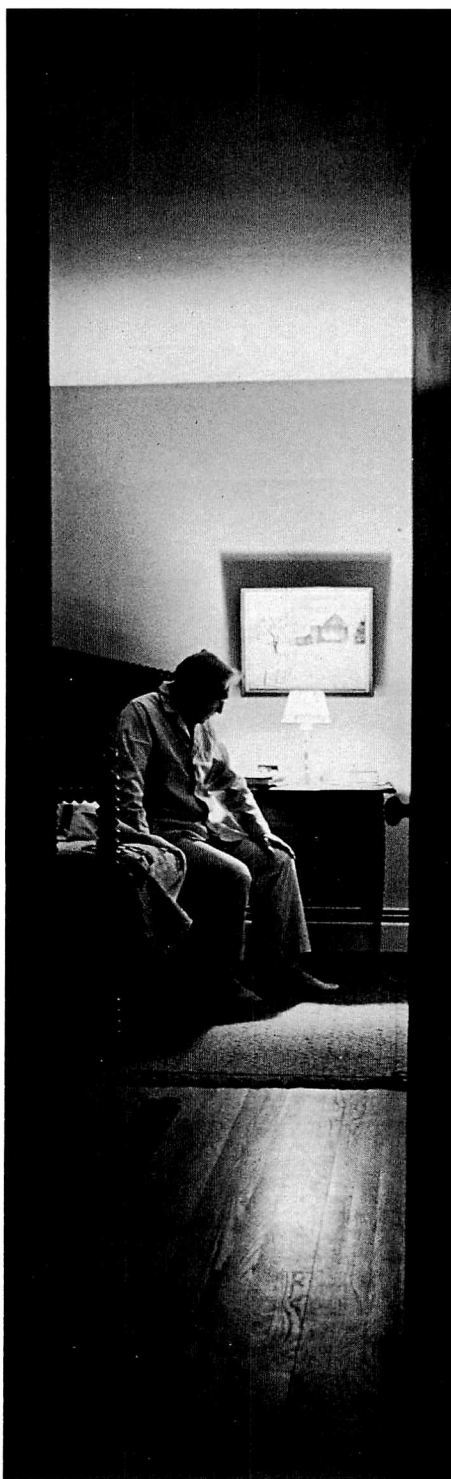
Then there is pathological insomnia which may be a sign of emotional illness. For example, early morning awakening is often a sign of depression.

If an insomniac's problem does not seem to fall into any of these areas, then he or she should look to environment and habits.

Irregular times of going to bed and awaking may make sleeping more difficult because the body gets used to sleep at certain times. There is the lark and owl syndrome—the larks being those who are at their best when they go to sleep and arise early, and the owls those who excel when they go to bed and get up at later hours. This variation is apparently linked to individual biological rhythms and possibly heredity, and can vary greatly from one individual to another. Therefore, insomniacs might do well to experiment with different times of going to sleep and arising, to see if they can get a better synchronization with their natural body rhythms.

Another factor that can affect sleep is age. People require less sleep as they grow older, and this becomes increasingly evident after age 55.

There's sexism in tossing and turning. Several studies indicate that women have more trouble with insomnia than men. The question arises whether this is because, as with other physical or psychological complaints, women tend to seek help more often than men or whether there is an actual biological difference. It is known that women can be more easily roused from sleep than men and that, at an earlier age, they start requiring less sleep than men. In addition, there may be a hormonal factor, the sleepiness of early pregnancy due to progesterone release and the insomnia of pre-menstrual tension being



two examples.

Besides these factors, there are environmental variables, such as diet and exercise, which are more amenable to change.

Interestingly, that old folk remedy for sleeplessness, a glass of warm milk, had some scientific basis. In a study, one of the amino acids found in milk was given in large doses to volunteers and was found to have a sedative effect. In another experiment, when persons were deprived of two other amino acids that occur in high protein foods, there was a drop in the amount of REM sleep. Therefore, a good rule of thumb might be to have a high protein dinner and a glass of milk before bedtime.

On the other hand, insomniacs would be wise to avoid beverages containing caffeine, such as coffee, tea, and colas, because they act as stimulants in most people. Smokers should note that nicotine is also a stimulant and that many ex-smokers have reported improved sleep after quitting.

Alcohol, in that old standby the nightcap, may not always work to induce sleep because it, too, can be a stimulant. In addition, some alcoholics report that their problem began with bedtime drinking. There also is evidence showing that at some dosage levels alcohol reduces REM sleep.

Exercise—the right kind at the right time—can be a sleep aid. Exercise during the daytime, especially if followed on a routine basis, has a beneficial effect on sleep. However, exercise at night may make sleeping a bit more difficult, especially if you are not used to it. Similarly, mental stimulation before bedtime can make it harder to fall asleep.

Controlling the environmental factors will often alleviate or completely eliminate sleep problems. Those for whom this approach is insufficient may want to try some of the alternatives to

*"O sleep! O gentle sleep!
Nature's soft nurse, how have I
frighted thee,
That thou no more wilt weigh my eye-
lids down
And steep my senses in
forgetfulness?"*

From Shakespeare's HENRY IV

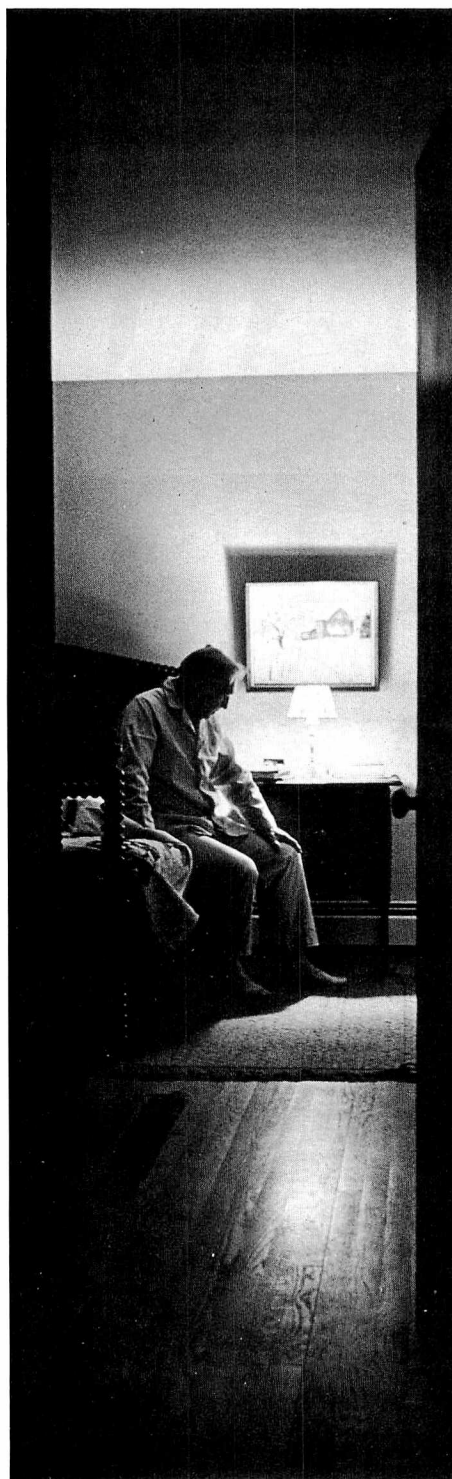
medication alluded to in the JAMA and MEDICAL FORUM articles and also discussed by Luce and Segal.

One solution is referral by a physician to a sleep clinic. Some sleep clinics are set up as part of hospitals. Others are connected with privately owned sleep labs and are thus more research oriented. Some sleep clinics accept people on an in-patient basis only; others accept both in- and out-patients. The program in most sleep clinics includes a thorough physical exam and psychological testing preceding several nights of EEG studies during which the insomniac is monitored to determine what abnormalities exist in his sleep pattern. A list of sleep clinics is available from Peter Bent Brigham Hospital Sleep Clinic, 721 Huntington Avenue, Boston, Mass. 02115, or Dr. William Dement, Association of Sleep Disorders Centers, Stanford University School of Medicine, Stanford, Calif. 94305.

Biofeedback, which came into wide use in the late 1960's as a way of reducing tension, has also been used to relieve insomnia. Although medical experts differ on the extent of its effectiveness for various problems, laboratory tests have shown that people can learn to control, at least partially, body functions—such as blood pressure and heart rate—that are not usually subject to conscious control.

In BIOFEEDBACK: TURNING ON THE POWER OF YOUR MIND (Lippincott, Phila., 1972), Marvin Karlin and Lewis M. Andrews describe a biofeedback training program for insomniacs. In this program, people overcome sleep difficulties by first learning to relax their forehead muscle through feedback from an EMG (electromyograph) that emits a rising tone when the forehead muscle contracts and a falling tone when it relaxes.

After learning to control the forehead muscle, the subjects then learn,



through similar EEG feedback, how to produce the alpha brain waves that precede sleep.

Although some insomniacs have found relief through biofeedback techniques, their acceptance is by no means universal, and some experts, such as Beata Jencks, Ph.D., in YOUR BODY: BIOFEEDBACK AT ITS BEST (Nelson Hall, 1977), suggest that the body itself, through exercises and relaxation techniques, can be taught to act as its own biofeedback mechanism.

Certainly a number of relaxation techniques have been successful in helping people attain more beneficial sleep. Simply tensing and relaxing each muscle in the body can make a person more receptive to sleep. Similar methods are included in programs of Hatha Yoga and some forms of meditation.

Hypnosis, in the hands of a qualified professional who gives a posthypnotic suggestion that the subject will sleep and feel rested, can also be a solution to insomnia. Another, similar method, is self-hypnosis. With both these methods, however, one should be certain that there is not a deep psychological problem underlying the insomnia—a problem that may resurface in another perhaps more destructive manner. For those whose insomnia is rooted in emotional problems, psychotherapy may be the best answer.

Whether or not one of these alternatives appeals to you, one thing seems fairly certain: there is a growing body of medical opinion, including the IOM report and the FDA panel recommendations, which sees sleeping pills as, at best, a temporary solution to insomnia. The informed consumer, with expert medical advice, will explore the alternatives to drugs to find an effective, safe, long lasting solution to sleep difficulties.

Judith Willis is a member of FDA's Public Affairs staff.



FDA Makes Elbow Room For Small Business

The Federal Government is big—many people think too big. The Food and Drug Administration is but a small part of the Federal establishment and yet it regulates large industries. Big governments get to thinking in big terms, which sometimes leaves out the little guy. In FDA's Bureau of Medical Devices there is an Office of Small Manufacturers Assistance that has the job of seeing that FDA has time for the little businesses that operate in the medical devices field.

Although there are lots of him, that paragon of enterprise and ingenuity called the small businessman nevertheless has been regarded for some years as an endangered species. It may be true that the world loves a lover, but in a hotbed of capitalism like the United States the small businessman is the person many think of as the epitome of a way of life that must be preserved.

In Congress, several committees and subcommittees are concerned with the plight of the small businessman, and when he tells of his frustrations and struggles with the big boys and with paperwork and the difficulty of finding operating capital he gets an empathetic ear. There are laws on the books aimed at assuring the survival of small business and there is a Federal Small Business Administration that helps underwrite small business ventures and financing. Some types of Federal Government contracts specify that funds be set aside for small business enterprises.

Other Federal Government agencies with responsibilities for regulating business affairs have services, where authorized, to make life easier for those small businesses affected by their regulatory activities. One such service operates within the Office of Small Manufacturers Assistance (OSMA) of FDA's Bureau of Medical Devices.

This office was included in the 1976 enactment of the Medical Device Amendments to the Food, Drug, and Cosmetic Act. This legislation provided for the establishment of an identifiable office to help small manufacturers of medical devices understand and comply with the new FDA requirements for these products under that law.

OSMA opened its doors in June 1977, and after 2 years is now ready to look at itself and the small manufacturer of medical devices and how it is all working out.

But what has this got to do with the consumer, who isn't necessarily a small businessman?

Well, to paraphrase a well publicized remark by the late General Motors executive Charlie Wilson while he was a member of the Eisenhower cabinet, what's good for small business is good for the rest of us; it ultimately results in better and less costly medical devices.

The rest of us are all at one time or another users of medical devices, such as cardiac pacemakers, pregnancy test kits, x-ray generators, toothbrushes, artificial hip joints, thermometers, and vascular grafts. Most makers of medical devices happen to be small businessmen.

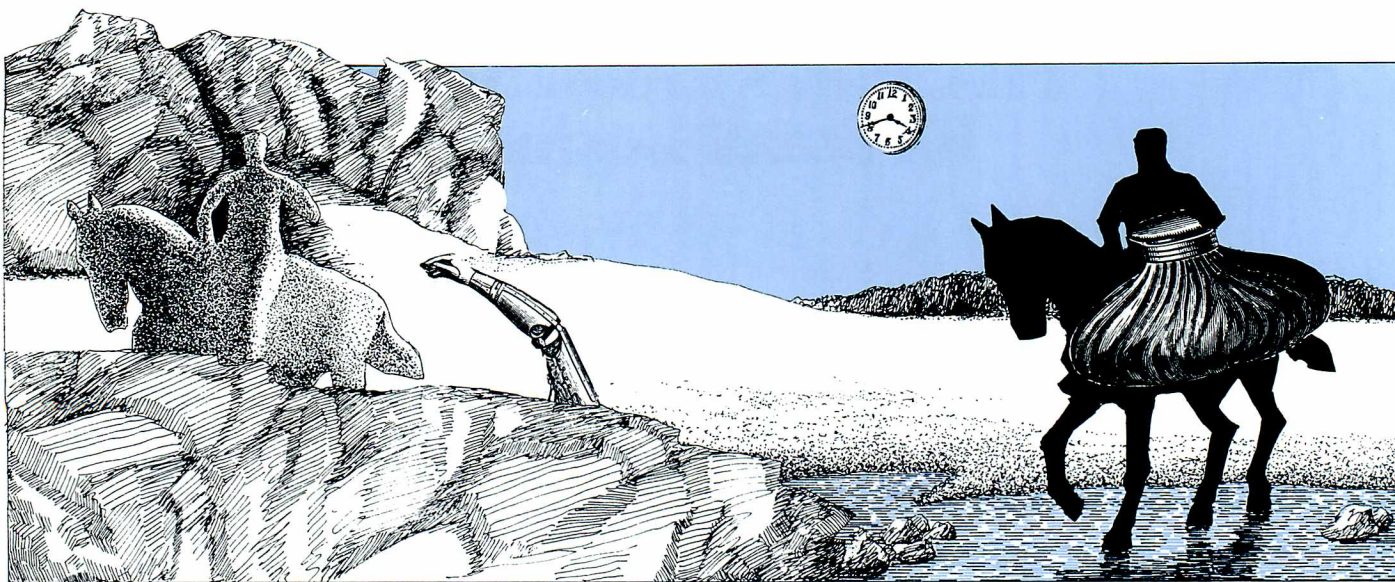
The office has yards of statistics to show that nearly half of all "innovative" business ideas—inventions, new products, new technology—originates with a small business; that small business is the "major source" of the high productivity that has raised standards of living in this country; that small firms account for 98 percent of all businesses, and hire three out of four new employees; and that in an 8-year period studied, small high-technology companies operated on a more competitive footing than big ones and had three times the increase in output of other economic sectors while their

prices rose only about a sixth of that for the remainder of the economy. In other words, one of the dividends from small businesses is lower prices for the goods they produce.

The section of the law setting up the Office of Small Manufacturers Assistance was a happy solution to the national problem of helping small businessmen understand and comply with rather comprehensive and complex new safety and performance requirements for medical devices and to FDA's problem of assuring that the consumer's rights to safe and effective medical devices would not be compromised during the time the new regulations were being implemented, and beyond.

OSMA's primary functions are to provide technical and other nonfinancial assistance to small manufacturers of medical devices. More than one-half of such firms have 10 or less employees. OSMA serves small manufacturers by reviewing and commenting on drafts of proposed and final regulations with the objective of assuring that they are not unduly burdensome to the small manufacturer. The services provided by OSMA are intended to make it unnecessary for small firms to hire technical and legal consultants to understand and keep abreast of FDA regulations. The office also helps the manufacturer reach the right place or person, including those at other agencies.

During the 2 years, OSMA staff members have met with hundreds of manufacturers and industry spokesmen, held a number of conferences, and visited many small manufacturers. All registered device companies are on a general information mailing list, and special mailings of FEDERAL REGISTER notices of limited interest go to selected companies. Publications explaining laws, regulations, and policies are mailed out periodically. The SMA



Memo, the most popular publication so far, describes new developments in device regulation.

