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# FDA CONSUMER

MARCH 1974



Combating  
Drug  
Abuse

The Government's mandate under the Comprehensive Drug Abuse Prevention and Control Act of 1970 is to reverse the frightening and expanding

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trend of recent years in the indiscriminate, excessive, or illicit use of chemical substances that alter the mind, behavior, or health of the abuser. It is a phenomenon that has touched all parts of our society.

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## This Month

Can your kitchen pass the food storage test? We'll bet most kitchens can't. This month, FDA CONSUMER takes a tour through a kitchen to point out the main food storage problems. We hope you'll use the information in the article to go over your own kitchen and correct the deficiencies you find.

This month, FDA CONSUMER continues its effort to inform the public about vitamins. "Myths of Vitamins" describes some of the false or inaccurate qualities some people have claimed for vitamins, and what the scientific evidence actually shows. In a few months, we'll present "A Primer on Vitamins," which will look at the same subject from another viewpoint.

"Combatting Drug Abuse" describes FDA's contribution to the Federal Government's fight against the abuse of legitimate and illicit drugs. FDA is not the enforcement arm of the Federal Government in this important area, but its recommendations to the Drug Enforcement Administration and its other activities are important elements in the Government's program.

The word "recall" has become familiar to every consumer in the past decade. But many misconceptions exist about them and FDA's role in food and drug recalls. "How Defective Products Are Recalled" tells you exactly what recalls are, when and why they're made, who makes them, the three kinds of recalls, and how the recall tool fits into overall consumer protection.

## Quotes

**“I**t might be well for me to summarize the general philosophy with which I approach my job as Commissioner of Food and Drugs.

“First of all, I intend to be guided by the basic premise that FDA is a scientific regulatory agency with a single responsibility—consumer health and safety. We are a regulatory agency by law, a scientific agency by necessity, and a consumer protection agency by design.

“I am convinced that for the FDA to serve the consumer most effectively, we must continue to broaden the base of expertise and advice upon which our regulatory programs are erected. This expertise and this advice must be brought to bear across the boundaries of bureaucracy and across the barriers which separate the public and the private sectors.

“As you may have heard, one way we are assuring the close working of the private and public worlds is to utilize more advisory committees, seeking their advice more often and earlier than heretofore. We will also seek out and use scientific expertise, adding it to our own in order to build the best scientific base we can for our actions.

“At the same time, the consumer must be heard. He must know why and how and if we in the FDA are acting in his best interest. And if he is to know, the consumer must have the same opportunity as industry to participate in regulatory decision-making. As you know, we are moving in a number of specific ways to ensure consumer access to our process of decision-making as well as our decision-makers.”

*Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, before the food group of the American Frozen Food Institute, Washington, D.C., January 9, 1974.*

**“A**s consumerism has become a new and powerful force in the marketplace, Government agencies have constructively responded to rightful demands by the new consumer movement, and have often anticipated what some of these demands and requirements might be.

“The larger function of Government, however, should be to do more than react. It should be to better understand the context within which the smaller situation has developed, and then to deal with that larger context. This is especially true of the regulatory agencies, among them, the Food and Drug Administration.

“The FDA was once little more than an inspection agency with certain police powers which it exercised with varying effectiveness. It is now a scientific, regulatory agency that draws on expert talent from throughout the country to assure the safety of the Nation’s food and drug supplies. It has had new authorities given it by the Congress which have greatly increased its responsibilities and the requirements made of it.

“The FDA also operated in earlier times behind a screen that kept the public removed from the Agency, whereas today it is open not only to public scrutiny but also to public participation in its decision-making. Most of these changes have occurred within the past 5 years.

“In the course of making these changes, many bureaucratic traditions have been discarded. Such traditions tend to accumulate in a bureaucracy, even as the outside world may be changing. Bureaucracies, of course, exist in Government, industry, and elsewhere, and all must, from time to time, undergo fundamental revision. This the Food and Drug Administration has recently accomplished, again in a process accelerated by the new consumerism. And the FDA which has emerged is appropriate to the times, even as the earlier style of the Agency may have been what those times required.”

*Sherwin Gardner, deputy commissioner, Food and Drug Administration, before the New York State Bar Association annual meeting, New York City, January 23, 1974.*



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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.