Members of the staff, during visits to small manufacturers, can sometimes spot potential problems and advise the companies how they can correct them. Right now the office is planning a series of workshops at places convenient to small manufacturers. At these, the staff will hold briefings and answer questions.

When the 1976 amendments were first enacted, many small manufacturers were concerned about the difficulties and costs of compliance. OSMA was able to allay many of these unfounded fears. The office made it clear that the regulations would be put into

effect gradually, giving small manufacturers a chance to review and comment on proposed regulations. Many manufacturers found it easy to take the first steps, such as registering their companies and listing their products.

The Office of Small Manufacturers Assistance was deliberately kept separate from the Bureau's enforcement functions. The office does not intervene once FDA regulatory action is initiated against a company, but, if requested, will advise the company about procedural safeguards available to it.

At first, some companies wondered how an office dedicated only to the industry's well-being could exist. Others hesitated to talk freely to the office staff for fear of encountering a regu-

latory trap. But gradually, OSMA established a reputation for really helping small device manufacturers. One indication of success has been the willingness of companies to seek information. The office has handled over 4,700 inquiries, a large response, considering that there are a total of 5,200 registered device manufacturers.

Another sign of success is negative. There has been no flight of device manufacturers to other fields where product safety and performance requirements may not be so high. In fact, things have gone so well that FDA is now looking at ways to extend similar services to small business manufacturers of other products under its regulatory jurisdiction.

Agencywide Small Business Efforts

Pleased with the experience of the Medical Device Bureau's Office of Small Manufacturers Assistance, and in response to a directive issued by President Carter on June 14, 1978, calling for regulatory agencies to give special assistance to *all* small businesses, FDA has established four new activities to assist small businesses under its jurisdiction.

- Service desks have opened in four FDA offices. The East Orange, New Jersey, and Santa Ana, California, desks will specialize in working with small medical device firms. The other two desks, in Atlanta, Georgia, and Chicago, Illinois, will be serving all small businesses regulated by FDA. Personnel at these pilot service desks will answer such questions as how regulations affect manufacturing processes, how to complete applications and other forms, and what must be done to market a new product. They also will make on-site visits to small manufacturers, conveying company information needs to FDA headquarters. Inquiries

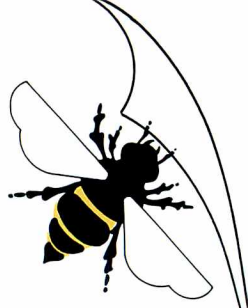
about these service desks may be addressed to Brian Rafferty (HFO-22), U.S. Food and Drug Administration, Rockville, Md. 20857.

- Small business impact statements will be incorporated, when appropriate, with analyses of major regulations, clarifying their impact, anticipating problems, and providing opportunity for alleviation.

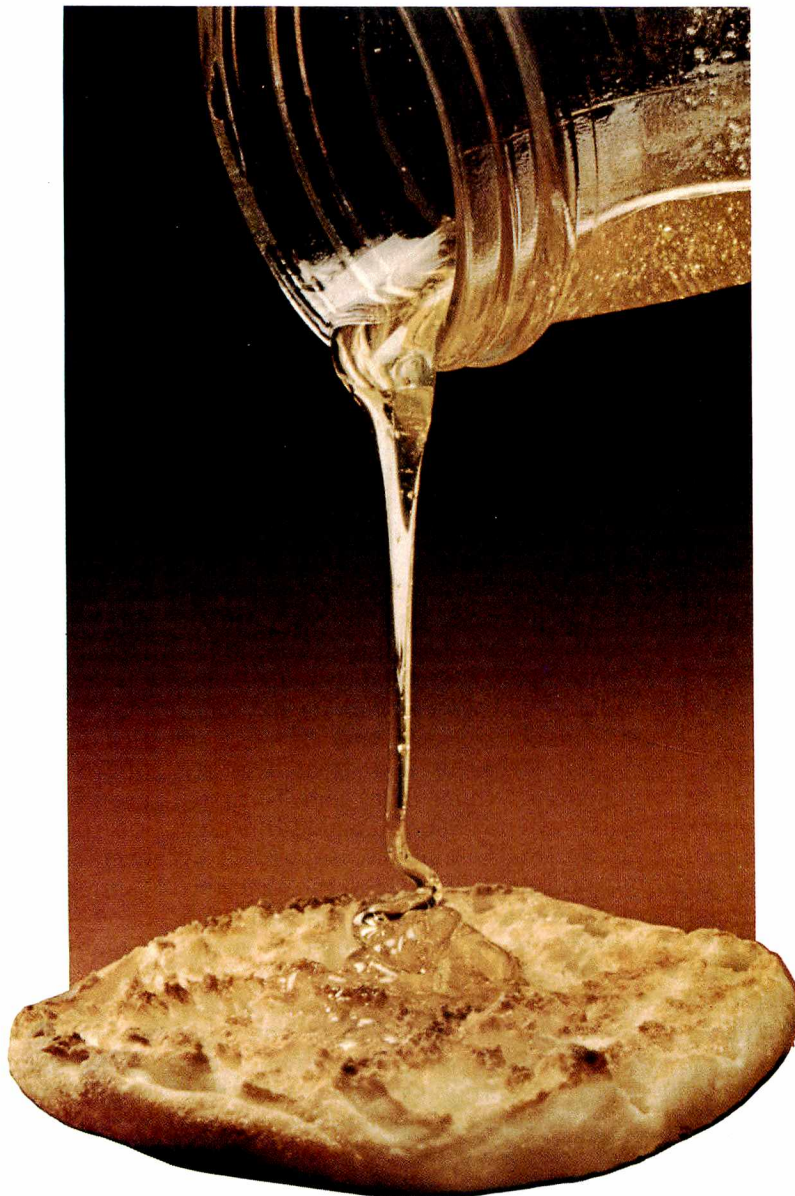
- Views from small business will be sought by FDA in the Agency's annual priority-setting process, and the small business sector will be encouraged to participate in policy-making proceedings, such as hearings and comments on proposals in the *FEDERAL REGISTER*. Nominations for representatives on Agency advisory panels will also be sought from small business representatives.

- An Agency-wide coordinator of small business activities has been appointed to the FDA Commissioner's staff to provide consistent policy for small businesses, advise the Commissioner of small business concerns, and review regulatory documents for undue impact on small businesses.

HONEY



Honey is one of Nature's better concoctions. However, it is not without problems that concern FDA—problems such as drugs used on bees, botulism, and adulteration. Here's a look at what FDA does to keep honey flowing to the marketplace in its sweetest, safest form.



HONEY:

Making Sure It's Pure



by Roger W. Miller

Mother Nature outdid herself when she taught bees to convert nectar into honey. For, in doing so, she created not only a super sweet food but also a naturally sweet additive that's also useful for its ability to absorb and retain moisture, thus retarding drying in foods, such as bakery products. What's more, Ms. Nature perfected a pollination system along with the honey factory—a system that farmers have relied on through the ages and that fathers have utilized to instruct emotionally awakening sons about the “facts of life.”

Facts of life aside, some facts about honey are these:

- Honey is very much in demand today, just as it was in ancient times when the Bible spoke of the “land of milk and honey” (and when honey was fermented to make mead, a forerunner of beer).

- Honey is slapped on bread and poured into cake batter as fast as it can be extracted from the hives in this country—in 1978 domestic bees produced 230 million pounds, and another 56 million pounds were imported.

- It takes more than 550 bees visiting 2.5 million flowers to create just one pound of honey—thus it's easy to understand the term “busy as a bee.” At those figures, bees dipped their snouts into some 575 trillion flowers in the United States during 1978.

But then 1978 was a year the local bees could be proud of, particularly when compared with 1977, when weather and other factors limited domestic production to just 178 million pounds. That year imported honey totaled 63.9 million pounds.

Although 1978 was a banner year, the bee business has not been that good. In fact, since the end of World War II, the number of hives and colonies in the United States has declined more than 25 percent. Rising costs and creeping urbanization have taken their

toll, but beekeepers also bemoan the increased use of pesticides. Their moans have not gone unheard and the U.S. Environmental Protection Agency and many States have taken steps to limit the use of pesticides near bee colonies.

The declining number of colonies has caused crop problems in some agricultural areas. California, the No. 1 food growing State, finds it necessary to import thousands of colonies each year from as far away as the Midwest to assure that its many blossoming fruit and vegetable crops are pollinated.

The Food and Drug Administration has more than a passing interest in honey as a packaged food product, and there are some (you'll excuse the expression) sticky problems with the sweet stuff that FDA has to contend with. For one thing, some drugs are used in raising bees, since the species is subject to a variety of illnesses. For another, a form of botulism is alleged to be associated with honey and has been linked to the sudden infant death syndrome. And finally, because honey is expensive and high fructose corn sirup, or invert sugar sirup, is cheap but looks and tastes similar to honey, some adulterated honey finds its way onto the market.

Two drugs used to treat bees are Fumidil-B (fumagillin) and Terramycin (oxytetracycline). Fumidil-B is used to prevent nosema disease, caused by a parasite that attacks the digestive tracts of the insects. Terramycin is another preventive drug, used as an aid in the control of American and European foulbrood disease, a bacteria-borne malady that gets into the hive and destroys young bees. FDA's concern about drugs used with bees is that residues can end up in honey.

Clostridium botulinum is the offending organism believed to be responsible for some cases of the sudden infant death syndrome. Reporting in the June 1979 AMERICAN JOURNAL OF DISEASES

OF CHILDREN, a California research group said that infants less than a year old should not be fed honey because of the danger of transmitting “infant botulism.”

Studying a number of children who had become ill from infant botulism, the researchers discovered that almost half had been fed honey prior to the onset of the illness. Testing honey samples, they found up to 10 percent contain viable *C. botulinum* spores. In a California portion of the study, no spores were found in any of the several hundred food items tested other than honey, according to Drs. Richard O. Johnson, Susan A. Clay, and Stephen S. Arnon.

That study confirmed previous indications that honey was the source of some infant botulism deaths. These studies have been reported by the Food and Drug Administration in “Talk Papers” issued by its Office of Public Affairs.

Typical of the honey adulteration cases was one earlier this year in Bowling Green, Kentucky. That State's Department of Human Resources was suspicious but not certain of some samples it collected of honey being sold in Bowling Green. The State agency notified FDA, which provided more complete testing of the samples and ascertained that the honey had indeed been watered down—or, if you will, “siruped down.” The product, packed by Anthony's Syrup Co. of Philadelphia, Mississippi, was subsequently seized by a deputy U.S. marshal. Taken were 467 quarts and 83 pint jars valued at \$846.50.

The reason for the adulteration is simple economics. In mid-1979 honey was being sold by the producers at about 50 cents per pound. On the other hand, a high fructose corn sirup, which acts much like honey in some lab tests, was selling in bulk for about 10 cents a pound. It doesn't take much more



than fourth grade arithmetic to figure out that substituting a 10 cent product for a 50 cent product can lead to many trips to the bank.

Adulteration may range from less than 10 percent to more than 70 percent, although the usual adulterated mixture is believed to be 20 to 35 percent invert sugar sirup. The extent of the problem is indicated by the detention of a total of 1.3 million pounds of imported honey in 1976 because it didn't meet Mother Nature's (and FDA's) exacting standards.

Recently, more sophisticated laboratory techniques had to be developed to detect the adulterated honey. That's because the cheaters have been using a high fructose corn sirup that, in mixture, would pass for pure honey under some older testing methods.

In addition to FDA efforts to keep honey pure, the honey industry does its own self-policing, often relying on Dr. J. W. White, a retired U.S. Department of Agriculture honey expert who has set up his own business, Honeytech, Inc., in Navasota, Texas, to test honey samples. White also gets referrals from honey packers, dealers, and users who want to be sure they're getting the real thing.

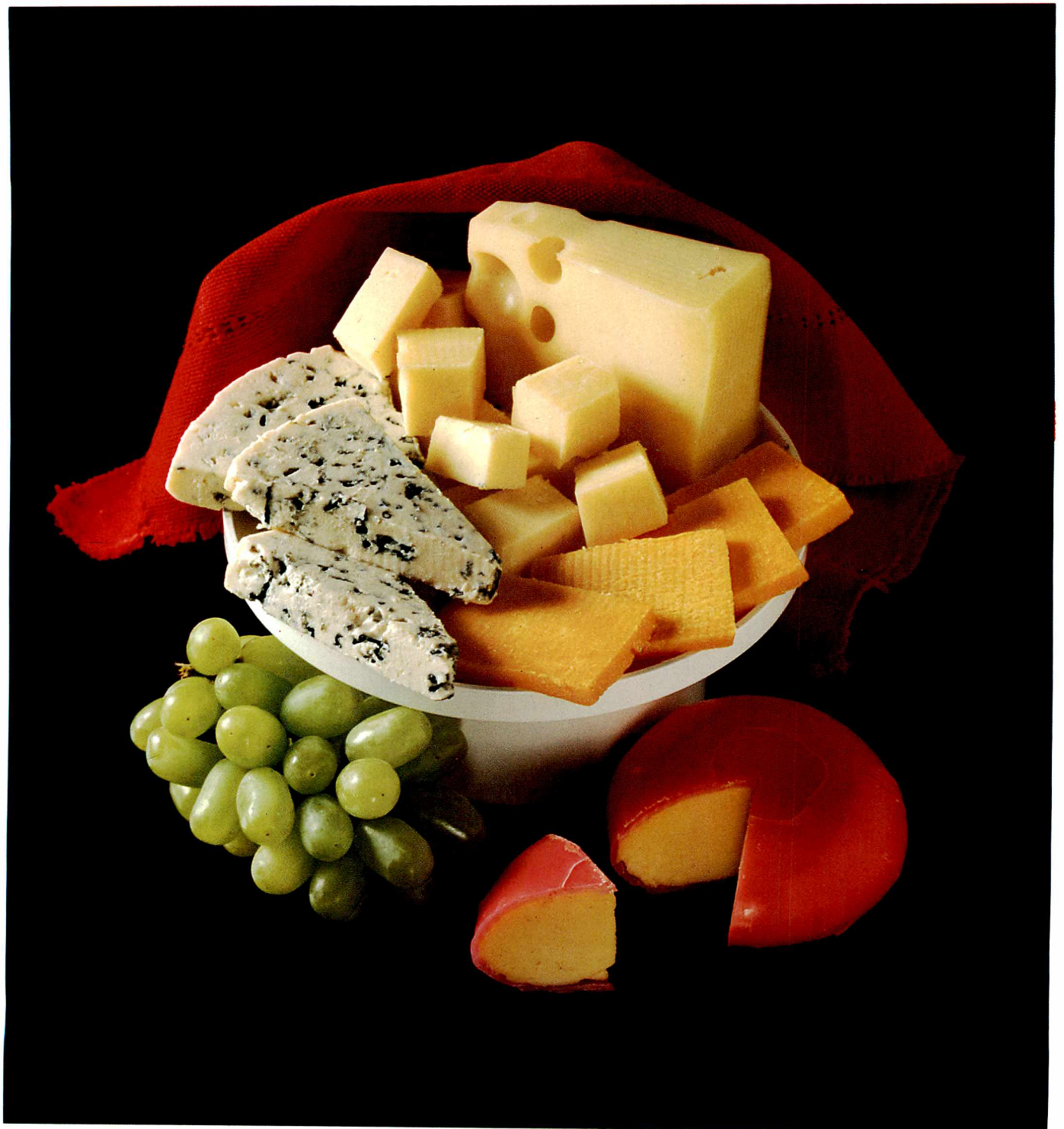
Dr. White says most of the defiled honey is sold to the commercial food processing market. However, for individual consumers, he advises them to watch out for honey that is thin, that is selling below the regular market price, and that has a mild or faint flavor of honey.

Consumers who get a batch they suspect should notify FDA.

Those who get the real thing should enjoy . . . enjoy . . . and say a word of thanks to that genius, Mother Nature, as well as those 550 or so bees that made it all possible.

Roger W. Miller is editor of FDA CONSUMER.

Cheese!