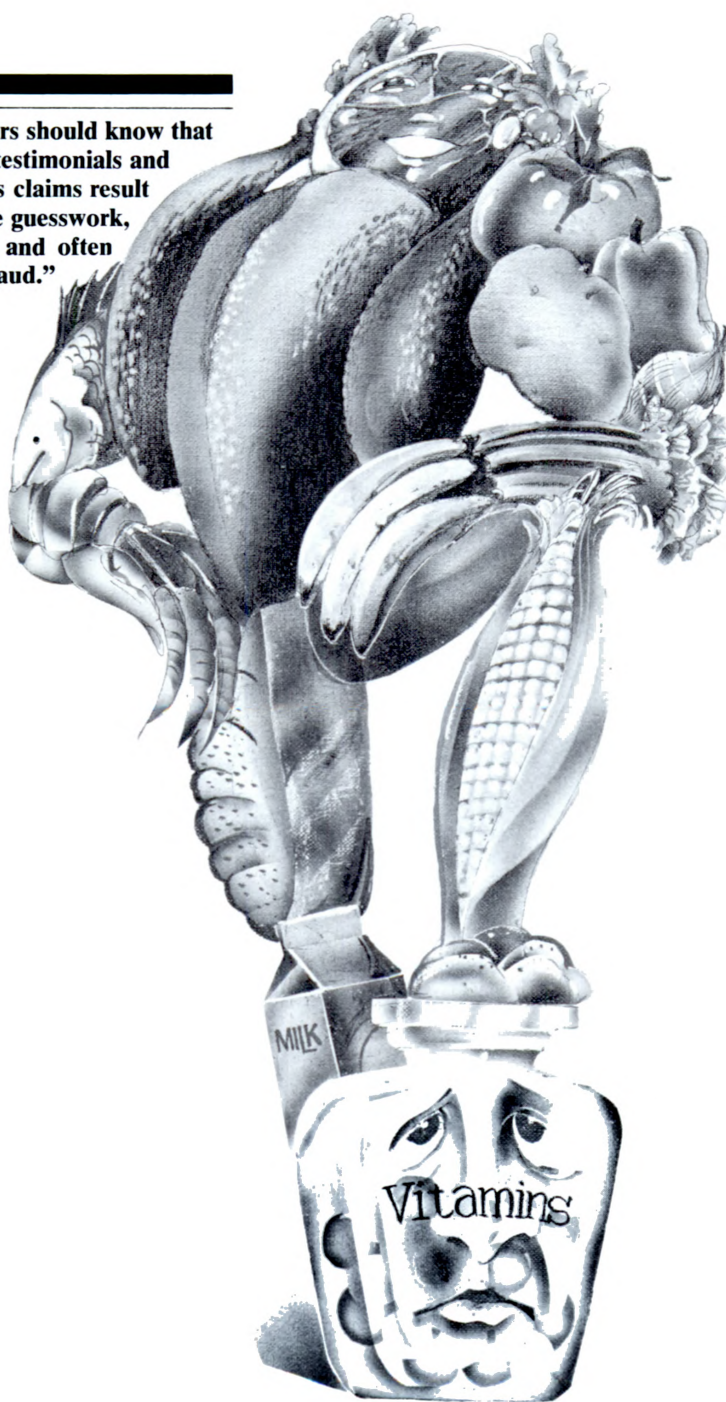
# **FDA CONSUMER**

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# Myths Of Vitamins

**"Consumers should know that elaborate testimonials and miraculous claims result from mere guesswork, confusion, and often outright fraud."**



*In today's health-conscious society, many Americans hold myths about the proper role of vitamins. While vitamins are essential for good health, excessive amounts are unnecessary and can be harmful.*

by Jane Heenan

Once a day, "just to be sure," millions of Americans take a multivitamin pill. Then, when cold season comes around, some stock up on vitamin C.

Others whose sex lives seem to be lagging may reach for vitamin E, with the added hope that it will stave off heart disease. And if all these vitamins don't prevent that "rundown feeling," they might try a little—or a lot—of all the vitamins, with an added boost of vitamin B<sub>12</sub>.

According to some of the latest "literature" appearing in books by nutrition "experts" and in magazine articles, this sort of therapy should do the trick. But as millions of Americans now know, it doesn't necessarily mean you can even win a tennis match.

And as a 4-year-old boy in Kansas will never forget, taking a whole bottle of 40 children's vitamins at once won't help him grow stronger, faster. He spent the following 2 days in intensive care with vitamin A and iron poisoning. His experience was added to the statistics compiled by FDA's National Clearinghouse for Poison Control Centers which reveal that 4,000 cases of vitamin poisonings are reported each year,



with some 3,200 involving children.

Other Americans, with rashes, diarrhea, or headaches, may also be unwary victims of the belief that since vitamins are good for them, the more the better.

Of course, this is just one of the many myths about vitamins that is accepted by many health-conscious Americans. Some of the myths have been with us so long they're difficult to distinguish from fact. For instance, many people will tell you that vitamins provide extra energy. False. Some of the B vitamins do aid in the conversion of food to usable energy, but in amounts greater than the U.S. Recommended Daily Allowance (U.S. RDA), they provide nothing of value. Only people with a relatively rare medically diagnosed deficiency of a vitamin would benefit from an amount greater than the U.S. RDA levels.

FDA has promulgated regulations which are designed to prohibit false and misleading promotional and labeling claims about vitamins and minerals, and to distinguish between vitamins and minerals that are dietary supplements, and those that should be sold as drugs. (See "Vitamins, Minerals, and FDA," FDA CONSUMER, September 1973.) Still, educational efforts are required for the public to be able to know what vitamins can, and cannot, accomplish.

### **The Daily Multi-Myth**

An advertisement on television shows a person explaining how he stays healthy and looking "great." He says he watches his diet, gets plenty of exercise, and, "just to be

sure," takes a vitamin-mineral supplement every day.

This is the way we have come to expect the marketing of dietary supplements. They are promoted as an "insurance" policy to guarantee good health. The implication of such advertising has contributed to the myth that even a balanced diet cannot provide adequate nutrients.

Some people have gone further and maintain that modern farming methods have depleted the soil and that food itself no longer contains adequate nutrients.

This is untrue. More is known about the nutrient content of food today than ever before. And more is done, through modern farm practices, to protect and enrich the soil than was even known about in the good old days. Crop rotation, soil tests, and routine enrichment of crop soil were developed because the oft-revered "natural" way of farming was quantitatively and qualitatively unreliable.

In addition, the protein, carbohydrate, fat, fiber, and vitamins are controlled primarily by the plant's genetic structure, not by the soil. Excess mineral elements in soil beyond the plant's requirements may be reflected in the plants, but these differences are usually small. Both desirable (magnesium, zinc, iron, etc.) and undesirable (lead, cadmium, selenium, etc.) elements are similarly accumulated.

A balanced diet which generally meets the U.S. RDA requirements for vitamins A, B<sub>1</sub>, B<sub>2</sub>, C, and D will nearly always provide the needed amounts of other vitamins, despite the claims of some people

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**"Some of the myths have been with us so long they're difficult to distinguish from fact."**

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**"Many people will tell you that vitamins provide extra energy. False."**

that these other vitamins are hard to find and therefore must be eaten in special foods or taken by pill. Even though eating is a personal thing and the acceptability of foods varies from person to person, it is possible to obtain the U.S. Recommended Daily Allowance (U.S. RDA) in many different diet patterns because of the wide variety of foods containing similar nutrients. But the simplest, surest guide to follow for a good daily balance of nutrients is still the selection of foods from each of four larger groups—milk, meat, vegetable/fruit, and bread/cereal.

There are substances in food which some "experts" glibly term vitamins although they are of no importance in the diet for human nutrition. Examples are inositol, PABA (para-aminobenzoic acid), citrus bioflavonoid complex, hesperidin, and rutin. Many companies have marketed these substances individually or in combination with essential vitamins, but consumers should not be misled by claims for them that ignore the fact that their absence from the diet does not cause a disease or any form of illness.