Say 'Cheese' And You've Said A Mouthful

"Bread and cheese." This phrase conjures up age-old images of simplicity: the peasant's lunch, the lovers' blissful repast, the miser's weekly meal. But cheese is far from simple. This article describes the assortment of cheese products, the requirements for ingredient labeling for them, and the changes that FDA has proposed.

by Carol Ballentine

Cheese has been made and eaten for over 4,000 years, according to ancient records. Legend has it that the first cheese was discovered when an Arabian merchant put his evening meal of milk into a pouch made of a calf's stomach and set out by camelback on his day's journey across the desert. The rennet in the lining of the pouch, combined with the heat from the sun, caused the milk to separate into curd and whey. When the merchant sat down to his dinner at the end of the day, he found the whey satisfied his thirst and the curd (cheese) satisfied his hunger, and he had a delightful meal.

Today there are over a hundred varieties of cheese (referred to in the trade as "natural" cheeses), as well as many foods made from cheese, such as pasteurized process cheese and cold-pack cheese food. In addition, the last 5 years has seen the burgeoning development of a new type of food, referred to somewhat haphazardly—and sometimes erroneously—as cheese substitutes, imitation cheese, or cheese analogs. The thing that sets this new type of food in a category all its own is its ingredients, which include predominantly vegetable fat and protein and milk by-products in place of cow's milk. FDA's problem is how to tell the consumer what he or she is really buying by picking up a package of what—apparently—is cheese.

Try making some generalizations about what has to go on a package of cheese, and you'll find yourself mired in a morass of exceptions: "Manufacturers don't have to list required ingredients—such as milk—on the labels of cheese packages"—except on some cheeses, such as cold-pack cheese food and cream cheese. "All cheese contains undeclared amounts of salt"—except if the salt is potassium chloride and the cheese is a low-sodium variety. "All optional ingredients must be listed

on the label"—except for artificial colors and a few additives.

Confusing? Sure. But maybe a closer look at labeling regulations for cheese—that is, natural cheese, cheese foods, and cheese "substitutes"—will make things clearer.

FDA has established standards of identity for 73 varieties of natural cheese and cheese foods (including Cheddar, Swiss, Gouda, pasteurized cheese spreads, cottage, and cream cheese). A standard defines the food and sets the levels of fat and moisture, the manufacturing procedure, and the ingredients to be used. For instance, according to the standard for Cheddar cheese, it must contain not more than 39 percent moisture, its solids must be at least 50 percent milkfat, and it must be cured for at least 60 days—if it is made from unpasteurized milk. If a product does not meet these requirements, it cannot be called Cheddar cheese.

Some varieties of cheese, such as Jarlsberg, Brie, and Camembert, are included under one of the general standards, such as "semisoft cheeses," "hard cheeses," or "soft ripened cheeses." However, some cheeses, such as Port du Salut, Feta, and many imported cheeses, simply do not fall under any standard at all.

Cheese "substitutes" currently do not have a standard of identity. However, FDA has proposed to divide these foods into three categories, each with its own separate standard:

- Cheese substitute—a food that is nutritionally equivalent to and which conforms to the fat and moisture content requirement of the cheese it simulates, but which does not meet the standard of identity for that cheese. For example, if a product contained vegetable protein instead of cow's milk, it would not meet the standard even if it met the fat and moisture requirements.

- Cheese product substitute—a food that is nutritionally equivalent to the cheese product it simulates, but that doesn't conform either to the fat and moisture requirement or the standard of identity for that cheese.

- Imitation cheese substitute/cheese product substitute—a food that is nutritionally inferior to the cheese it simulates.

What all this boils down to is that most cheeses have standards of identity and some don't. The ones that don't must include a list of all ingredients on their labels. The problem is with the ones that do.

The typical consumer complaint is that foods that are standardized—that is, foods that have standards of identity—are confusing because the required ingredients in such foods don't have to be declared and consumers don't know what's in them. And many consumers want to know. For instance, some consumers want to know if cheese contains salt and how much; others want to know what cheeses contain microbial milk clotting enzymes instead of animal enzymes, such as rennet; still others want to avoid artificial colors.

The introduction of cheese and cheese product substitutes—and three petitions from the dairy industry suggesting how these foods should be regulated—helped to spur FDA to try to clear up the confusion. A joint Food and Agriculture Organization/World Health Organization committee provided added impetus to act by submitting standards of identity for 34 natural cheeses, which would bring them into closer conformance with international standards.

FDA feels that the wisest course is to change and amend current regulations for cheese to require full ingredient declaration, permit relaxation of recipe requirements, and make standards more consistent with international



standards for cheese. Such changes would have a three-fold effect. First, and most obviously, consumers would know exactly what they were buying. All ingredients—as well as the percentage of milkfat—would have to be declared. Currently, for instance, consumers may be eating cheese with from 4 to 35 percent total milkfat content without knowing it. Second, manufacturers could use any safe and suitable ingredients—such as condensed and dry forms of milk, skim milk, and cream—that would not change the chemical and physical properties of the cheese. Cheese could thus be manufactured more economically—since manufacturers could take advantage of fluctuating availability of ingredients—and consumers would save money. Finally, the standards would become more uniform for cheeses all over the world.

FDA already has established regulations requiring full ingredient declaration on some standardized cheeses, which include all cold-pack cheese foods, all pasteurized process cheese foods and cheese spreads, and Neufchatel, cottage, and cream cheese.

So, the Agency has proposed:

- That the standards for nine cheeses be revised to require a declaration of the percentage of milkfat (by total weight) and a list of all ingredients. The cheeses in question are Blue, Cheddar, Edam, Gouda, Gruyère, Limburger, Provolone, Samsøe, Swiss, and the cross-referenced cheeses—Cheddar for manufacturing, low-sodium Cheddar, and Swiss for manufacturing.

- That the names for substitute and imitation cheeses include the percentage of vegetable fat and milkfat and that all ingredients used in these foods—such as casein, whey, and lactose (milk sugar)—be declared in the ingredient statement in descending order of predominance.

The exception—there always is one—to the requirement that all ingredients be listed is food coloring. The Food, Drug, & Cosmetic Act specifically says that natural cheeses, butter, and ice cream may contain undeclared artificial coloring. Specifically, cheeses such as Blue, Cheddar, Asiago, Parmesan, and Colby will probably contain artificial colors but the manufacturer doesn't have to say so—now or when the new regulations become effective.

The time may come when you can pick up a package of cheese or cheese substitute—standardized or not—and see listed the percentage of fat and all the ingredients (with only the single exception of food coloring). But that time is not now. Only a few cheeses and products made from cheese require a full declaration of ingredients. So what does the consumer see on the labels and what ingredients are undeclared in most cheese?

Most cheese is made by combining milk with calf rennet (an enzyme that causes milk to clot) and heating it to form solid curd. Microbial milk clotting enzymes—substances produced from bacteria or mold—may be used in place of, or in addition to, animal enzymes (e.g., rennet). The curd is cut, pressed, and cured with salt. Most cheese contains from 1 to about 3 per-

cent salt. In the case of Blue cheese, and a few others, mold—usually undesirable in cheese—is used in the curing process to impart a characteristic flavor. The rind of Asiago, Blue, and a few other cheeses may be coated with vegetable oil to prevent the cheese from drying and stop the growth of undesirable mold.

None of these so-called required ingredients—milk, salt, enzymes (rennet), and mold spores—has to be listed in the ingredient statement on the label. In addition, no distinction is made between animal enzymes and microbial milk clotting enzymes; and vitamin A and calcium chloride may be added in undeclared amounts. Vitamin A is added to all bleached cheeses to replace the nutrient lost during the bleaching process. Calcium chloride is added in minute quantities to many cheeses to aid in curd formation. However, when this ingredient is added to cheese substitutes and imitation cheese as a nutrient it must be declared on the label.

Again, there are exceptions. If a salt substitute (such as potassium chloride) is used in curing low sodium cheese, the label must include a statement indicating this, such as “potassium chloride added as a salt substitute.” And if milk other than cow's milk is used in the food, this fact must appear on the label. Most cheese in the United States is made from cow's milk, but milk from any animal can be clotted to form curds. Ewe's milk is the major ingredient in some Blue cheese, and Feta cheese can be made with either goat's milk or ewe's milk. Domiati, a

Standardized Cheeses and Cheese Products

Asiago fresh and Asiago soft cheese
Asiago medium cheese
Asiago old cheese
Blue cheese
Brick cheese
Brick cheese for manufacturing
Caciocavallo Siciliano cheese
Cheddar cheese
Cheddar cheese for manufacturing
Low-sodium Cheddar cheese
Colby cheese
Colby cheese for manufacturing
Low-sodium Colby cheese
Cold-pack and club cheese
Cold-pack cheese food
Cold-pack cheese food with fruits, vegetables, or meats
Cook cheese, koch kaese
Cottage cheese
Dry curd cottage cheese
Lowfat cottage cheese
Cream cheese
Cream cheese with other foods
Washed curd and soaked curd cheese
Washed curd cheese for manufacturing
Edam cheese

Gammelost cheese
Gorgonzola cheese
Gouda cheese
Granular and stirred curd cheese
Granular cheese for manufacturing
Grated cheeses
Grated American cheese food
Hard grating cheeses
Gruyère cheese
Hard cheeses
Limburger cheese
Monterey cheese and Monterey Jack cheese
High-moisture Jack cheese
Mozzarella cheese and Scamorza cheese
Low-moisture Mozzarella and Scamorza cheese
Part-skim Mozzarella and Scamorza cheese
Low-moisture part-skim Mozzarella and Scamorza cheese
Muenster and Munster cheese
Muenster and Munster cheese for manufacturing
Neufchatel cheese
Nuworld cheese
Parmesan and Reggiano cheese
Pasteurized blended cheese
Pasteurized blended cheese with fruits, vegetables, or meats

Pasteurized process cheese
Pasteurized process cheese with fruits, vegetables, or meats
Pasteurized process pimiento cheese
Pasteurized process cheese food
Pasteurized process cheese food with fruits, vegetables, or meats
Pasteurized cheese spread
Pasteurized cheese spread with fruits, vegetables, or meats
Pasteurized Neufchatel cheese spread with other foods
Pasteurized process cheese spread
Pasteurized process cheese spread with fruits, vegetables, or meats
Provolone and Pasta Filata cheese
Soft ripened cheeses
Romano cheese
Roquefort, sheep's milk blue-mold, and blue-mold cheese from sheep's milk
Samsøe cheese
Sap Sago cheese
Semisoft cheeses
Semisoft part-skim cheeses
Skim milk cheese for manufacturing
Spiced cheeses
Part-skim spiced cheeses
Spiced, flavored standardized cheeses
Swiss and Emmentaler cheese
Swiss cheese for manufacturing

pickled Egyptian cheese, is made from whole or partly skimmed buffalo milk, and Laplanders make a product similar to very hard Swiss cheese from reindeer milk.

All other ingredients are considered optional and must be declared on the label. Optional ingredients include:

- Bleaching agents, such as benzoyl peroxide or a mixture of benzoyl peroxide, potassium alum, calcium sulfate, and magnesium carbonate. Cheeses that are bleached include Blue, Gorgonzola, Provolone, Caciocavallo, Siciliano, Parmesan, Romano, and Asiago.

- Water-binding gums that help to

bind the moisture to the curd. These gums include gum tragacanth, carob bean gum, guar gum, carrageenan, and gelatin. Neufchatel, cream cheese, and pasteurized process cheese spreads may contain this additive.

- Preservatives—such as sorbic acid or potassium sorbate—can be added to consumer-sized cuts and slices of most cheeses to inhibit growth of mold.

- A smoked flavor is imparted to some cheeses by the addition of a clear solution, prepared by discharging wood smoke into water. The label on these cheeses must include the statement: "with added smoke flavoring."

The Arabian merchant, whose cheese

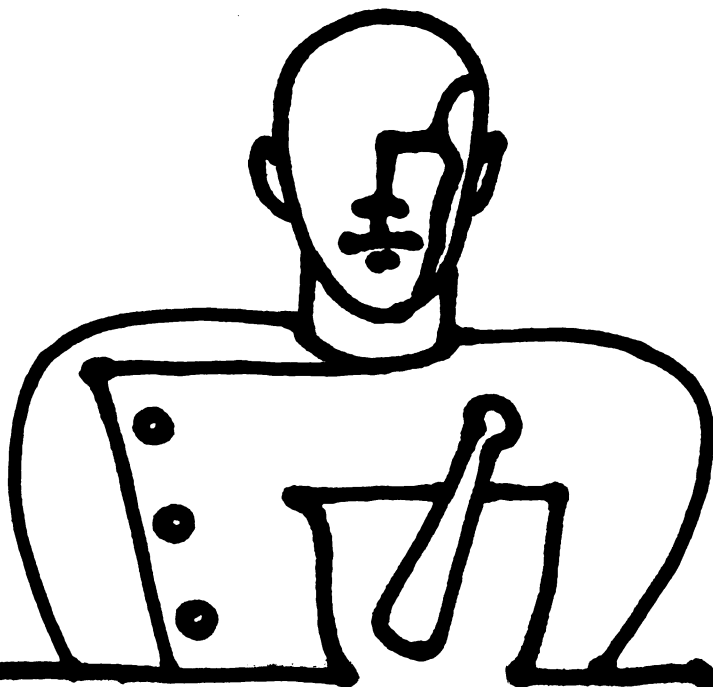
never would have measured up to FDA standards, probably would be as confused as many consumers are by the current negotiations about cheese and cheese substitutes (and imitations and analogs and all the rest). But, when the regulations go into effect and the present confusion is ended, consumers will be better able to choose the cheese—or cheese substitute—they want.

That merchant and his camel sure didn't know what they started, did they?

Carol Ballentine is a member of FDA's Public Affairs staff.

The View From Behind The Rx Counter

Mary Munson Runge is an Oakland, California, pharmacist and the president of the American Pharmaceutical Association. She is questioned here on pharmacists' views on a wide range of topics—from education to PPI's to counseling to free ice cream cones. Doing the questioning is Roger W. Miller, editor of FDA CONSUMER.



Q. *Mrs. Runge, let's talk first about your profession. Where is pharmacy headed as a profession? Will there be multiple subspecialties, such as nuclear pharmacy, or will most pharmacists still be retail-based generalists?*

A. Fortunately for the public, the pharmacy profession has become as strongly patient-oriented as it historically has been product-oriented. We have a new clinical dimension to our traditional role. Pharmacy has had special interest areas for years, but now we are starting to develop formally recognized specialties, nuclear pharmacy being the first to achieve this status. I don't think we'll ever see the disappearance of the general practitioner—the family pharmacist who is the most available health professional to the public. Whether the pharmacy is the entire physical plant or an integral self-contained entity of a large retail outlet, it is basically a medical and health center featuring professional service and products. It's interesting to note that other professionals including dentists and lawyers are experimenting with the concept of providing their services in a retailing environment. It will be interesting to see how the public reacts.

Q. *What about women in the profession? I believe you're a trail-blazer as the first woman president of your association. Will women be taking over the profession? I noticed just the other day that the incoming class at the University of Texas College of Pharmacy is 55 percent women.*

A. There are schools of pharmacy now that have 50 percent or more women. We are here to stay, but we will not be taking over the profession. We will become equal members. I think we see this throughout the general population. Fields that were predominantly male fields, or thought of as male fields, are now being entered by women.

Q. *You draw a distinction between "taking over" and "being equal members."*

A. Right! Exactly.

Q. *What's your position on the 6-year professional doctorate degree versus the current 5-year bachelor's degree as the sole degree for pharmacy?*

A. My position is the same as the policy of APhA: that we should have one degree which is oriented toward clinical practice and that should be a doctoral degree. But, as to the length of time this degree should require, I think there should be more study by people more qualified than I am as a practitioner.

Q. *Does Eugene V. White's concept of family pharmacy practice and patient counseling have a chance to succeed in pharmacy practices other than in small suburban or semi-rural communities?*

A. Yes, I think it does. As the consumer is made more aware of the pharmacist's capability and the

information the pharmacist can supply, the consumer will be demanding more and more patient consultation—not only on prescription drugs but non-prescription drug products as well.

Q. *Let's take your practice and that of your husband as examples. I believe you have a pharmacy in a lower income urban area, while your husband's, in a higher income area, is of a different nature but still urban. In your dinner table conversation, who talks the most about counseling? Or is it different types of counseling you both do?*

A. I think we both do an equal amount of counseling. We both feel quite strongly that we must assist the patient—counsel each patient individually—because this is a part of our professional duty, even though we work in opposite ends of the income spectrum. The only difference might be in the manner in which it is presented—depending on the educational level of the patient.