Foods can and do supply most Americans with adequate nutrients, and consumers should not expect any major physical benefits from multivitamin pills, contrary to the myth.

#### **Much Ado About E**

Vitamin E supplements have been found useful in only two conditions—in premature babies who because of poor placental transfer may have received too little of the vitamin before birth, and in persons with intestinal disorders in which fats are poorly absorbed.

This view by the National Academy of Sciences Committee on Nutritional Misinformation is vastly different from claims that have more than doubled the sales of vitamin E in the last 5 years.

Among the latter claims are assertions that the vitamin can promote physical endurance, enhance sexual potency, prevent

heart attacks, protect against air pollution, and slow the aging process. But there is virtually no scientific proof for the majority of these claims.

In fact, the new interest in E has been based on misinterpretations of animal research studies: Male rats that deliberately had been deprived of dietary sources of vitamin E became sterile, but the use of large doses in treating human sterility or impotence has not been successful. Similarly, it is known that E is essential to maintain pregnancy, but it has not been found to be a factor in fertility.

One reason so little is known about vitamin E is that E deficiency is almost impossible to produce in human subjects. To withdraw all sources of vitamin E is almost to withdraw food itself, since the vitamin is present to some extent in most foods and in large amounts in vegetable fats and oils.

Discovered about 50 years ago, the vitamin has also been described as a cure, preventive, or treatment of cancer, muscular dystrophy, ulcers, burns, and skin disorders. Again, science does not back this up. In muscular dystrophy patients, for example, no deficiency of vitamin E has been found and large-dosage treatments have been ineffective.

The vitamin has been used in some cosmetics for its antioxidant properties, but one popular new deodorant containing E was recalled last year when widespread incidence of severe rashes were reported after use.

#### **C for Colds?**

James Lind, surgeon's mate on the H.M.S. *Salisbury*, and "the father of nautical medicine," conducted the first properly controlled clinical therapeutic trial on record in 1747. Aboard ship, his experiment determined the value of citrus fruit in the prevention and cure of scurvy.

Forty-two years later, the Royal Navy adopted the administration of 1 ounce of lemon juice to



each man each day. It wiped out scurvy in the Royal Navy and preserved its numbers to the extent that vitamin C is credited with having done as much as Lord Nelson to break the power of Napoleon.

So began the recorded and gradual recognition of vitamin C, which was isolated and so named in 1933.

Today, these things are known about C: It helps hold body cells together and strengthens blood vessels; it helps heal wounds; it helps tooth and bone formation; and it helps in resistance to infection.

It is also known that C does not cure or prevent colds. The claims that C lessens the number and severity of colds remains controversial, for in several clinical

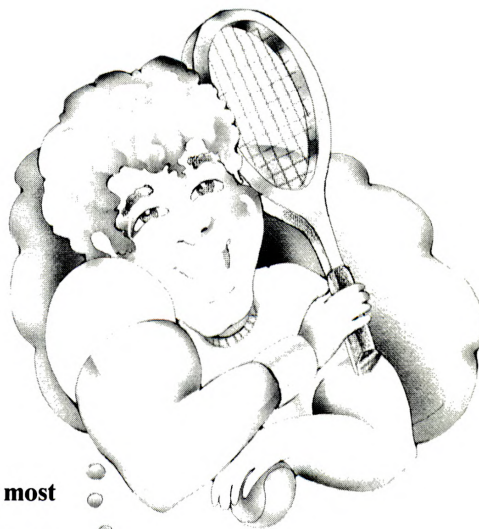
studies, subjects who believed they were being given C but who were actually receiving inert tablets reported fewer colds than they expected to have, and, in some cases, those taking C reported no change.

Some research has indicated difficulties associated with large doses of C, including kidney stones, severe diarrhea, and possible harm to diabetics. Also, because the body does pass off excesses of vitamin C, its presence in the urine makes accurate testing for diabetes impossible, since it gives a false indication of sugar levels. At this point, unless a physician has diagnosed vitamin C deficiency, the safe, practical course is to get the U.S. Recommended Daily Allowance of 60 milligrams per day (see table).

## B Vitamins

A common belief about B vitamins is that the old "rundown feeling" can easily be overcome by vitamin B<sub>12</sub> supplements. But unless there is actually a deficiency—which is extremely rare—amounts beyond the U.S. RDA will not be of any benefit to the body, and any apparent effect has been shown to be psychological. In the case where vitamin B<sub>12</sub> treatment is recommended, when a person actually cannot absorb the vitamin properly, the treatment must be carried out through injections, and it is relatively ineffective when administered orally.

Another exotic claim for vitamins involves pantothenic acid and is also based on misinterpretation of animal experiments. When a severe deficiency was produced



**"Foods can and do supply most Americans with adequate nutrients, and consumers should not expect any major physical benefits from multivitamin pills, contrary to the myth."**





deliberately in male rats, their hair turned grey, and when the process was reversed, the color was restored. From this, some "experts" have deduced that deficiencies of pantothenic acid are responsible for greying hair in humans. Although greying hair may occur because of severe deficiency, grey hair per se does not mean a deficiency, since there are many other reasons for the condition. Clinical deficiencies in man are truly rare. There has been no discovery so far to prevent grey hair.

Skimping on protein and overcooking vegetables in water will cut back on the amount of B vitamins in a diet. But a rush for vitamin pills or expensive brewer's yeast does more damage to the budget and offers far fewer benefits to health than consuming a proper selection of foods carefully prepared.

#### **Natural vs. Synthetic**

"Getting back to nature" can sometimes be an expensive trip—especially when you wind up where you started. Such is the case for persons paying close to \$5 for 100 tablets of vitamin C "from pure rose hips," from acerola cherries, or for a host of combinations with natural but ungermane ingredients, such as honey, when the same amount of pure ascorbic acid can be bought for under \$1.

Two major fallacies lie behind the rush for so-called "natural" vitamins: (1) Natural vitamins are superior to those synthesized by man; (2) vitamin products sold as "natural" don't contain synthetic ingredients.