Q. *Do you do more OTC counseling than he does?*

A. No, because the pharmacy in which I practice is a prescription pharmacy with a very small OTC inventory. His pharmacy is of a more general nature.

Q. *Obviously, you feel very strongly about patient counseling. Do you think pharmacy students today are being adequately prepared to perform patient counseling?*



"I have all the confidence in the world that the neighborhood pharmacy will continue to exist because there will always be patients who want personal service and are willing to pay for personal service."

A. Very definitely. With the advent of the clinical programs in the schools and the introduction of formal internship and externship programs that are administered by the schools, the students are being very well prepared.

Q. *Let's dwell a bit on communicating to pharmacists. Don't the drug companies with the "detail men" have pretty much of a stranglehold on prescription drug communicating? After all, they go right into the store, put a big smile on their faces, and sell their products by simply providing information.*

A. I would say that maybe in past years this was true, but it is no longer true and is becoming less and less true. As the new graduates come out into practice, their knowledge of clinical pharmacology, bioavailability, and drug interactions is much greater than when I graduated—30 years ago.

Now the detail men cannot come in with what I call "snow jobs." Pharmacists are more and more aware of biopharmaceutics and they're asking penetrating questions. Continuing education programs are assisting pharmacists to ask for technical information. In our pharmacy, if we are heavily detailed and we ask what we consider very important and pertinent questions about the drugs and when we don't get what we consider to be proper answers, we tell the detail men to go back and find out.

Q. *Why are the pharmacists today better qualified to ask these questions?*

A. The educational and continuing educational process is better.

Q. *Is the trade press also better?*

A. Well, I think that the regulation that requires that all advertisements in trade journals list everything that is included in the package insert is excellent. This gives the pharmacist an opportunity even when he doesn't have much time to otherwise obtain information. Just leafing through a trade press journal provides a lot of basic information on which to make a decision on a drug.

Q. *What about the information on OTC drugs? Aren't pharmacists forced to rely pretty much on labels, package inserts, and drug company advertisements?*

A. No. They were at one time but APhA is just getting ready to release the sixth edition of its "Handbook on Nonprescription Drugs," which has been widely used, not just by pharmacists, but also by pharmacy schools. Because of this, pharmacists are well able to get information other than that given to them by the manufacturer. But I would like to point out that in the beginning it was like pulling teeth to get any information out of a manufacturer.

Q. *What about FDA? Is it doing the job of communicating that it should do? We put out the DRUG BULLETIN; it comes out six or seven times a year and goes to nearly a million professionals—doctors, dentists, pharmacists. . . .*

A. Yes, we get two in our household.

Q. *—of course, but the DRUG BULLETIN is a drop in the communications bucket, isn't it?*

A. In a sense. But we can't just rely on one source of information. Pharmacists read widely. APhA communicates with its members via a weekly newsletter. There is a column in the newsletter on drug recalls, and with the multiplicity of journals we have now on the market the pharmacist is able to get the necessary information.

Q. *Getting around to the OTC panels: Are pharmacists being informed in a timely fashion of the conclusions of these panels?*

A. Yes, we have been reporting the panel conclusions in our association publications. However, if you remember, when the Antacid Panel released its findings pharmacists went up in smoke because, as you know, one of the panel's recommendations was to include on the label of the antacids, "ask your physician or pharmacist." The FDA Commissioner disagreed with that statement and deleted the reference to pharmacists. Of course, pharmacists didn't agree with that



"You have to realize that when a patient comes into the pharmacy and buys an antacid, the pharmacist is there to be asked questions. Nine times out of ten the patient is not going to go home and call his physician."

deletion. You have to realize that when a patient comes into the pharmacy and buys an antacid, the pharmacist is there to be asked questions. Nine times out of ten the patient is not going to go home and call his physician.

Q. *Mrs. Runge, you are quoted in a recent issue of AMERICAN PHARMACY as saying: "We are being overlegislated to the detriment of our profession." Could you give us any specific examples in terms of overlegislation or overregulation, particularly by FDA?*

A. The first one that comes to mind is the most recent one where hospitals that are doing unit dose packaging for their own use are being required to follow the Good Manufacturing Practices. In my opinion that is a little far out.

Q. *That's where the hospital was using a machine to do the packaging.*

A. Yes, because many drugs are not put out by the manufacturer in unit dose packages. Yet APhA and others have recommended that this is a way to overcome medication error and provide identification from the bottle to the patient, or, as they say, from the manufacturer to the mouth. It is unreasonable to expect any pharmacist who does repackaging—or split packaging—to comply to all the standards and tests that FDA is requiring.

This is just one instance of FDA overdoing it, but usually when I talk about overlegislation I'm talking about it on a State level, which of course affects the pharmacists to a much greater

extent than the Federal regulations. It is on a State level that we are really getting clobbered, with such things as mandatory patient consultation, mandatory patient profiles, mandatory price posting, and mandatory continuing education. Everything is becoming mandatory.

Q. *Your association has been in the forefront of the movement to pass drug product selection laws. Are you satisfied by the way most of these State laws have been written, and what do you think of the Federal Trade Commission's model law?*

A. I am not satisfied with some of the State laws. I think if they had utilized the model law that APhA proposed over a decade ago, we would have been better off. The FTC model follows very closely what we had recommended except we feel that there should be an addition that will prevent anyone other than the pharmacists making the (drug product) choice. In other words, those of us who are employee-pharmacists cannot be dictated to by an employer or a corporation. It should be up to the pharmacist to make the selection.

Q. *Which, in a way, brings us around to patient package inserts, which your association has also endorsed for some time. But you testified recently that you believe that pharmacists, as well as physicians, should have the discretion on supplying the PPI. I think it is hard for the public to understand why a patient shouldn't be given the information about the drug he's taking. Can you give us some examples about when you think the patient should not be supplied with medication information?*

A. When either the physician or the pharmacist knows that the patient is not capable of weighing the ratio of benefit to risk in taking the drug, the patient should not be provided PPI information. Now, as we know, almost every drug can cause a reaction or have some side effects in somebody. Many patients who read the side effects immediately get the side effects. This is especially true with chemotherapy. If a patient is given a PPI on some of the chemotherapeutic drugs, he may immediately stop taking them. Somebody has got to be there to explain to him that there is a risk in taking the drug—but there is also a benefit—and that the risk in not taking it is greater because, as you know, you might die.

Most physicians know their patients. Many pharmacists know their patients. I've worked in the same pharmacy for 10 years and served the same people for 10 years. I know the ones you can tell everything to and the ones you can't. To have a law that makes it mandatory—that says you give the information regardless—such a law serves no purpose. You've got to allow for professional prerogative—professional knowledge about the patient.

Q. *Is the consumer really benefiting from generic substitutions?*

A. Yes, and there are studies in Florida and the FTC report that prove they are.

Q. *Do you think they are in your own practice?*

A. Yes, I know they are.

Q. *Is the FDA Approved Drug List getting wide circulation*



"When either the physician or the pharmacist knows that the patient is not capable of weighing the ratio of benefit to risk in taking the drug, the patient should not be provided PPI information."

among pharmacists? If not, how are they making their generic substitutions?

A. For one thing, as I understand it, the FDA list is being held up and is not approved for general distribution. So, of course, it is not being widely distributed. Pharmacists are making generic drug substitutions—or drug product selections—through bioavailability data made available by our association. Pharmacists are now asking the manufacturers for bioavailability data before they order the product, and it is becoming available. Pharmacists are not pulling straws out of hats.

Q. Along the lines of generics, what do you think of the recently adopted practice of some drug companies printing prescription forms for doctors? You know these are those convenient forms in which the doctor's name and the drug company's brand name are also printed along with wording such as "dispense as written." They make it so easy for the doctor; all he has to do is put the number of tablets and dosage.

A. It is highly unethical. In some States it is even illegal. I think it removes professional judgment. I think sooner or later the drug firms will alienate both pharmacists and physicians if they continue to do this.

Q. I take it you don't want to hire a sign painter for your store. Well, how does the consumer get protected against price gouging?

A. The only way is by communication with the pharmacist and dealing with the family pharmacist. APhA has campaigned to make the consumer aware that there is no advantage in, and there is some danger

in, shopping for a pharmacist every time a patient needs a prescription dispensed. As you pick a physician you should also select a family pharmacist—one you have confidence in and you communicate with.

The "sign painter" refers to the fact that in California the State Board of Pharmacy requires drug prices to be listed, in each of three quantities, on a sign. With the rising inflation, the price has gone up on practically every order that comes in, which means that the prices are continually changed on one of the items on that sign. Our (California) regulations state that the prices must be up to date. Which means that you can be changing prices daily.

Q. So you've found the California law difficult to live with?

A. Yes, and it really has not served the consumer. Take the elderly, for example. Old people take a lot of drugs but in order to use the signs they would have to go from pharmacy to pharmacy to check out the signs. These people often are not capable of doing that.

Q. Do any people price shop on prescription drugs?

A. There are a lot of people on maintenance medication who do, but many times they still can't. I've had patients who've come in and looked at the signs and they'll say "Well, how does this work? The sign says the price is for 30 but my prescription is for 15. Does that mean that it's half the price?" You see, it really is not helping the consumer.

Q. Finally, Mrs. Runge, what happens to neighborhood

pharmacists? Aren't they being slowly gobbled up by the chains because of the economic facts of life? Or can that person who practices personal pharmacy, who builds up consumer trust, and who even gives out a free ice cream cone once in a while—can he or she continue to compete?

A. Well, in California you can't give out free ice cream cones. It's against the law. You can't offer anything free. But I have all the confidence in the world that the neighborhood pharmacy will continue to exist because there will always be patients who want personal service and are willing to pay for personal service. They don't want to become a number. I know of prescription-only and chain pharmacies that exist in the same block. The prescription-only pharmacist competes simply because his patients want personal service. They want him to call them by name when they come in—which he will usually do. They want to be able to charge prescriptions. They want to have them delivered and all. So, I think, as we go down the pike, that many pharmacists will no longer have the general type pharmacy. I think that pharmacists will go more and more into the professional pharmacy with related over-the-counter items . . .

Q. More genuine drugstores—?

A. Yes, because I think it will become more difficult for one individual to open a massive number of stores like the chains. I don't think we can compete on that basis. But certainly in the prescription department, with personal service, we can compete any day.

Back about 40 years ago, the comedy team of Olson and Johnson appeared in a zany stage show called "Hellzapoppin." They did one routine that went like this: The phone rings and Olson answers. "Hello," he says.

"Yes . . . that's good . . . that's bad . . . that's good . . . no, that's bad . . . that's good . . . okay. You're welcome. Goodbye." After he hangs up the phone, Johnson looks at him and says, "What was that all about?"

"Oh, that was a friend," Olson replies, "and I was helping him sort strawberries." This article is about making decisions.



FDA's regulatory actions of recent years concerning unsafe food additives or other food contaminants—cyclamates, nitrites, diethylstilbestrol (DES), and saccharin, for instance—have been opposed by those who believe their interests are adversely affected by these actions. Some have suggested that consumers should have more “freedom of choice” to buy or not buy a product whose use has been determined by the Agency to be a risk to health. Instead of banning a risky product from the market, these arguments run, FDA should devote its primary efforts to educational programs and correct labeling about the risk so the consumer would have the information he needs to decide for himself whether he wants to take the particular risk. In a recent talk to the Association of Food and Drug Officials in Washington, FDA General Counsel Richard M. Cooper took issue with these arguments and pointed to some consequences of such a “freedom of choice” policy that make it clearly unacceptable to this Agency. The paragraphs below come from the closing part of Mr. Cooper's address: “Freedom of Choice in the Real World.”

“We are committed to freedom of choice in the important matters of life, about which we believe individual autonomy should govern. In religion, in morals, in politics, in arts, sciences, and ideas generally, we believe that people should be free to choose as their inner lights guide them. We believe that people do not need or want to be protected from the risk of error in such matters, and that the history of Governmental efforts to say what is error and to seek to prevent it demonstrates that such efforts are the essence of tyranny. We also believe that people should be free to make fundamental decisions about their lives—where to live, where to work, whom to marry, whether to have children, how to spend free time, and so on. Here, too, we as a society believe with Augustine that the value of free choice outweighs all the harms and unhappiness that may result from decisions that may prove to have been wrong.

“When we come to choices among foods, however, the claims of individ-

ual autonomy are very different. Certainly the Government shouldn't tell me what to eat; that would be unthinkable. Free exercise, however, is a quite different matter. The banning of food additives cannot be compared to the banning of religious sects or political parties or literary clubs. . . .

“When Patrick Henry said, ‘Give me liberty or give me death,’ he wasn't talking about the composition of foods. Some things in life are vastly more im-

Food Safety And The Freedom Not To Choose

portant than others. Our human dignity, our distinctively human faculties, our spiritual, moral, political, emotional, intellectual, aesthetic, and social values *are* expressed in decisions about religion, politics, art, science, and the course of our lives. But, in general, they are not expressed in decisions about additives in foods.

“I enjoy consumption about as much as the next person, but I am quite content to leave it to the Government to decide on safety grounds what substances may not be added to food I eat, or what pollutants may not be added to the air I breathe (should there be freedom of choice in pollutants?), or what defective parts may not be included in the engines of airplanes I fly in. In general, I believe that when the Government bans an additive or a pollutant or a defective part, it doesn't interfere with my ability to live in accordance with my personal beliefs and values.

“I say ‘in general’ because there are exceptions. There *are* some substances

that are peculiarly important and that people feel strongly about. Such substances are, as a practical matter, unbannable. Examples are alcohol and tobacco. I suspect we are learning that saccharin—or, at least, the last non-nutritive sweetener—is a third. In this democracy, if a majority of the people (as reflected by their elected representatives) want to go on consuming these substances, they should be able to.

“But the public demand for these substances that have special appeal does not justify any general argument that the centerpiece of food safety policy should be freedom of choice. I submit that, as to the generality of risks that may arise in the food supply, the public wants protection, not information and not freedom of choice. People would rather spend their time and energy on the areas of life where freedom is really important and not have to worry about the toxicology of the food supply. Indeed, freedom of choice on food safety matters would distract time and energy away from activities that are expressions of far more important freedoms.

“The general and strong presumption in food safety policy should be for protection and against freedom of choice.* Where the public registers its determined preference to keep a particular risky substance in the food supply, our democratic political system can and should find a way to keep it in. I would expect such cases to be quite rare.”

*I am, of course, referring to the policy toward risks that foods pose to the generality of the population and that under current law would warrant a ban (e.g., risks of cancer, risks of acute poisoning). Foods that present risks only to a relatively small and relatively well-defined group within the population (e.g., people allergic to a particular additive, people on salt-free diets, people with certain nutritional diseases) warrant a different policy. In general, such people have been told by their doctors to avoid certain substances. Consequently, they are not looking for information with which to make complex risk-benefit decisions; they simply want a complete list of ingredients: if a food contains the substance to be avoided, they won't buy the food. Here, an information strategy is tolerably effective; although a ban would protect those who should avoid the substance but whose condition has not been diagnosed, it would impose an unacceptable loss on the rest of society. . . .

Regional Reports

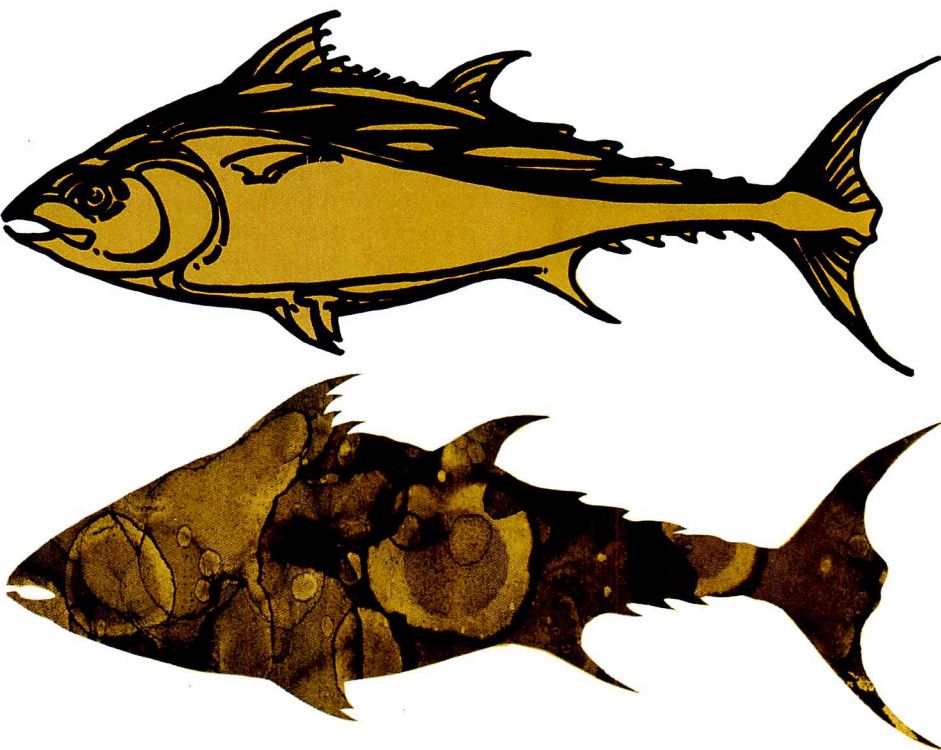
The Case of the Cases of Decomposed Tuna

Donna Pascarella felt a distinct sense of déjà vu that day in September. After swallowing a second spoonful from a can of tunafish, she began to feel definitely ill. Her throat burned. She was nauseated. She stopped eating the tuna and called the Monroe County Health Department.

Mrs. Pascarella recalled a similar experience she had once before after eating tunafish. After the first adverse reaction, she always tested tuna by eating it directly from the can with no other foods. That's what she told Jim Evans, investigator with FDA's Syracuse Resident Post, when he called to check out her complaint, relayed to FDA by the county health department. The reaction lasted about 12 hours, Mrs. Pascarella told Evans, and afterward she felt fine. She hadn't bothered to call a physician. No one else in her family had eaten the tuna. She said she had bought the product—a 6½-ounce can of Breast O'Chicken Chunk Light Tuna—at a supermarket in Greece, New York, about 2 weeks earlier. The code number on the can was GPHCO/11519, known in FDA terminology as the lot number.

The manager of the supermarket told Evans he had received no complaints of illness caused by canned tuna. He and Evans checked both the store shelves and the stockroom, but all the cans with that code apparently had been sold. However, the manager supplied the next bit of information needed to locate lot GPHCO/11519: the name and location of the warehouse that supplied the tuna to the supermarket.

Buffalo District took up the search. Investigator Joseph Famiglietti and Inspector Russell Thompson visited the Niagara Frontier Food Services Lakeside Warehouse in Buffalo to examine the firm's records and collect samples of tuna with the suspect code. The two men found 171 unopened cases of the product, each containing



48 cans, and one opened carton that held 24 cans. An examination of the records showed the product had been packed by Sun Harbor Industries in San Diego. The samples, collected by Thompson, were sent to the San Francisco District laboratory for analysis.

Mrs. Pascarella's symptoms were typical of scombroid-histamine allergic reactions. Histamine and histamine-like substances are chemicals formed in the flesh of scombroid fishes (such as tuna, bonito, and mackerel) by bacterial action that occurs during the decomposition process after the death of the fish. Some people are not sensitive to these chemicals. Others, like Mrs. Pascarella, have what approximates an allergic reaction, experiencing nausea, vomiting, blistering of the mouth, diarrhea, headache, and cramps.

From the symptoms Mrs. Pascarella reported, the laboratory personnel in San Francisco guessed they were looking for histamine. However, the organoleptic test failed to reveal any evidence of the decomposition that leads to formation of this chemical. But the chemical test, made with a photofluorometer, turned up positive

results of the presence of histamine. In fresh tuna, histamine is present at a level of 1 milligram (mg) per 100 grams (gm). In the samples from lot GPHCO/11519 chemist John Newton found levels of histamine ranging from 13 mg per 100 gm to 61.9 mg per 100 gm (with an average of 28 mg per 100 gm).

The varying results between organoleptic and laboratory tests were explained by Walt Staruszkiewicz, the FDA chemist who developed the fluorometric test, as follows: since in commercial practice tuna undergoes pre-cooking prior to canning, much of the odor of decomposition is lost and the effectiveness of the odor test is impaired.

The laboratory sent the test results back to the Buffalo District Compliance Branch, which filed for seizure of the cases held at the Buffalo warehouse.

On December 7, a U.S. marshal seized approximately \$5,050 worth of the tunafish at the Niagara Frontier Food Services warehouse. The tuna was eventually destroyed, under supervision by the Buffalo District, by being buried in a local sanitary landfill.

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.

REGION I

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

The 200-milligram size tablets of a drug labeled as being quinidine sulfate were recalled by Danbury, Inc., a drug manufacturer in Danbury, Connecticut, because of a labeling mixup on containers of raw ingredients used to prepare the firm's products. The firm notified FDA's **Boston District** of the recall and told investigators that containers of bulk quinine sulfate had been labeled mistakenly as quinidine sulfate. Quinidine sulfate is a prescription cardiac depressant used in treating arrhythmia; quinine sulfate is used to treat malaria. The investigators checked the firm's records and found several violations of Good Manufacturing Practice Regulations that may have contributed to the mixup. The firm agreed to correct the violations. Since the product had not reached the consumer level, there were no injuries from the mistake.

Final analysis of all samples collected around the Three Mile Island Nuclear Power Station following the March crisis confirmed earlier reports based on initial sampling: food and water supplies in that area contain no detectable radiation—with the exception of some milk samples that showed traces of iodine-131. The levels of iodine-131 in the samples are many times lower than FDA's protective action levels and demonstrate no threat to public health. The samples were collected by FDA's Region III investigators and flown to the Agency's Winchester Engineering and Analytic Center (WEAC), Win-

chester, Massachusetts, in the Boston District, for analysis. The 1,895 samples included: 1,206 of raw, skim, and processed milk; 48 of raw goat's milk; 14 of animal feed; 145 of river and tap water; 7 of animal thyroid specimens; 112 of eggs; and 359 of processed foods and fresh vegetables. The samples were analyzed for the presence of iodine-131, cesium-137, barium-140 or ruthenium-106, and potassium-40.

REGION II

New Jersey, New York, Puerto Rico, Virgin Islands

Following up a trade complaint, a **New York District** investigator found 240 cans of ackee, the "national fruit" of Jamaica, at C Kenneth Imports Co., Bronx Terminal Market, New York City. FDA has systematically detained imports of canned ackee since 1975, because there is no known chemical method to isolate two naturally occurring poisonous substances—hypoglycin-A and hypoglycin-B—that are found in the seeds and in the pulp when it is green or over-ripe. The importer destroyed the fruit.

The U.S. Court of Appeals for the Third Circuit in Philadelphia upheld FDA's authority to seize an unapproved formulation of the drug furosemide. The product in question was manufactured by Pharmadyne Laboratories, Inc., Hackensack, New Jersey. FDA's **Newark District** inspected the Pharmadyne plant in response to a trade complaint and found the firm was marketing furosemide, a diuretic, without an appropriate NDA. The District warned the firm that this was illegal, but the company ignored the warning and continued to market the drug.

Reports that three people ended up in the hospital after taking the drug reached FDA. When the Agency began action to seize all unapproved versions of furosemide—at Pharmadyne and two other companies—Pharmadyne challenged the Agency's actions in court and contin-

ued to distribute the drug.

Approximately 5 months after the initial inspection the court ruled in FDA's favor. Pharmadyne sent letters to all distributors requesting the return of the product. Newark District reviewed all the firm's products and found a total of 15 generic drugs—including furosemide—that required NDA's before they could be marketed legally: opurinol tablets (100 and 300 milligrams); carisoprodol (350 mg); chlorothiazide (250 mg containing 0.125 mg reserpine); dicyclomine HCl tablets (10 mg); diethylpropion HCl T.D. tablets (75 mg); dipyrindamole tablets (25 mg); doxylamine succinate with B₆ tablets; furosemide tablets (20 and 40 mg); hydroxyzine HCl tablets (10, 25, and 50 mg); hydroxyzine pamoate tablets (25, 50, and 100 mg); and probenecid tablets.

When Newark District investigators inspected Importers Service Corp., Jersey City, New Jersey, they found insects crawling in bags of gelatin. The bags themselves were contaminated by rodent urine and excreta. When laboratory analysis confirmed the investigators' findings, the District initiated seizure action. Forty-two 50-pound bags of gelatin, valued at \$3,700, were seized.

FDA districts on both sides of the country got involved when the owner of Sierra Nuthouse, a retail shop in Fresno, California, reported to the San Francisco District that some dried Australian figs smelled like mothballs. When laboratory analysis revealed that the figs were contaminated with naphthalene, a chemical used to make mothballs, the District notified the Newark District, requesting an investigation of Homa Co., of Parsippany, New Jersey, the product's distributor. The investigation revealed that figs—as well as dried pears and peaches—at the distributor's warehouse were also contaminated with the chemical. The firm destroyed approximately 6,500 pounds of the contaminated fruit, valued at about \$12,000, by denatur-

ing it and burying it in a local landfill.

Officials from the U.S. Department of Agriculture (USDA) told FDA's **Buffalo District** that New York farmers were buying prescription veterinary drugs from unauthorized dealers. The District investigated and found that the dealers had obtained the drugs from Richard Ball, doing business as IBA, in Varysburg, New York. After discussion with his legal representative and the District investigator, Ball agreed to retrieve all unsold prescription drugs and to cease the illegal practices. Prescription veterinary drugs, if misused, could result in unsafe residues in edible animal tissues.

The records kept by Sterling Cooperative, Inc., were incomplete, Buffalo District investigators reported, and the employees reviewing the records weren't noticing significant deviations that could point to food contamination. Inaccurate temperatures were being recorded; foods were not being processed properly. The situation was serious since the firm was a canner of low-acid foods, such as green beans and pumpkin, that are particularly susceptible to contamination by *Clostridium botulinum*, the cause of the deadly food-borne disease, botulism. Employees told the investigators that 54 cases of canned green beans had been destroyed because of swollen cans—a sign of food spoilage. The District ordered the firm to stop production until it obtained a Temporary Emergency Permit, and then asked for assistance from the New York Department of Agriculture and Markets to stop the distribution of the firm's products within the State or in interstate commerce. Shortly thereafter the firm went out of business.

The U.S. District Court for the Southern District of New York ruled that \$18,000 worth of Hilo Ear Remedy for cats and dogs must be destroyed because the distributor could not provide evidence that the drug was either safe or effective. Under FDA regulations, veterinary drugs—like drugs for people—must be proven safe and effective for their intended use before they can be legally

marketed. The drug, distributed by Hilo Products, Inc., Glenford, New York, is recommended for treatment of eczema caused by ear mites in dogs and cats. The Buffalo District initiated seizure of the product, an action contested by the firm, after a series of inspections revealed violations of Good Manufacturing Practice regulations.

Two sizes of Acetamin, an over-the-counter sedative, were seized by a U.S. marshal at Dorasol Laboratories, Hato Rey, Puerto Rico, because the drug wasn't as soothing as it should have been. FDA's **San Juan District** initiated the seizure of 12 1-gallon and 1,440 15-cubic centimeter bottles of the product after laboratory analysis revealed samples to be 20 percent subpotent. The samples were collected as part of a routine inspection. In addition, the District sent a regulatory letter warning the firm that recurring violations could result in prosecution.

San Juan District investigators made a routine inspection at Pueblo International, Inc., the largest food distribution warehouse in Puerto Rico, and found food contaminated by insects and rodents, packaging that was gnawed, and nests of baby mice. As a result of the inspection, the firm destroyed \$2,000 worth of contaminated food, including baby cereal, ricemeal, and pancake and pie mix. The District initiated seizure of an additional \$26,000 worth of products, which the firm intends to recondition.

REGION III

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

One lot of contaminated cocoa beans brought on a legal battle between FDA's **Philadelphia District** and a Philadelphia warehouse, Atlantic and Gulf Stevedores. The District initiated seizure of the lot—650 bags—after a routine wharf inspection revealed the beans were contaminated by mold and insect filth. The warehouse agreed that the beans were adulterated but contended in the U.S. District Court for the East-

ern District of Pennsylvania that it had the right to export the product under Section 801 (d) of the FDC Act. One stipulation of this section is that food adulterated under FDA standards may be exported if it meets the standards of the foreign buyer's country. The Government contended, however, that this section applies to goods only under certain conditions, none of which were met by the firm. In this case the beans could not be exported because they became adulterated after attaining domestic status. Judge Edward Becker found that the beans were adulterated and ineligible for export, and condemned them. The firm appealed the decision, then withdrew the appeal and posted a bond for reconditioning of the product.

Colley Provision Co., Norfolk, Virginia—a meat packer and distributor of foods for ocean-going ships—has reopened after being closed down by the U.S. Department of Agriculture (USDA). USDA ordered the firm closed after a routine inspection of the food distribution facilities by FDA's **Baltimore District** revealed widespread rodent infestation. The District requested assistance from USDA, through the Interagency Regulatory Liaison Group (IRLG), because that department can take immediate action. IRLG is composed of five Federal regulatory agencies that have joined together to increase their efficiency and better protect the public. The firm had to recondition its products and make its premises rodent proof before it was permitted to reopen.

REGION IV

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

Over 180 mice were killed during a massive cleanup operation by Food World Warehouse, a North Carolina supermarket chain. The firm cleaned its warehouse in High Point after investigators from FDA's **Atlanta District** inspected the premises and found evidence of rodent infestation. Approximately 1,400 lots of food, valued at almost a million dollars, were seized at the District's request.

The chain destroyed approximately 64,000 pounds of defiled food, an estimated loss of \$50,000.

FDA's **Orlando District** recommended a mass seizure of foods stored at the Grand Union warehouse after an inspection revealed the Miami food storage facility had widespread rodent infestation. Before seizure could be initiated, however, the firm agreed to recondition all foods susceptible to rodent contamination. Under supervision by the District, the firm segregated and destroyed all foods that had become contaminated—about 300,000 pounds. In addition, the firm repaired and renovated its facility to prevent further rodent problems.

REGION V

Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Ingman Laboratories, Inc., agreed in the U.S. District Court for the District of Minnesota to stop analytical testing of drugs until the firm can bring its laboratory facilities into compliance with FDA Good Manufacturing Practice regulations. Ingman, an independent testing laboratory in Minneapolis, was testing medicated animal feeds and drugs for both humans and animals. Small manufacturing firms submit these products to Ingman for potency and identity testing required by FDA's Good Manufacturing Practice regulations. The court action was initiated by FDA's **Minneapolis District** after a routine inspection revealed that the analytical procedures used by the firm were unlikely to yield correct test results.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

The abrupt closing of a Dallas firm that performed synthetic hair implants caused grief to the firm's customers, many of whom had received—and were stuck with—only partial transplants. Affiliated Laboratories of Dallas, Inc., permanently closed its Dallas office after being inspected by the Texas State Health Department and FDA's **Dallas Dis-**

trict. The inspection was part of a national FDA investigation implemented after the Agency received numerous complaints from consumers about firms that perform this operation. The investigators found the Dallas firm's employees, who were not wearing appropriate sanitary garb, using apparently unsterilized needles to sew synthetic "hair" fibers to patients' scalps. Bags of the fibers were lying open and apparently never had been sterilized. Employees told the investigators that heat sterilization would ruin the fibers; the employees seemed unaware of other aseptic procedures. The District filed for and received approval to have the fibers seized; but before this action could be taken the firm's officials fled, leaving behind both unhappy customers and, according to the investigators, several unpaid creditors.

Leroy Slack's mistake was selling veterinary drugs to two FDA investigators. It was a mistake because Slack, owner of Moreau's Drug Store in Vinton, Louisiana, sold the prescription drugs to the men without the necessary prescriptions, even though he had been warned by FDA 6 months earlier that dispensing prescription drugs without prescriptions was illegal. The investigators—from FDA's **Baton Rouge and Lafayette, Louisiana, Resident Inspection Posts**—made a series of undercover purchases from Slack and reported his violations to New Orleans District, which filed for legal action in the U.S. District Court for the Western District of Louisiana. Slack signed a consent decree of permanent injunction that prohibits him from dispensing prescription drugs illegally. The decree also provides ways for FDA to monitor his activities in the future.