In truth, each vitamin has a particular molecular structure that remains the same whether it's synthesized in a laboratory or extracted from an animal or plant or consumed as part of an animal or plant. To be called "vitamin A," for example, there has to be a specific molecular arrangement that is identical no matter where it is found or how it is derived. The body cannot distinguish in

any way between a vitamin from a plant or animal and the same vitamin from a laboratory. Only the pocketbook "knows for sure."

Perhaps even more revealing is that some synthetic ingredients many persons are trying to avoid today are also present in the "natural" products. In processing tablets and capsules, vitamin manufacturers must use excipients and binders, such as ethyl cellulose, Polysorbate 80 (a synthetic emulsifier), as well as gum acacia, etc.

So it comes back down to some basic rules about eating. Your body not only needs vitamins and other nutrients, it needs the bulk and textures of real food. And it needs a *balance* of those foods, a balance that may not be provided in fad dieting or in an endless array of tablets and capsules.

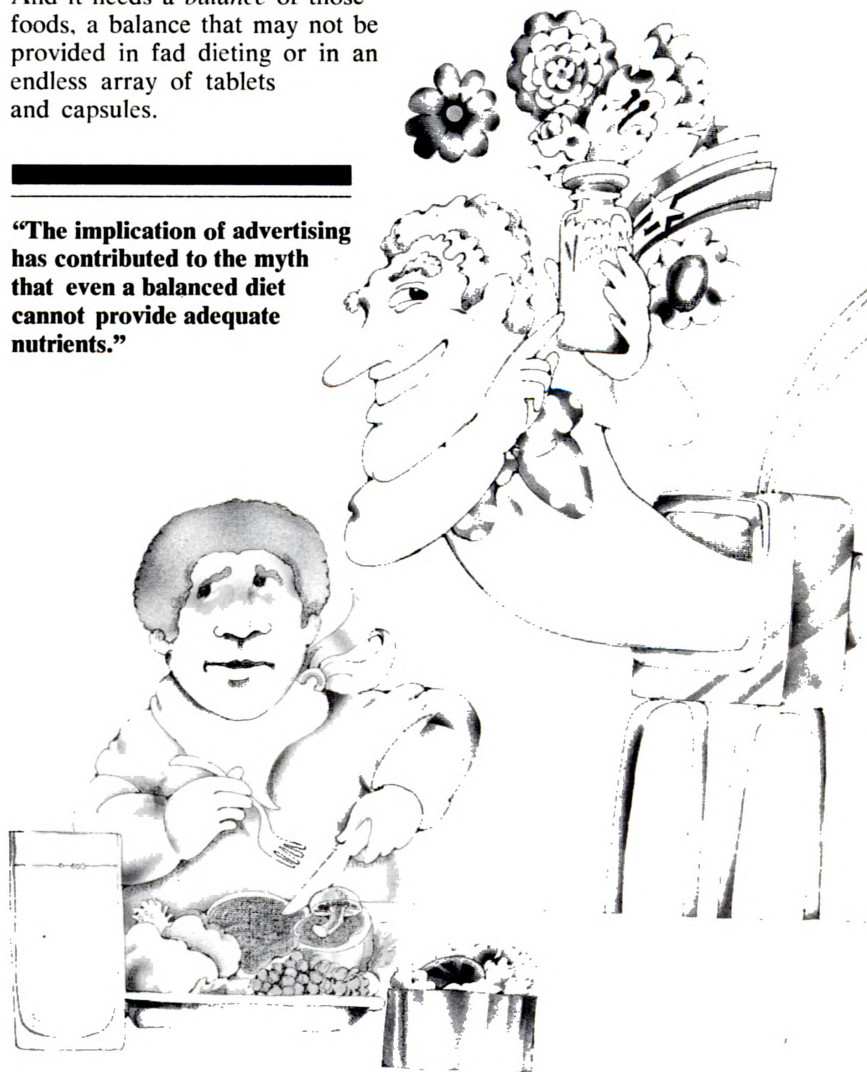
#### **Vitamins A and D Toxicity**

Vitamins A and D were the first to explode the myth that vitamins are not toxic when administered in doses beyond body requirements.

Excessive amounts of vitamin A taken over long periods can increase pressure within the human skull and may mimic a brain tumor. In fact, one teenager actually was hospitalized and prepared for brain surgery only to find out the trouble was simply an overdose of vitamin A. Large doses of this vitamin taken over extended periods have also been known to retard growth in children and cause dry and cracked skin, headaches, bone pain, and other symptoms—in fact, almost the

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**"The implication of advertising has contributed to the myth that even a balanced diet cannot provide adequate nutrients."**





same symptoms as for a severe deficiency.

Excessive doses of vitamin D has been known to retard mental as well as physical growth in children. It can also cause nausea, weakness, stiffness, constipation, hypertension, and even death.

Because of this, FDA prohibits, except by prescription, any daily recommended intake of a tablet or capsule of more than 10,000 International Units (IU) of vitamin A and 400 of vitamin D. While this in no way prevents the consumer from taking as much as he chooses at any one time, it does control the strength and labeling for each package. (See "New Regulations on Vitamins A and D,"

FDA CONSUMER, October 1973.)

From this regulatory action a new myth may have arisen: That all vitamins are nontoxic except for A and D. In fact, the correct interpretation of this action is that the only conclusive, actionable proof of toxicity so far is with excessive A and D. Medical libraries contain numerous references to adverse side effects from ingestion of high levels of niacin or vitamin C. In addition, the interaction of nutrients within the body is affected by high intakes of certain vitamins and minerals.

Other problems, involving

vitamins E, C, and folic acid, have also been reported recently. For instance, there is evidence of a possible antagonistic effect of high intake levels of vitamin C on the nutritional status of A.

As research continues, there will be more answers as to how much is too much of a vitamin, what the entire scope of usefulness of each vitamin is, and which medical conditions may respond well to vitamin therapy. In the meantime, consumers should know that elaborate testimonials, miraculous claims, and vitamins supposedly derived from exotic sources result from mere guesswork, confusion, and, often, outright fraud.

#### Best Sources

**Vitamin A**—Fish-liver oils, liver, butter, cream, whole milk, whole-milk cheeses, egg yolk, dark green leafy vegetables, yellow vegetables, yellow fruits, fortified products.

**Vitamin D**—Fish-liver oils, fortified milk, activated sterols, exposure to sunlight.

**Vitamin E**—Plant tissues—Wheat germ oil, vegetable oils (such as soybean, corn, and cottonseed), nuts, legumes.

**Vitamin K**—Green leaves such as spinach, cabbage; cauliflower, and liver.

**Vitamin C**—Citrus fruits, tomatoes,

strawberries, cantaloupe, cabbage, broccoli, kale, potatoes.

**Folic acid**—Widespread in foods. Liver, kidney, yeast, deep green leafy vegetables are highest sources.

**Thiamine**—Pork, liver, and other organs, brewer's yeast, wheat germ, whole-grain cereals and breads, enriched cereals and breads, soybeans, peanuts, and other legumes, milk.

**Riboflavin**—Milk, powdered whey, liver, kidney, heart, meats, eggs, green leafy vegetables, dried yeast, enriched foods.

**Niacin**—Lean meat, fish, poultry, liver, kidney, whole-grain and enriched cereals and breads, green vegetables, peanuts, brewer's yeast.

**Vitamin B<sub>6</sub>**—Wheat germ, meat, liver, kidney, whole-grain cereals, soybeans, peanuts, corn.

**Vitamin B<sub>12</sub>**—Amplly provided by small daily intakes of animal protein.

**Biotin**—Liver, sweetbreads, yeast, eggs, legumes.

**Pantothenic acid**—Almost universally present in plant and animal tissue. Liver, kidney, yeast, eggs, peanuts, whole-grain cereals, beef, tomatoes, broccoli, salmon.

**Choline**—Egg yolk is best source. Liver, heart, sweetbreads, milk, meats, nuts, cereals, vegetables, soybeans.

#### — U.S. RDA's For Vitamins —

	Unit of measurement	Infants	Children under 4 years of age	Adults and children 4 or more years of age	Pregnant or lactating women
Vitamin A	International units	1,500	2,500	5,000	8,000
Vitamin D	"	400	400	400	400
Vitamin E	"	5	10	30	30
Vitamin C	Milligrams	35	40	60	60
Folic acid	"	0.1	0.2	0.4	0.8
Thiamine	"	0.5	0.7	1.5	1.7
Riboflavin	"	0.6	0.8	1.7	2.0
Niacin	"	8	9	20	20
Vitamin B <sub>6</sub>	"	0.4	0.7	2.0	2.5
Vitamin B <sub>12</sub>	Micrograms	2	3	6	8
Biotin	Milligrams	0.15	0.15	0.30	0.30
Pantothenic acid	"	3	5	10	10

# Combating Drug Abuse

by Harold C. Hopkins  
and Edward C. Tocus, Ph.D.



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*FDA plays an important role  
in the Federal Government's  
effort to bring drug abuse  
under control.*

The widespread abuse of drugs, which at times in the past decade reached epidemic proportions and brought tragedy to many individuals and their families, is being brought under control by a Federal Government effort in which FDA plays a major role.

The Agency's knowledge of drugs, its storehouse of information about existing and new drugs, and its experience in drug regulation are vital in the Government's methodical campaign to remove one of the most pernicious threats of modern times to the health and welfare of our society.

The Government's mandate under the Comprehensive Drug Abuse Prevention and Control Act of 1970 is to reverse the frightening and expanding trend of recent years in the indiscriminate, excessive, or illicit use of chemical substances that alter the mind, behavior, or health of the abuser. It is a phenomenon that has touched all parts of our society and led to such descriptive catchwords as "flower children," "drug subculture," "turned-on generation."

Under the Controlled Substances Act, Title II of the 1970 law, the Secretary of Health, Education, and Welfare is charged with providing medical and scientific information and recommendations to the Justice Department's Drug Enforcement Administration for prevention of drug abuse and the control of these drugs. Since November 1972, FDA has been the DHEW agency responsible for collecting this data, incorporating suggestions from other DHEW agencies.

Under another part of the law,

FDA is responsible for determining acceptable methods for treatment of narcotic addiction, and authorizing researchers to protect the identity of research patients. FDA thus regulates methadone maintenance programs for treatment of heroin addiction (see "Getting a Handle on Methadone," FDA CONSUMER, September 1973).

Broadly defined, drug abuse is the use of any drug in a way or to an extent that harms the health of the person using it or threatens the health or welfare of society. But in the sense contemplated by the 1970 law, the term is associated with drugs that alter a person's mood by acting on his central nervous system.

Most of these drug actions can be beneficial in certain types of therapeutic or experimental treatment, but they also can be harmful when the drug is abused. These drug actions are narcotic, hypnotic, sedative, depressant, antidepressant, central stimulant, anorexigenic (appetite suppressant), euphoriant, or hallucinogenic. Alcoholic beverages and tobacco are specifically excluded from the legal definition.

Most drugs that have shown potential for abuse also have recognized medical or scientific uses, and many are considered essential in modern health care. Therefore, information and recommendations provided by FDA are particularly significant, since legitimate medical needs and all available information on abuse and dependency potential must be looked at in determining just how far a drug should be controlled.

The rise of drug abuse over the years—and especially the dramatic

increase in the misuse of mind-altering drugs among young people in the 1960's—has been laid to a number of causes. Much of the Government's effort has been directed toward alleviating or eliminating them through social, health, rehabilitation, or educational programs.

But two things have been common to all epidemics involving abuse of a drug: its availability on the market, and the ease with which it could be obtained for nontherapeutic purposes. A 1970 report by the House Committee on Interstate and Foreign Commerce estimated, for instance, that as of late 1969 almost half the amphetamines and barbiturates produced legitimately in the country were being diverted to illicit use.

Congress had dealt with the abuse of narcotics in the past, beginning with the Harrison Narcotic Act of 1914. In subsequent legislation, notably the Drug Abuse Control Amendments of 1965, Congress turned its attention to other drugs of abuse.

But the Comprehensive Drug Abuse Prevention and Control Act of 1970—enacted in response to public concern about the alarming increase in use of "mind-bending" drugs by young people—was a declaration of war on abuse or potential abuse of all existing or future drugs. Its purposes, scope, and effect are comprehensive in every sense of the word.