REGION VII

Iowa, Kansas, Missouri, Nebraska

FDA's **Kansas City District** supervised the destruction of \$19,000 worth of Banfi wines that had been irreparably damaged by seawater. Cases of the wine were shipped from Italy in a large sealed container designed to fit onto a semitrailer. The

shipment landed in New Orleans, Louisiana, and was trucked to St. Louis, Missouri, where inspection by customs officials revealed the container was filled with seawater. The broker for the importing firm, a distributor in Springfield, Illinois, requested FDA's assistance. The firm destroyed the shipment after District investigators examined the shipment and found extensive water damage, wet and damaged labels, and possible contamination of the bottle caps.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

FDA's **Los Angeles District** inspected Ultra Drug Co., Inc., San Diego, after learning from the New-ark District that the firm had received a shipment of an illegal formulation of the drug furosemide from Pharmadyne Laboratories in Hackensack, New Jersey. Pharmadyne does not have an approved New Drug Application for the product, a generic version of an approved diuretic drug produced by Hoechst-Roussel. Hoechst-Roussel is the only firm with FDA approval to market furosemide. The District initiated seizure of over \$10,000 worth of the product.

Several former employees of the Tucson Plasma Corp., Tucson, Arizona, brought on an FDA inspection at the company by reporting to FDA's **Tucson Resident Post** that the firm was engaging in practices hazardous to health. The inspection confirmed the reports, revealing improper storage of blood plasma, failure to test plasma for hepatitis, and other violations that constituted health hazards. The Bureau of Biologics suspended the firm's license to ship plasma. The firm cannot resume interstate operations until FDA is satisfied that the violations have been corrected.

REGION X

Alaska, Idaho, Oregon, Washington

Suffering from diarrhea and flushing, the woman called the Seattle-King County Health Department and reported she had become sick after

eating at a local restaurant. The department called FDA's **Seattle District** and described the symptoms, which were identified as a possible histamine reaction. Histamine is a chemical which may form in food—particularly fish—during the process of decomposition. Although some people are not sensitive to this substance, others have what approximates an "allergic" reaction. District investigators collected samples of mahi mahi (fish)—the food they thought was most likely to have been the source of the problem—at Booth Fisheries Corp., the Seattle distributor that supplied the fish to the restaurant, and at Washington Fish and Oyster Co., another Seattle company that distributes mahi mahi. Analyses of the samples revealed that the fish, a product of Taiwan, did not contain significant amounts of histamine but

were partly decomposed. The District initiated seizure of 1,450 pounds of decomposed fish, valued at \$1,461.

Between January and March 1979, FDA's Bureau of Medical Devices received nearly 150 complaints of skin injuries resulting from implantations of synthetic fibers into the scalp as a "cure" for male pattern baldness. Consumers reported various injuries, including infections and fibers breaking off in the scalp. In response, FDA issued a news release warning the public of the dangers of this practice, and FDA field offices began investigating firms which were performing the implantations. Seattle District initiated seizure of \$5,000 worth of acrylic fibers used for implantations after investigating one firm, United Laboratories, Inc., in

Bellevue, Washington. The District charged that the product was misbranded because the labeling failed to list hazards, contraindications, side effects, adequate directions for use, and precautions under which licensed practitioners could use the product safely.

About 30 firms around the country—some with additional franchise operations—have been performing the implantations, which consist of implanting hundreds to thousands of synthetic fibers into the scalp. The procedure can cost thousands of dollars, may require 8 hours a day for 2 or more days to be done, and usually is performed by nonphysicians. The procedure can result in skin injuries including infections, scarring, pitting, and other complications requiring medical treatment and, in some cases, plastic surgery.

State Actions

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

Freezing Ruins Cider

A spring trip for 918 cases of Hardin sweet cider turned out to be too cold, when they arrived frozen at their destination. A truck trailer containing the cider was being transported piggyback by railroad flatcar from Seattle to Denver. The liquid evidently froze during the trip and damaged the seals on the bottles. A representative of the Atchison, Topeka, and Santa Fe Railway Co. reported the problem to the Colorado State Department of *Health* after railway employees saw the cider leaking from the truck while it was being unloaded. State

officials consulted with FDA's Denver District and then advised the railway either to destroy the cider or return it to the manufacturer in Seattle for reprocessing. Under direction from Safeway Stores, the product's Denver consignee, the railway destroyed the cider by crushing and burying the containers at a local landfill. State officials witnessed the destruction of the product, valued at about \$3,700.

Kerosene Mystery

Safeway Stores recalled two lots of Horizon Bread after consumers complained to the Virginia Department of Agriculture and Consumer Services that the bread tasted like kerosene. Analysis of samples collected by the State revealed that the bread contained pyrethrins and Malathion—two insecticides—and kerosene. The State notified the Baltimore District, which inspected the Safeway-owned

bakery in Landover, Maryland; the inspection failed to disclose the source of the contamination. The recall involved distributors in Virginia, Maryland, North Carolina, Delaware, and Pennsylvania.

Maple Syrup That Wasn't

The Michigan Department of Agriculture embargoed \$1,700 worth of a product labeled as "maple syrup" at the distributor's warehouse in Detroit and is holding it until it is properly labeled as "table syrup." The misbranding violation was discovered when analysis of samples, collected during a routine inspection, revealed that the product was not maple syrup. Products labeled as "maple syrup" must be made either from the sap of a maple tree or from a water solution of maple sugar. The distributor purchased the product from Oliver Anthony, head of Anthony's Syrup Co., Philadelphia, Mississippi.

FDA Calls for Labeling Yellow No. 5

Beginning in the next 2 years, the Food and Drug Administration will require that the labels of all foods and most drugs that contain Yellow No. 5 (tartrazine), the most widely used color additive, identify the color by name in the ingredient list.

At the present time, the Food, Drug, and Cosmetic Act permits spices, flavorings, and colorings to be declared collectively on food labels. Identifying Yellow No. 5 on labels will enable people allergic to this substance to avoid it. As many as 100,000 people in the United States may be allergic to Yellow No. 5. Most of these people also are allergic to aspirin.

The labeling requirement applies to all foods—including butter, cheese, and ice cream—shipped in interstate commerce after July 1, 1981. This date was chosen because several other labeling changes concerning food products will become effective at that time.

The new requirement establishes two firsts in application of the Color Additive Amendments of the Food, Drug, and Cosmetic Act. It's the first time FDA has required that a specific color be named on the label of any product and it's the first time the Agency has required any mention of the use of color on the labels of ice cream, cheese, and butter. The law specifically exempts these dairy products from having to mention the use of color on labels.

FDA cited Sec. 706 (b)(3) of the FDC Act as authority to make an exception in the case of Yellow No. 5. This provision permits FDA to prescribe conditions under which a color additive may be safely used and the Agency holds that identification of Yellow No. 5. is necessary to establish such safe conditions of use.

For drugs, the labeling requirement goes into effect June 26, 1980, or at the next printing of the labeling, whichever occurs first. The new regulation applies to both over-the-counter and prescription drug products administered orally, nasally, rectally, or vaginally. It does not affect drugs applied only to the skin.

The color must be identified on drug products as both Yellow No. 5 and tartrazine. For prescription drugs, the following statement is to be included in the "Precautions" section of the labeling that goes to physicians: "This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity is low, it is frequently seen in patients who also have aspirin sensitivity."

FDA has required cosmetic products to identify Yellow No. 5 and all other colors by name on the label since May 1976. Notice of the requirement for foods and drugs was published in the June 26, 1979, FEDERAL REGISTER.



Cyclamate Hearing to Reopen

FDA's administrative law judge has been instructed to reopen the hearing on cyclamate to consider some specific questions about the safety of the artificial sweetener that were not adequately addressed at the hearing.

Acting just prior to leaving his post as Commissioner of Food and Drugs, Donald Kennedy said the additional evaluation is needed before a final decision can be made to approve or disapprove cyclamate.

Cyclamate, once widely used in diet sodas and foods, was banned by FDA in 1970 after two studies indicated it caused cancer in test animals. The manufacturer, Abbott Laboratories, on the basis of new studies, petitioned FDA in 1973 to reapprove cyclamate. FDA denied the petition. Under available administrative procedures, however, the company asked the Commissioner to make a fi-

nal Agency ruling on the basis of a record in a formal hearing before an administrative law judge. The hearing was held March 4, 1977.

The judge who presided at the hearing, Daniel Davidson, recommended in his "Initial Decision" last October that the Commissioner deny the petition. The judge found that cyclamate had not been shown to be safe and that Abbott had failed to show it did not cause cancer in man or animals.

In reviewing the judge's recommendation, the Commissioner found that before a final decision can be reached, a more comprehensive analysis of data is needed to make sure that the hearing record is complete and that the decision was based on a careful analysis of all pertinent information.

For example, the Commissioner asked for further information on certain studies that bear on the question of whether cyclamate causes cancer and on the statistical methods used to analyze cyclamate's safety.

After the reopened hearing is held, the judge will make a further recommendation to the Commissioner for approval or disapproval of the sweetener.

X-ray Conference Proceedings

FDA's Bureau of Radiological Health has available the Proceedings of the National Conference on Referral Criteria for X-ray Examinations as well as a series of five videocassettes summarizing the conference.

The conference, which took place in October 1978, explored ways in which the Government and the private sector could cooperate to reduce unnecessary x rays. The Department of Health, Education, and Welfare and Congressman Paul Rogers, chairman of the House Subcommittee on Health and the Environment, cosponsored the meeting.

The five videotapes, each about 25 minutes long, consist of "live" footage with narrative interspersed to provide continuity. The five tapes together give an abbreviated overview of the conference, although each can be viewed by itself. The tapes follow the format of the conference agenda: Introduction and Background; Papers on Causes of Low-Yield X-ray Examinations; Viewpoints on Roles in the Radiological Process; Physician Panel; and Summary of Workshop Reports.

Any or all of the videocassettes may be borrowed without charge from the Training Resources Center (HFX-70), Division of Training and Medical Applications, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, Maryland 20857.

Copies of the proceedings, already mailed to participants and other interested persons, can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. The

stock number is 017-012-00279-0 and the price is \$3.75. The proceedings also will be available in microfiche from the National Technical Information Service at a later date.



Ice Cream Ingredient Labeling

If you're looking for a new label to read, check the ice cream carton in your grocer's freezer. As of July 1, 1979, FDA has required that all frozen dessert products carry full ingredient labeling.

The ingredient list will allow shoppers to make comparisons among various competing brands and will help consumers avoid ingredients which may cause allergic reactions or other adverse health conditions.

Under FDA's new regulation, all frozen dessert products shipped in interstate commerce must list all ingredients in descending order of predominance. For certain dairy ingredients, manufacturers have the option of either listing the ingredients specifically—such as milk, cream, skim milk, and butter oil—or by using the term "milk fat and nonfat milk." Ice cream is exempted by law from requirements for label statements concerning the use of color (as also are cheese and butter).

Ingredients that must be listed by name include products derived from milk, such as whey and caseinates, and all sweeteners, stabilizers, and texturizers.

Frozen desserts covered by the new regulation are: ice cream, frozen custard, ice milk, sherbet, and water ices. Products made from these desserts such as sandwiches and bars are also covered.

Seizures and Postal Service Cases

FILED SEIZURE ACTIONS

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

A total of 24 actions to remove from the consumer market products charged to be violative was reported in June. These actions included 16 of foods: all 16 involved charges concerning contamination. Others included 1 of animal food, and 7 of drugs (including 1 of veterinary).

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
FOOD/Contamination, Spoilage, Insanitary Handling		
Basil, and aniseed/U.S. District Court for the Eastern District of New York 3/28/79	Gel Spice Co., Inc./Brooklyn, N.Y.	Held under insanitary conditions; rodent contaminated.
Beans, rice and annatto seeds/U.S. District Court for the District of Puerto Rico 4/18/79	Monllor & Boscio Sucrs., Inc./Rio Piedras, P.R.	Held under insanitary conditions; contain insect and/or rodent filth.
Beer, canned & bottled, beverage sirups, canned & bottled carbonated beverages, and other foods/U.S. District Court for the District of Wyoming 4/5/79	Western Wyoming Beverages, Inc./Rock Springs, Wyo.	Held under insanitary conditions (warehouse fire).
Cloves, whole/U.S. District Court for the District of New Jersey 3/22/79	Marlo Transportation Corp./South Kearny, N.J.	Held under insanitary conditions.
Flour/U.S. District Court for the Middle District of Florida 3/28/79	Shipped from Coffeyville, Kans.	Rodent contaminated.
Flour/U.S. District Court for the District of Puerto Rico 4/25/79	Miguel Montero, Inc./Hato Rey, P.R.	Held under insanitary conditions; rodent contaminated.
Flour, and starch/U.S. District Court for the District of Delaware 4/19/79	Doxsee Food Corp./Lewes, Del.	Held under insanitary conditions; the starch was rodent contaminated.
Fruit mix, dried/U.S. District Court for the Eastern District of New York 2/2/79	Shipped from Passaic, N.J.	Contains insects and human hair.
Gelatin, ground, bulk/U.S. District Court for the District of New Jersey 4/24/79	Importers Service Corp./Jersey City, N.J.	Held under insanitary conditions; contains insect filth.
Nuts, mixed, unshelled, and unshelled walnuts/U.S. District Court for the District of Massachusetts 5/2/79	Eaton and Eustis Co., Inc./Chelsea, Mass.	Held under insanitary conditions; mixed nuts contain rodent filth.
Pancake mix, pinto beans, popcorn, and rice/U.S. District Court for the District of Nevada 4/30/79	CFS Continental-Nevada, Inc./Sparks, Nev.	Held under insanitary conditions; pinto beans are rodent contaminated.
Peanuts, shelled, salted, and salted mixed nuts/U.S. District Court for the Southern District of Iowa 4/16/79	Hiland Potato Chip of Des Moines/Des Moines, Iowa	Held under insanitary conditions.
Pecans, shelled, and other foods/U.S. District Court for the District of Colorado 4/13/79	Weaver Potato Chip Co./Longmont, Colo.	Held under insanitary conditions; rodent contaminated.
Potato flakes, instant/U.S. District Court for the Western District of Kentucky 4/25/79	Davis Cookie Co./Louisville, Ky.	Held under insanitary conditions.
Rice/U.S. District Court for the Northern District of California 5/3/79	J. Wong's Oriental Foods d/b/a Pacific Oil and Rice Co./San Jose, Calif.	Held under insanitary conditions; some lots are rodent contaminated. Labeling of one lot lacks name and place of business of manufacturer, packer, or distributor.
Rice, popcorn, and stuffing mix/U.S. District Court for the Eastern District of North Carolina 3/20/79	Commercial Bonded Warehouse Co./Raleigh, N.C.	Held under insanitary conditions; rodent contaminated.
ANIMAL FOOD		
Dog food bits containing soybean meal/U.S. District Court for the Western District of New York 4/18/79	Specialized Warehouse Enterprises Corp./Rochester, N.Y.	Held under insanitary conditions.

PRODUCT, DISTRICT & DATE FILED	FIRM & PLACE OF BUSINESS	CHARGES
DRUGS/Human Use		
Acetaminophen drops/U.S. District Court for the District of Puerto Rico 4/23/79	Dorasol Laboratories/Hato Rey, P.R.	Subpotent; circumstances used for article's processing, packing, and holding not in conformity with current good manufacturing practice.
Amitriptyline plus perphenazine combination tablets/U.S. District Court for the Southern District of Florida 3/14/79	MD Pharmaceutical, Inc./Santa Ana, Calif.	New drug without an effective approved New Drug Application.
Diethylpropion HCl T.D. tablets; furosemide tablets; and chlorothiazide with reserpine tablets/U.S. District Court for the Eastern District of New York 3/28/79	Pharmadyne Laboratories, Inc./Hackensack, N.J.	New drugs without effective approved New Drug Applications.
Furosemide tablets; diethylpropion HCl T.D. tablets; chlorothiazide with reserpine tablets/U.S. District Court for the Eastern District of New York 3/28/79	"	"
Progesterone injection/U.S. District Court for the Eastern District of New York 4/9/79	Bel-Mar Laboratories, Inc./Inwood, N.Y.	Labeling lacks adequate directions for use and article not exempt, since new drug without an effective approved New Drug Application.
Triptan perphenazine & amitriptyline HCl tablets/U.S. District Court for the Eastern District of New York 4/12/79	MD Pharmaceutical, Inc./Santa Ana, Calif.	New drug without an effective approved New Drug Application.
DRUGS/Veterinary		
Triple Sulfa powder/U.S. District Court for the District of Minnesota 2/28/79	Northern States Labs./Pipestone, Minn.	New animal drug and no New Animal Drug Application in effect with respect to its use and intended use.

U.S. POSTAL SERVICE actions taken in medical cases as authorized in the Mail Fraud Statute (18 U.S.C. 1341) and/or the False Representation Statute (39 U.S.C. 3005) as reported by the Chief Postal Inspector.

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

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| <p>March 15, 1979: Ronshel Marketing, P.O. Box 246, Nesconset, New York. Advertising and sale through the mail of the product "Multidex and Long Life," representing the ability to fight against the effects of aging, disease, fatigue, acne, psoriasis, brown spots, etc.</p> <p>March 20, 1979: Rogly Research, Inc., P.O. Box 44008, Miami, Florida. Advertising and sale through the mail of the product "Hair Farming Kit," representing the ability to stop hair loss and aids growth of new healthy hair.</p> <p>March 26, 1979: Stimulex Corp., P.O. Box 523988, Miami, Florida. Advertising and sale through the mail of the product "Stimulex Capsules," representing the ability to increase sexual desire.</p> <p>March 29, 1979: Life Line Labs, Box 73B, Colfax, Illinois. Advertising and sale through the mail of the product "Histidine—Amino Acid Food Supplement," representing the ability to relieve stiff, painful joints.</p> <p>March 30, 1979: Stellar Products, P.O. Box 2010, Dearborn, Michigan. Advertising and sale through the mail of the product "Thin-U-Capsules," representing the ability to cause weight loss.</p> | <p>April 4, 1979: Sunset House, 314 Sunset Building, Beverly Hills, California. Advertising and sale through the mail of the product "Salon Slim Wrap Set," representing the ability to cause weight loss.</p> <p>April 11, 1979: Standard Research Labs, P.O. Box 9547, Fort Lauderdale, Florida. Advertising and sale through the mail of the product "Biotin Hair Restoration Gel," representing the ability to reduce hair loss.</p> <p>April 12, 1979: Rush Industries, 300 Park Avenue, New York, New York. Advertising and sale through the mail of the product "Hair Plus," representing the ability to promote hair growth.</p> <p>April 13, 1979: Personal Motivation Institute, 4866 NE 12th Avenue, Fort Lauderdale, Florida. Advertising and sale through the mail of the product "Breast Enlargement," representing the ability to increase the bust.</p> <p>April 16, 1979: Universal, 507 Fifth Avenue, New York, New York. Advertising and sale through the mail of the product "Hair Activator," representing the ability to promote hair growth.</p> |
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False Representation Orders Issued by Judicial Officer Under 39 U.S.C. 3005

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| <p>March 13, 1979: Against Romeran, Inc., P.O. Box 5921, Lakeland, Florida. Advertising and sale through the mail of the product "Steromine (Weight Loss Tablets)," representing the ability to cause weight loss.</p> <p>March 13, 1979: Against Ton-Ann Company, P.O. Box 150, Tallevast, Florida. Advertising and sale through the mail of the product "Ton-Ann Diet Plan," representing the ability to cause weight loss.</p> | <p>March 22, 1979: Against Health Purifiers, Inc., 200 Madison Avenue, New York, New York. Advertising and sale through the mail of the book "Natural Aids for the Prostate Gland," representing the ability to rid the ailing gland of toxic debris.</p> <p>April 10, 1979: Against Health Headquarters, P.O. Box 50350, Castleton, Indiana. Advertising and sale through the mail of the product "Arthron Pain Relief Kit," representing the ability to relieve pain from arthritis, rheumatism, bursitis, and muscle fatigue.</p> |
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Notices of Judgment

NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Tuna chunks, canned, Breast O'Chicken, at Buffalo, W. Dist. N.Y.

Charged 11-29-78: when shipped by Sun Harbor Industries, San Diego, Calif., the article contained the poisonous or deleterious substance histamine in a quantity which might render the article injurious to health; and the article contained decomposed tunafish (i.e., contained histamine); 402(a)(1), 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61966; S. No. 78-107-538; N.J. No. 1)

FOOD/Contamination, Spoilage, Insanitary Handling

Beans, Great Northern, dried; pinto beans; and other dried beans, at Greeley, Dist. Colo.

Charged 10-5-78: while held by D & D Bean Co., Greeley, Colo., the articles had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 61905; S. No. 78-118-265 et al.; N.J. No. 2)

Cassia, at Garrison, Dist. Md.

Charged 6-16-78: when shipped by Reliable Mercantile Co., Inc., New York, N.Y., after storage at Pittston Warehouse Corp., Brooklyn, N.Y., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the shipper for salvaging. (F.D.C. No. 61794; S. No. 78-147-014; N.J. No. 3)

Cheese loaves, and white kidney beans, at Cambridge, Dist. Mass.

Charged 3-14-79: while held for sale, the articles had been held under insanitary conditions, and the cheese loaves contained rodent filth; 402(a)(3), 402(a)(4). Consent decree authorized release to Musolino LoConte Co., Cambridge, Mass., for salvaging. (F.D.C. No. 62190; S. Nos. 79-197-097/8; N.J. No. 4)

Cocoa presscake, and coffee beans, at Brooklyn, E. Dist. N.Y.

Charged 1-13-78: while held by Van Brunt Stores, Inc., Brooklyn, N.Y., the cocoa presscake contained rodent filth, and both articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered the coffee beans destroyed. Consent decree authorized release of the cocoa presscake to Bauer & Loewy Trading Corp., New York, N.Y., for salvaging. (F.D.C. No. 61563; S. Nos. 78-140-022/3; N.J. No. 5)

Coffee beans from Guatemala and Columbia, and cassia, at Brooklyn, E. Dist. N.Y.

Charged 8-30-78: while held for sale, the articles contained insect and/or rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized: release of the cassia to Morris J. Golombeck, Inc., New York, N.Y.; release of the Guatemalan coffee beans to Carl Borchsenius Co., Inc., New York, N.Y.; and release of the Columbian coffee beans to Jaime Rivas & Co., New York, N.Y., for salvaging. (F.D.C. No. 61855; S. No. 78-140-666; N.J. No. 6)

Corn-grits snacks, cheese-flavored, Elmer's Chee-T's, at New Orleans, E. Dist. La.

Charged 9-28-78: while held by Elmer's Fine Foods, Inc., New Orleans, La., who manufactured the article using interstate corn grits, the article contained insect filth and had been prepared under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 61897; S. No. 78-137-449; N.J. No. 7)

Crabmeat, frozen, at Miami, S. Dist. Fla.

Charged 3-15-78: when shipped by Frigorifico Altagracia, Maracaibo, Venezuela, the article, labeled in part "Crabmeat, Neptune Pasteurized Claw Meat [or "Cocktail Claw" or "Deluxe"] . . . Product of Venezuela," contained decomposed crabmeat; and the labels of the individual containers (cans) lacked the place of business of the manufacturer, packer, or distributor; 402(a)(3), 403(e)(1). Default decree ordered destruction. (F.D.C. No. 61645; S. No. 78-141-125 et al.; N.J. No. 8)

Crackers, sandwiching a peanut butter-flavored filling, at Hialeah, S. Dist. Fla.

Charged 5-10-78: while held by Pan Am Tobacco Corp. (Pan Am Vend-Tronics), Hialeah, Fla., the article contained insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61733; S. No. 78-142-337; N.J. No. 9)

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

Charged 7-31-78: while held by Fahie's Bakery, Frydenhoj, St. Thomas, V.I., the article contained rodent and insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61840; S. No. 78-157-362; N.J. No. 10)

Potatoes, diced, dehydrated, at Roseville, Dist. Minn.

Charged 5-26-78: while in transit, the article had been held under insanitary conditions; 402(a)(4). Consent decree authorized release to Hart Motor Express, Inc., St. Paul, Minn., for salvaging. (F.D.C. No. 61776; S. No. 78-130-253; N.J. No. 11)

Rice, at Columbia, Dist. Md.

Charged 4-2-79: while held by East West Food Products, Inc., Columbia, Md., the article contained rodent and insect filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 62238; S. Nos. 79-168-938, 79-168-936; N.J. No. 12)

Sage leaves, bay leaves, cassia, mustard seed, poppyseed, annatto seeds, and other spices, at Brooklyn, E. Dist. N.Y.

Charged 3-21-78: while held by Pittston Warehouse Corp., Brooklyn, N.Y., the articles had been held under insanitary conditions and contained rodent filth; 402(a)(3), 402(a)(4). Consent decree authorized release to various claimants for salvaging. (F.D.C. No. 61646; S. No. 78-140-783 et al.; N.J. No. 13)

Soybeans, sunflower kernels, peanuts, almonds, and other foodstocks, at Berthoud, Dist. Colo.

Charged 1-12-79: while held by Colorado Sutler, Berthoud, Colo., lots of soybeans, sunflower kernels, peanuts, and almonds contained rodent filth, and all of 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. 62139; S. No. 79-196-004 et al.; N.J. No. 14)

Topping for sundaes, pineapple, canned, at Brooklyn, E. Dist. N.Y.

Charged 3-13-78: when shipped by Land Authority of Puerto Rico, Barceloneta, P.R., the article, labeled in part "Pineapple Sundae Topping . . . Alpha Aromatics Incorporation . . . Brooklyn, N.Y.," had been prepared under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 61599; S. No. 78-147-485; N.J. No. 15)

FOOD/Economic and Labeling Violations

"Juices," blended, Juicy Juice Golden 100%, at Schenectady, N. Dist. N.Y.

Charged 3-21-79: while held for sale (after manufacture by Fruitcrest Corp., Garden City Park, N.Y., using interstate grape juice concentrate, as well as water, sweetener, and other ingredients), the article had had water and a sweetener substituted for the article (which was represented to be 100% juices)—402(b)(2); the article's labeling falsely and misleadingly represented that the article was composed of 100% juices when, in fact, the article contained excess water and a sweetener and when, contrary to fact, the predominant ingredient was represented as apple juice from concentrate—403(a)(1); the label lacked the common or usual name of the food, since "Juicy Juice 100% Juices" was not the common or usual name for a blend of sweetened juices from concentrate diluted with water—403(i)(1); the article's label lacked the common or usual name of each ingredient since water was not declared, and the ingredients were not listed in descending order of predominance by weight—403(i)(2); and required information (i.e., the name and place of business of the manufacturer,



packer, or distributor, and the common or usual name of each ingredient) was not prominently placed, since such mandatory information on the label's information panel did not appear in one place without other intervening material, and since all lettering in the declaration of name and place of business of the manufacturer was in a type size less than 1/16 inch high—403(f). Default decree ordered destruction. (F.D.C. No. 62183; S. No. 79-155-594; N.J. No. 16)

"Maple" sirup, at Salt Lake City, Dist. Utah.

Charged 1-14-79: when shipped by Clark's Farm, Philadelphia, Miss., the article, labeled in part "Pure Pioneer Maple Syrup No Preservatives Made By: Dewey Clark, Philadelphia, Mississippi . . . Distributed By: Brown Sales and Services . . . Salt Lake City, Utah," had had a sirup containing dextrose and levulose substituted for maple sirup; and the article failed to conform to the definition and standard of identity for maple sirup, since it was not made from the sap of the maple tree or by a water solution of maple sugar but was, in fact, made with some other sirup; 402(b)(2), 403(g)(1). Default decree ordered constructive destruction (i.e., donation to a Government or charitable institution). (F.D.C. No. 62113; S. No. 79-118-825; N.J. No. 17)

"Maple" sirup, at Lincoln Park, E. Dist. Mich.

Charged 2-28-79: when shipped by Nathan Pilgrim, DeKalb, Miss., the article, labeled in part "Milford's Pure Maple Syrup Packed for Milford Stidham Lincoln Park, MI," or "Milford Pure Maple Syrup Made By Milford Stidham . . . De Kalb, Mississippi," had had a sirup other than maple sirup substituted for the article; and the article failed to conform to the standard of identity for maple sirup, since it was not made from the sap of the maple tree or from a water solution of maple sugar, but was made with sirup from another source; 402(b)(2), 403(g)(1). Default decree ordered destruction. (F.D.C. No. 62164; S. No. 78-182-399; N.J. No. 18)

FOOD ADDITIVES

Calcium pangamate tablets, at Atlanta, N. Dist. Ga.

Charged 8-30-78: while held by Braswell, Inc., t/a Quest Research, Atlanta, Ga., the article contained the nonconforming food additive calcium pangamate—402(a)(2)(C); the article also was a new drug without an effective approved New Drug Application—505(a); and the article failed to bear adequate directions for use for the therapeutic claims made in national magazine advertising in BODY FORUM (i.e., "Increase the lifespan for your cells! Improve the oxidation process in your blood . . . Stimulate your body's immune response . . . Detoxify dangerous pollutants in your body! Help make proteins! Help protect your liver! Speed your recovery time from fatigue!"), and the article was not exempted, since it was a new drug without an effective approved New Drug Application—502(f)(1). Default decree ordered destruction. (F.D.C. No. 61858; S. No. 78-197-230; N.J. No. 19)

DRUGS/Human Use

Amygdalin powder, at Miami, S. Dist. Fla.

Charged 8-31-78: when shipped by United Shipping Co., Freeport, Bahamas, the article, labeled in part: (label) "From Darpin Co. . . . Shih-lin, Taipei, Taiwan . . . To United Shipping Co. . . . Freeport, GBI Bahamas," and (customs declaration) "Amygdalin A Drug (Chinese name Kuuchin, a kind of food)," was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered delivery to the U.S. Marshal, Milwaukee, Wis., for use in a Federal proceeding in the Eastern District of Wisconsin. (F.D.C. No. 61832; S. No. 78-140-900; N.J. No. 20)

Amygdalin powder, at Tampa, M. Dist. Fla.

Charged 11-3-77: when shipped by Senn Chemicals, Ltd., Zurich, Switzerland, the article was a new drug without an effective approved New Drug Application—505(a); and the article's labeling lacked adequate directions for use and was not exempted therefrom, since its labeling lacked adequate information for use by licensed practitioners—502(f)(1). Carl Heinman (K. Heinmann), Tampa, Fla., claimed

the article and moved to dismiss the Government's complaint on the grounds that the article was not a "drug" but rather was a raw material and that there was no interstate commerce. The claimant also asserted that the article was in an import status. The court denied plaintiff's motion to dismiss. Subsequently, the claimant failed to file an amended claim in accordance with the court's orders. Accordingly, the court entered an order of default. Upon such default, the Government moved for a decree of condemnation. The court granted such a decree and ordered the article destroyed. (F.D.C. No. 61459; S. No. 77-141-202; N.J. No. 21)

Benylin diphenhydramine cough sirup, at Dallas, N. Dist. Tex.

Charged 11-30-78: when shipped by Parke, Davis & Co., Allen Park, Mich., the article was a new drug without an effective approved New Drug Application—505(a); the article's labeling lacked adequate warnings against unsafe use (e.g., do not use in patients with: hypersensitivity to components, stenosing peptic ulcer, and pyloroduodenal obstruction; do not use in patients receiving monoamine oxidase inhibitors; avoid use with hypnotics, sedatives, and tranquilizers; may inhibit lactation; may, in large quantities, produce convulsions or death and side effects, such as: confusion, nausea, vomiting, photosensitivity, diarrhea, hemolytic anemia, diplopia, vertigo, insomnia, etc.)—502(f)(2); and the article lacked the prescription legend—503(b)(4). The shipper appeared specially to have the case held in abeyance pending a decision by the 6th Circuit Court of Appeals in a suit by the shipper against the Government involving the product (*Parke, Davis & Co. v. Califano*). This action was held in abeyance. Subsequently, a consent decree authorized release to the shipper for salvaging. (F.D.C. No. 61016; S. No. 77-65-800; N.J. No. 22)

Danbury hydralazine hydrochloride tablets, at Danbury, Dist. Conn.

Charged 11-2-78: while held by Danbury Pharmacal, Inc., Danbury, Conn., who had manufactured the article using interstate hydralazine hydrochloride, the article's strength differed from the U.S. Pharmacopeia standard (i.e., contained approximately 91 percent of the declared hydralazine hydrochloride); 501(b). Default decree ordered destruction. (F.D.C. No. 61921; S. No. 78-104-992; N.J. No. 23)

Danbury hydralazine hydrochloride tablets, at Fort Lauderdale, S. Dist. Fla.