Significant sections relating to FDA's responsibilities in Title II, the Controlled Substances Act, classify drugs for control or restrictions on use according to the problems they present as a result of abuse or



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*"Two things have been common to all epidemics involving abuse of a drug: its availability on the market, and the ease with which it could be obtained."*

abuse potential; establish production quotas or import requirements for certain of these drugs to keep unneeded supplies off the market; and provide authority to determine qualifications and establish standards for any ongoing research with those drugs for which there is no recognized therapeutic or scientific use. FDA's functions in these areas are advisory to the Justice Department's Drug Enforcement Administration, which has primary responsibility for enforcing the 1970 legislation. But FDA also performs several other basic functions under the Food, Drug, and Cosmetic Act which are necessary to the implementation of the newer legislation.

Under the Controlled Substances Act, FDA, upon request by DEA, makes a scientific and medical evaluation of a drug after gathering the necessary information, and recommends to DEA whether it should be controlled, removed from control entirely, or moved from one schedule to another.

DEA places drugs subject to abuse into five categories or "schedules" for varying controls on distribution. This scheduled control is based on the drug's potential for abuse; known drug effects; history and current patterns of abuse; risk to the public health from abuse; and psychic or physiological dependence liability.

DEA can add any drug to a schedule, move a drug from one schedule to another, or remove any drug from any of the schedules after gathering relevant data, including a scientific and medical evaluation by FDA and FDA's recommendation as to whether it should be controlled and the extent of control, or whether it should be removed from control. FDA's recommendations are binding

in scientific and medical matters. If FDA recommends that a drug not be controlled, its recommendation is binding on DEA.

If a company wishes to challenge a DEA ruling in regard to scheduling a drug, it is entitled to an administrative hearing. After such a hearing, a hearing examiner then renders a decision, which can be appealed.

The five categories or schedules of drugs provided by the Controlled Substances Act:

Schedule I drugs have a high potential for abuse and have no currently accepted medical use in treatment in the United States. (A Schedule I drug may be capable of leading to severe dependency or to little or no dependency.) However, these drugs can be used by qualified researchers under protocols approved by FDA, the Alcohol, Drug Abuse, and Mental Health Administration, and their Joint Drug Abuse Research Advisory Committee, a group of outside experts on drug abuse. Examples of Schedule I drugs are LSD, mescaline, peyote, marihuana, tetrahydrocannabinols (active principles of marihuana), and heroin.

Most of the drugs in the remaining four schedules have established medical uses in the United States.

Schedule II drugs have a high potential for abuse and have an accepted medical use with severe restrictions. Abuse of these drugs may lead to severe psychological or physical dependence. Examples are opium and opiates such as morphine, synthetic narcotics such as methadone and meperidine, other drugs such as cocaine, and stimulants such as amphetamine, methamphetamine, and methylphenidate. Recently methaqualone and the short-acting barbiturates pentobarbital,

amobarbital, and secobarbital were added to Schedule II. Drugs in Schedule II are considerably more restricted in manufacturing and distribution, prescription procedures, and physical security requirements than drugs in the lower schedules.

Schedule III drugs have a potential for abuse less than those in Schedule II. Abuse may lead to moderate or low physical or high psychological dependence. Examples of drugs in this class are nalorphine, phencyclidine, and methyprylon. Also included are limited amounts of codeine, morphine, and certain of their derivatives combined with other medicaments.

Schedule IV drugs have a low potential for abuse compared to drugs in Schedule III. Abuse may lead to limited physical or psychological dependence compared to drugs in Schedule III. Examples of Schedule IV drugs are barbitol, phenobarbital, chloral hydrate, paraldehyde, and meprobamate.

Schedule V lists drugs with lower abuse and dependency potential than those in Schedule IV. Under this schedule are small amounts of codeine and opium and their derivatives and diphenoxylate, in each case when combined with nonnarcotic medicinal ingredients.

FDA is responsible for determining medical and scientific needs to be considered by DEA in setting production quotas and importation requirements for drugs in Schedule I and II. DEA over many years has developed a production-import quota system for drugs with abuse potential, assessing legitimate medical and scientific needs through consultation with DHEW. FDA has not found it necessary to reassess these needs except for drugs recently added to Schedules I or II.

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*"The Comprehensive Drug Abuse Prevention and Control Act of 1970 . . . was a declaration of war on abuse or potential abuse. . . ."*

FDA is charged with determining the qualifications of researchers and evaluating the research protocols for registration in which Schedule I drugs are used. A Joint Drug Abuse Research Advisory Committee, consisting of recognized experts in the drug abuse area, reviews the protocols and recommends action to be taken by FDA concerning studies with Schedule I drugs in humans and advises ADAMHA concerning supplies of Schedule I drugs maintained by that agency.