Charged 11-13-78: when shipped by Danbury Pharmacal, Inc., Danbury, Conn., the article's strength differed from the U.S. Pharmacopeia standard (i.e., contained approximately 92 percent of labeled strength); 501(b). Default decree ordered destruction. (F.D.C. No. 61922; S. No. 78-142-234; N.J. No. 24)

Ipecac sirup, tincture of iodine, and other finished drugs and drug ingredients, at Minneapolis, Dist. Minn.

Charged 2-20-79: while held by Bennett Pharmaceuticals Corp., Minneapolis, Minn., who was manufacturing the finished drugs using interstate drug ingredients, the circumstances used for the articles' manufacture, processing, and packing failed to conform with current good manufacturing practice—501(a)(2)(B); the tincture of iodine failed the U.S. Pharmacopeia requirements since it contained excess iodine content—501(b); the spirit of camphor, tincture of iodine, and hydrocortisone ointment were not labeled as prescribed in the U.S. Pharmacopeia, since the labels lacked an expiration date—502(g). Default decree ordered destruction. (F.D.C. No. 62150; S. No. 78-187-801, et al.; N.J. No. 25)

Premo spironolactone with hydrochlorothiazide tablets, at Ferndale, E. Dist. Mich.

Charged 12-18-78: when shipped by Premo Pharmaceutical Laboratories, Inc., South Hackensack, N.J., the article was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 62074; S. No. 79-188-986; N.J. No. 26)

Sulkamycin phthalylsulfacetamide tablets, at Lincoln, Dist. Nebr.

Charged 1-20-78: while held by Norden Laboratories, Lincoln, Nebr., who manufactured the article using interstate phthalylsulfacetamide, the article was a new animal drug and no approval of a New Animal



Drug Application was in effect with respect to its use or intended use (e.g., for enteric infections in small animals); 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61560; S. No. 78-149-738; N.J. No. 27)

Thyroid & anterior pituitary combination tablets, at Fort Worth, N. Dist. Tex.

Charged 1-23-79: when shipped by Alpha Pharmacal Co., St. Louis, Mo., the article, labeled in part "Thyroid Tablets . . . Mfg. For: Weight Control Clinic . . . Fort Worth, Tex. . . . Mfg. By: Alpha Pharmacal Co., St. Louis, Mo.," was a new drug without an effective approved New Drug Application—505(a); and the circumstances used for the article's manufacture and processing failed to conform with current good manufacturing practice—501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 62105; S. No. 79-123-455; N.J. No. 28)

Tri-vert pentylenetetrazol combination capsules, at Marion, S. Dist. Ala.
Charged 1-23-79: when shipped by Alpha Pharmacal, Inc., St. Louis, Mo., the circumstances used for the article's manufacture and processing failed to conform with current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 62103; S. No. 79-123-453; N.J. No. 29)

DRUGS/Veterinary

Chlortetracycline medicated feed containing soy flour, whey, & dried milk, 80/.50 Hi Fat Medicated, at Springville, M. Dist. Pa.

Charged 3-3-77: while held by Nu-Feeds, Inc., Springville, Pa., the article's labeling (a tag and a guide entitled "Herd Replacement Feeding Guide") failed to bear adequate directions for use, since it did not provide for adjusting dosages for animals of different weight and since it did not provide adequate directions for "dry feeding"—502(f)(1). Consent decree condemned the article and authorized destruction. (F.D.C. No. 62070; S. No. 77-45-438; N.J. No. 30)

MEDICAL DEVICES

Diapulse electromagnetic wave generator, at Olean, W. Dist. N.Y.

Charged 11-21-77: the article, which had been manufactured by Diapulse Corp. of America, New Hyde Park, N.Y., failed to bear adequate directions for use for its intended purposes, and was not exempted since neither adequate directions for lay use nor adequate information for use by licensed practitioners could be provided; 502(f)(1).

The article was claimed by Edward J. Belko, Olean, N.Y., who denied the charge. The Government served written interrogatories, but the claimant failed to serve answers. Subsequently, a default decree ordered destruction. (F.D.C. No. 61465; S. No. 77-94-824; N.J. No. 31)

Diapulse electromagnetic wave generator, at Hempstead, E. Dist. N.Y.

Charged 3-2-78: the labeling of the article (which had been manufactured by Diapulse Corp. of America, Great Neck, N.Y.) lacked adequate directions for use for its intended purposes and was not exempted, since neither adequate directions nor adequate information for use could be furnished for such purposes; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61625; S. No. 78-140-581; N.J. No. 32)

P/EmF electromagnetic wave generator, at St. Paul, Dist. Minn.

Charged 3-10-78: the labeling of the article, which had been shipped by DCA Leasing Corp. (Diapulse Corp. of America), New Hyde Park, N.Y., lacked adequate directions for use for its intended purposes, and neither adequate directions for lay use nor adequate directions for use by licensed practitioners could be provided; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61640; S. No. 78-30-222; N.J. No. 33)

PRODUCTS FOR IN VITRO DIAGNOSTIC USE

Blood and blood products for in vitro diagnostic use and/or for human use,

at Houston, S. Dist. Tex.

Charged 3-9-79: while held by Metabolic Inc., Houston, Tex. (who had processed the article using the interstate anticoagulant sodium citrate), the articles had been held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health (due to being held in coolers which failed to maintain appropriate storage temperatures)—501(a)(2)(A); some lots contained a filthy, putrid, or decomposed substance—501(a)(1); and the strength of some lots differed from, or their purity or quality fell below, their purported or represented strength, purity, or quality (due to the presence of filth)—501(c). Default decree ordered destruction. (F.D.C. No. 62217; S. No. 77-23-113 et al.; N.J. No. 34)

Fluoro-Kit for Toxoplasmosis, a kit for in vitro diagnostic, immunological, tests, at Whippany, Dist. N.J.

Charged 5-11-78: the article, which was manufactured by Clinical Sciences, Inc., Whippany, N.J., was accompanied by package inserts which contained the false claim that the article had been tested by the Center for Disease Control and had been found to meet the Public Health Service recommended specifications; 502(a). Consent decree ordered destruction. (F.D.C. No. 61740; S. No. 78-133-788; N.J. No. 35)

NOTICES OF JUDGMENT on Injunction Actions

Alaska Wholesale Inc., and Dean J. Deegan, president, and John I. Falcone, warehouse manager, Anchorage, Dist. Alaska.

Charged 5-19-77 in a complaint for injunction: that the defendants were engaged, at their Anchorage, Alaska, warehouse, in holding for sale various interstate foods, including flour, sugar, and rice, which had been held under insanitary conditions and which flour, sugar, and rice contained rodent filth; that FDA inspections disclosed a number of specified insanitary conditions and practices; and that, despite numerous warnings, the defendants continued to hold food under insanitary conditions; 402(a)(3), 402(a)(4).

A consent decree of permanent injunction enjoined the complained of violations and enjoined continued interstate operations unless and until a number of specified conditions were met and all food on hand was examined for filth, necessary analyses were made by FDA, and all food shown by examination or analysis to be contaminated was destroyed or otherwise brought into compliance. Pursuant to an addendum, however, the defendants were permitted to distribute food which had been determined by FDA to be uncontaminated. (Inj. No. 788; S. No. 77-70-949 et al.; N.J. No. 36)

Private Formulae, Inc., and Hans F. Jacob, president, and John Hampton, production manager, St. Louis, E. Dist. Mo.

Charged 4-26-77 in a complaint for injunction: that the defendants were engaged, at their St. Louis, Mo., plant, in manufacturing, processing, packing, labeling, holding for sale, and distributing in interstate commerce various articles of drug such as nitroglycerin, digitalis, and hormones (some of which articles had interstate components), which articles were variously adulterated; that FDA analysis of drugs manufactured by the defendants and released by the defendants' quality control laboratory showed the following: nitroglycerin tablets which were not within the limits of the U.S. Pharmacopeia for content uniformity and disintegration, S-C Green Lipotropic tablets which showed visible deterioration, "enteric-coated" potassium sulfate tablets which failed the disintegration test, conjugated estrogen tablets which were subpotent and failed to meet the U.S. Pharmacopeia requirement for constituent estrogens, and Parmin HP atropine sulfate and opium tablets which were subpotent; that FDA inspections disclosed a number of specified deviations from current good manufacturing practices; and that, despite written and verbal notices by FDA of inadequate conditions and despite other warnings, the defendants continued to manufacture and distribute violative drugs; 501(a)(2)(B), 501(b), 501(c).

The court issued a temporary restraining order enjoining the defendants from the complained of violations. Subsequently, a consent decree of permanent injunction enjoined such violations and enjoined



defendants' interstate operations, unless and until a number of specified conditions were met and unless and until all drugs on hand at the defendants' plant were examined, necessary analyses were made, all drugs found to be adulterated were destroyed or otherwise brought into compliance, and any portion of such article already distributed was recalled and similarly treated. (Inj. No. 780; S. No. 77-84-922 et al.; N.J. No. 37)

NOTICES OF JUDGMENT on Miscellaneous Actions

Amygdalin/Laetrile tablets, and suit to authorize their administration, Seattle, W. Dist. Wash.

Charged 9-14-76 by Roswell P. Keyes, M.D., Bellingham, Wash., against the United States of America and HEW Secretary David Mathews, in a suit for injunction: that plaintiff (a 75-year-old man who had cancer, had gained 15 pounds under a treatment with Laetrile tablets, and intended to far outlive the life expectancy estimates of his physicians) has his rights violated and was irreparably damaged by the denial of his freedom to choose Laetrile for the treatment of his cancer; that plaintiff prayed for an order directing the defendants to cease and desist from enforcement of any FDA order precluding the administration of Laetrile to plaintiff in the treatment of his cancer; that plaintiff prayed for a judgment authorizing the plaintiff to purchase, ship in interstate commerce, and have for his own personal use a supply of Laetrile tablets.

The Government moved to dismiss the complaint on the grounds that the plaintiff had failed to exhaust his administrative remedies and that Laetrile was an unapproved new drug and, prior to approving its interstate distribution, an initial determination must be made by FDA as to its safety and efficacy. The court denied the plaintiff's petition for a temporary restraining order and dismissed the action with prejudice, saying in part:

"In the first place, this is a drug; its intended use is for the treatment of cancer. No new drug application has ever been filed by Doctor Keyes or anyone else, nor is there an investigational new drug exemption in effect.

"Now, in my opinion, the FDA is not responsible for conducting research in developing new drugs. I can't agree with the court in the Rutherford case about the FDA obligation. Their obligation is, upon proper application, to pass upon the drug's effectiveness—as well as its safety—measured by the opinion of qualified experts. It is a question for qualified experts. We are dealing in a technical and scientific field in which the District Courts have neither the facilities nor the expertise. Congress has given primary jurisdiction to the FDA with appeal to the Court of Appeals.

"No matter how appealing the case is, my obligation is to interpret the law as set forth by Congress and, therefore, I am denying the temporary restraining order." (Misc. No. 352; N.J. No. 38)

Kemdalin (amygdalin/Laetrile) tablets and injectable, and suit to authorize the administration of such drugs, San Francisco, N. Dist. Calif.

Charged 2-8-77 by Connie Matteson (who was diagnosed as suffering from metastatic adenocarcinoma) against the United States of America and HEW Secretary David Mathews, in a suit for injunction: that the petitioner needed to initiate treatments with amygdalin, Mexican brand—Kemdalin; that petitioner requested an order enjoining the Government from preventing the petitioner from moving in interstate commerce and having for her personal use an amount of Kemdalin not in excess of a 3-month's supply; and that a medical physician, nurse, or trained family member be allowed to inject or treat the petitioner and such person be held immune from any civil or criminal sanction for administering the drug.

As requested by the petitioner, the court granted a limited order of injunction which read as follows:

"This case is indistinguishable from *Carnohan v. United States*, C-77-10, U.S.D.C., S.D. Calif., and I agree with Judge Thompson's views.

"Accordingly, it is ordered, adjudged, and decreed that the defendant, through any of its agents, servants and employees—especially including, but not limited to, the United States Customs Service and the Department of Health, Education, and Welfare—be enjoined from preventing the plaintiff only, from purchasing and moving in interstate commerce, and having for her own personal use—not for sale, barter or to be given away to any other person—an amount of Laetrile approved by this court, based on [an] affidavit by an attending physician licensed to practice medicine in the State of California, not in excess of a three (3) month supply of Laetrile, pending further order of this court.

"It is further ordered that the plaintiff give advance notification to the defendant of the date, place and quantity of h[er] transportation in interstate commerce of such amount of Laetrile as above authorized. Such quantity shall further be declared to the customs authorities, and custom duty or tax, if any, due thereon, shall be paid.

"It is further ordered that, should the plaintiff pass away prior to the expiration of the three month period, h[er] next of kin, executor or person charged with the posthumous care of h[er] affairs shall immediately surrender any unused supplies of Laetrile to the Food and Drug Administration.

"All other requests of plaintiff are denied." (Misc. No. 40; N.J. No. 39)

Release for marketing of fentanyl citrate & droperidol combination (Innovar), and suit for damages, Washington, Dist. Columbia.

Charged 8-3-76 by Christine Keno, East Orange, N.J., against the Federal Food and Drug Administration: that FDA was believed to be the agency whose policies allowed Innovar on the market; that such drug was believed to be the cause, or contributing cause, of the death of the plaintiff's mother; that FDA was believed to have restricted the release of information from drug information centers and to have tried to conceal the drug's dangers by directing that all mail and inquiries be directed to the same person for reply; and that plaintiff demanded compensatory and punitive damages for the loss of her mother.

The Government moved to dismiss and for the granting of summary judgment on the following grounds: that plaintiff had failed to effect service on the Attorney General and the U.S. Attorney; that plaintiff had failed to exhaust her administrative remedies; and that the plaintiff's complaint had been untimely filed. The court dismissed without prejudice, the suit, since it appeared that the plaintiff had failed to effect the required service. (Misc. No. 347; 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, HEW.

Published by direction of the Secretary of Health, Education, and Welfare.

Sherwin Gardner, *Acting Commissioner of Food and Drugs*
Washington, D.C., September 1, 1979

Cancer Information Service

Even though you hear a lot about cancer, when it strikes you — or someone in your family — suddenly there are many questions you want answered.

Cancer Information Service is there to help. CIS is a toll-free telephone inquiry system that supplies information about cancer and cancer-information resources — and it's available throughout the United States.

If you have questions about cancer — about detection, treatment, rehabilitation, medical assistance, or any related area — or if you want to know where to get additional information and help — call the CIS office nearest you (see list below).

If there is no office near you, call the national toll-free number: 800 — 638-6694. Get prompt answers to any questions you have about cancer from Cancer Information Service.

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1-800-638-6070

CALIFORNIA
LAC-USC Cancer Center
From Area Codes (213), (714) and
(805): 1-800-252-9066
Rest of California: (213) 226-2374

COLORADO
Colorado Regional Cancer Center
1-800-332-1850

CONNECTICUT
Yale University
Comprehensive Cancer Center
1-800-922-0824

DELAWARE
Fox Chase Cancer Center
800-523-3586

DISTRICT OF COLUMBIA
(Includes suburban Maryland
and Northern Virginia)
Cancer Communications for
Metropolitan Washington
(202) 232-2833

FLORIDA
Comprehensive Cancer Center
for the State of Florida
Florida: 1-800-432-5953
Dade County: (305) 547-6920

HAWAII
Cancer Information Line
Oahu: 536-0111
Neighbor Islands: Ask
operator for Enterprise 6702

ILLINOIS
Illinois Cancer Council
Illinois: 800-972-0586
Chicago: (312) 346-9813

MAINE
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1-800-225-7034

MARYLAND
The Johns Hopkins Oncology Center
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1-800-952-7420

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Minnesota Cancer Council
1-800-582-5262

MONTANA
Montana Cancer Information Service
1-800-525-0231

NEW HAMPSHIRE
New Hampshire Cancer Information Service
1-800-225-7034

NEW JERSEY
Fox Chase Cancer Center
800-523-3586

NEW MEXICO
New Mexico Cancer Information
Service
1-800-525-0231

NEW YORK
Roswell Park Memorial Institute
New York State: 1-800-462-7255
Erie County: (716) 845-4400

NEW YORK CITY
Memorial Sloan-Kettering
Cancer Center
(212) 794-7982

NORTH CAROLINA
Duke Comprehensive Cancer Center
North Carolina: 800-672-0943
Durham County: (919) 286-2266

PENNSYLVANIA
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