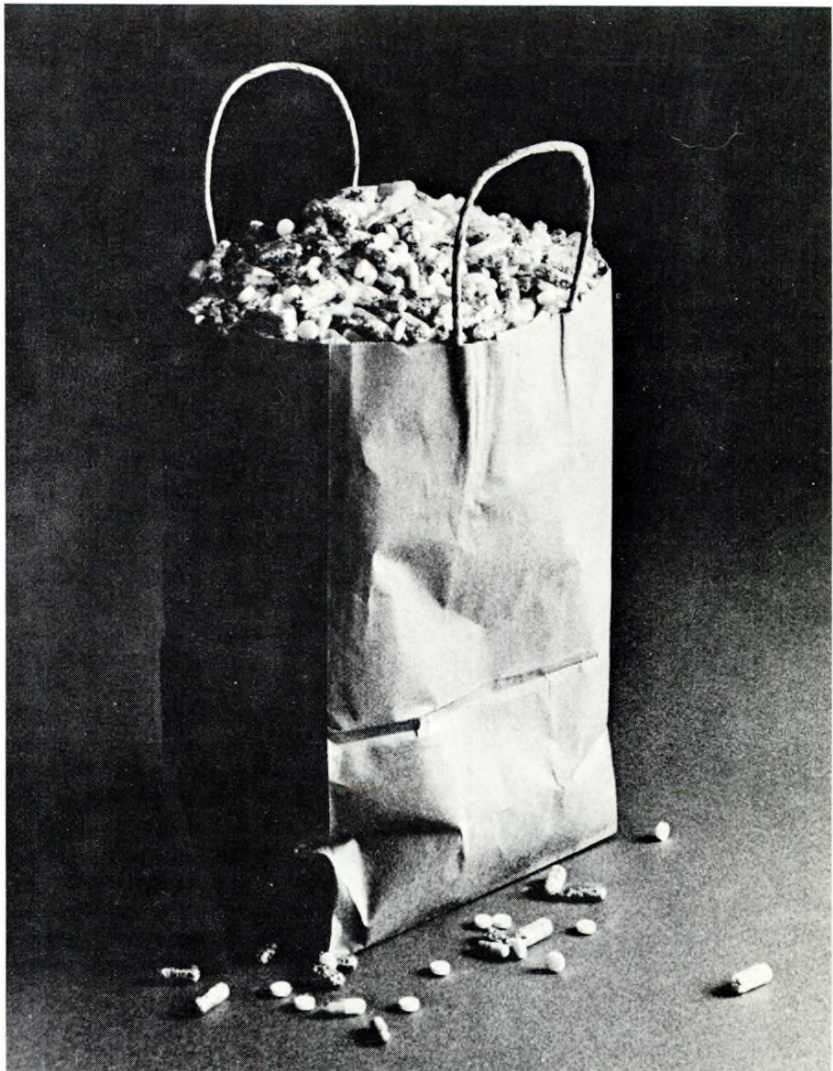
As a part of FDA's responsibilities under the Food, Drug, and Cosmetic Act, the Agency:

- Assures that the labeling of all drugs and the advertising of prescription drugs accurately reflect abuse and dependency potential and do not encourage unwarranted use. If information received by FDA shows that an over-the-counter drug presents an abuse problem, the Agency can take action to reclassify it as a prescription drug. If further action is warranted and the drug fits the legal description of a drug of abuse, the Agency can recommend that DEA place it on one of the control schedules.
- Evaluates the safety and efficacy of drugs used in the treatment of drug dependence before approving them for marketing.
- Requires that any new drug be tested for drug abuse potential when there is reason to believe abuse may occur.
- Works with other Government agencies, such as ADAMHA, DEA, the President's Special Action Office for Drug Abuse Prevention, and the Veterans Administration, in various drug abuse programs.

FDA has already worked closely with DEA in seeking to control many drugs of abuse.

In 1970, FDA, concerned with the abuse and dependency potential of amphetamines and methamphetamines, acted to curtail label claims for many questionable uses of these drugs, such as for depression. At DEA's request, FDA recommended the following year that these stimulants and two others with similar abuse-dependency potential be

moved from Schedule III to II. This was done by DEA in the same year. These actions brought a sharp drop in prescribing of these drugs and enabled FDA to make recommendations that resulted in sharp cutbacks in amphetamine production quotas in 1972 and further cuts in 1973, so that current production of amphetamine has been reduced 92 percent



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*"In making its recommendations concerning the scheduling of drugs, FDA considers the extent and variety of legitimate medical and scientific uses. . . ."*

or more from that in 1971.

In 1973, after DEA had reported extensive diversion of several short-acting barbiturates to the illicit market, FDA recommended transfer to Schedule II of certain short-acting barbiturates and glutethimide, the latter a drug that drug abusers might substitute for barbiturates. As a result of this recommendation, DEA has recently moved the three most abused barbiturates from Schedule III to Schedule II.

In 1972, evidence began to accumulate that methaqualone, a sedative-hypnotic that had not been listed on any of the control schedules, was being widely abused in this country. No problem of abuse and dependency potential had been indicated in industry test data supplied to FDA before methaqualone was approved for marketing in 1965. Although an epidemic of methaqualone abuse had been reported from Japan in the 1960's, this drug was left off the 1970 schedules by Congress largely because the World Health Organization's Expert Committee on Drug Dependence had not recommended control.

In February 1973, FDA asked DEA to investigate the extent of abuse of methaqualone. Upon being informed by DEA that abuse was indeed extensive, FDA recommended that the drug be placed in Schedule II. DEA agreed and, after a hearing in which one of the manufacturers of the drug contested the proposal, placed methaqualone in Schedule II in October 1973.

During 1973, FDA asked that eight existing and new appetite-suppressant drugs be placed on the control schedule and that three hallucinogens be added to Schedule I. DEA has placed these under the recommended control in the past

year. FDA also has ordered that injectable amphetamine be taken off the market as unsafe and that combinations of amphetamine with sedatives or other drugs be removed from the market because the ingredients in the various combinations do not contribute to weight reduction in the user as claimed for these products.

In making its recommendations concerning the scheduling of drugs, FDA considers the extent and variety of legitimate medical and scientific uses, the possibility that less restricted drugs might be substituted by drug abusers for those on which controls are tightened, the inhibitions that tightened controls might have on legitimate prescription needs, and the actual and potential abuse and dependency problems involved.

The Drug Abuse Staff of the Bureau of Drugs' Division of Neuropharmacological Products coordinates all FDA's activities related to drug abuse except for administration of the methadone maintenance regulations, which is handled by a separate unit. The Drug Abuse Staff, in evaluating and monitoring clinical research and the qualifications of researchers who use Schedule I drugs, collaborates with the Alcohol, Drug Abuse, and Mental Health Administration, which controls the distribution of these drugs and supports some of the research.

FDA's Drug Abuse Staff is responsible for assuring that FDA standards are met for all investigative new drugs and for New Drug Applications involving drugs used in the treatment of narcotics addiction, alcoholism, or any type of drug abuse. Of current interest is research involving four drugs—one opiate and three narcotic antagonists—which are being considered for

use in treatment of narcotic addiction. These four drugs were developed by the pharmaceutical industry, but the Federal Government has assumed primary responsibility for the research.

The staff also reviews New Drug Applications in behalf of drugs affecting the central nervous system for abuse potential and recommends the necessary control measures. The staff surveys drugs on the market for abuse trends and recommends to DEA any necessary changes in scheduling.

FDA also is seeking data from all available sources concerning the illicit use of drugs and the effects on public health as well as methods for determining the abuse potential of experimental drugs which may not be marketed. Thus FDA is hoping to obtain such data to head off problems such as that involving methaqualone, in which abuse reached serious proportions before the drug was placed under control.

Since 1970, FDA and DEA have imposed rigid controls on legitimate use of amphetamines, pentobarbital, amobarbital, secobarbital, and methaqualone. The abuse of these drugs has been a significant public health problem. In addition, FDA has limited the number of approved therapeutic uses for the amphetamines, markedly reducing their legitimate uses as well as reducing production quotas. Significant progress has been made since 1970, but further work needs to be done to reduce drug abuse—one of the country's most pressing public health problems.

Harold C. Hopkins is editorial director of FDA CONSUMER.

Edward C. Tocus, Ph.D., is chief of FDA's Drug Abuse Staff.



# How Defective Products Are Recalled

by Margaret Morrison



*Recalls of consumer products—from cars to foods—have become a common occurrence. This is how recalls of products regulated by FDA are effected.*

**I**t seems to crop up often in the news. Another product recalled from the market. The number of recalls has increased to the point where the very word “recall,” seldom used in relation to consumer products just a short time ago, is now understood by virtually everyone.

Even though the word is familiar, the actual way in which a recall is carried out may not be so well understood. For example, many people have the impression that a Government agency such as FDA conducts the recall. Actually, recalls are con-

ducted by the company that made or distributed the defective or hazardous product.

In the case of products which are regulated by FDA, the Agency may request a company to recall a product, and FDA monitors the recall to make sure it is accomplished. However, in many instances firms decide to recall products without a request from FDA.

FDA can remove hazardous or defective products from the market by seizure, which is undertaken by the courts at FDA’s request. However, seizures take time and do not always result in optimum consumer protection. Recall of a defective or hazardous product by the manufacturer or distributor has become the quickest and most practical means of getting an unsafe or unacceptable product off the market.

Use of recall procedures as a means of protecting the public has grown steadily over the years. There were 1,549 recalls monitored by FDA during the last fiscal year. A larger number of actual recalls probably took place, since a company is not required to tell FDA when it is recalling a product.

Companies may have a number of reasons for recalling a defective or hazardous product. If a company—or a consumer or the Government—finds something wrong with a product, the company may remove it in the best interest of its customers. Manufacturers and distributors today are very sensitive to consumer demands and their own responsibilities for quality products.

In addition, a company that makes or distributes a defective or hazardous product faces a number

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**“... many people have the impression that a Government agency such as FDA conducts the recall. Actually, recalls are conducted by the company that made or distributed the defective or hazardous product.”**

of less appealing alternatives. The government could seize the product, consumers could file private lawsuits should the product harm someone, there is a chance that company officials could be criminally prosecuted, and there could be adverse publicity due to public warnings by FDA when a company refuses to recall a product.

All actions classed as recalls by FDA appear on the weekly recall list, available from FDA's Office of the Assistant Commissioner for Public Affairs. The publication of this list was begun in 1967, as a further service in the interest of consumer protection.

The recalls of products regulated by FDA range widely in importance and in the amount of time and effort FDA devotes to them. To clarify its role, FDA published a recall policy in 1971 and last year reevaluated it and set forth some new procedures. Four changes in policy are of particular interest.

First, FDA extended its definition of recalls to cover the activities of the Agency's two newest bureaus, Radiological Health and Biologics. Before, neither Bureau routinely reported recalls of products to the public.

Second, FDA divided recalls into three classes. Previously there had been two.

Class I recalls are those which pose the most serious threat to health. Examples are botulism found in food, a label mix-up on a life-saving drug, or a defective heart valve.

Class I recalls receive top priority and command the attention of the top Agency officials. The product is removed from the market down to the *consumer* level (to the individual user); a public warning is issued;

the recall appears on the weekly recall list; and complete effectiveness checks are carried out to assure adequate removal of the product from the market.

Class II recalls involve products whose hazard is only potential. Examples might be the recall of a drug not used in life-threatening situations, or an x-ray machine giving off unnecessarily high but not acutely hazardous radiation. This also includes recall of a product that is adulterated, represents gross fraud or deception to the consumer, or has a label that is misleading to the point where it might pose a danger of injury or damage to the consumer.

In Class II recalls, the product is removed to the retail level (removed from retail store shelves); it is placed on FDA's weekly recall list; a press release may be issued; and FDA officials check the adequacy of the removal in accordance with the degree of consumer hazard associated with the product.

Class III recalls are those which involve violation of the law but in which a health hazard is remote or nonexistent. An example might be a product labeled to contain 10 ounces which actually contains only 9. Removal is made to the wholesale level, and the product is shown on the weekly recall list, but there is ordinarily no press release.

Class II and Class III recalls, since they deal with situations in which there is no imminent danger, do not require a 100 percent check of all known distributors of the product.

The third major change in FDA recall procedures is to make available to the public more information about regulatory actions, such as seizures, injunctions, and prosecu-

tions. Such information, formerly reported to the public only in FDA CONSUMER, has now been added to the weekly recall list, which can publish the information on a more current basis.

The fourth major change is the modification of FDA's policy of issuing a national press release for every recall which presents a hazard to health. This does not mean that FDA will "withhold" or "keep secret" any recall.

All recalls will continue to be listed as promptly as possible on the weekly recall list. The only change is to provide that in certain rare instances the Commissioner may decide to limit the manner and the degree of publicity the Agency will seek in addition to the weekly list.

For example, a botulism recall involves a high degree of risk and wide distribution of the risk among the population. Obviously, the broadest possible publicity is needed.

On the other hand, suppose that a defective heart-lung machine is distributed to 50 hospital operating rooms. The manufacturer can identify all 50 of the hospitals. A personal visit by FDA and a telegram or personal visit by the manufacturer to those hospitals would notify the affected public promptly and adequately.

Should a recall of this kind be widely publicized before it is conducted, it could cause unnecessary confusion and concern in thousands of other hospitals where similar machines, *not* involved in the recall, may be in use.

Recalls of life-saving products such as pacemakers or heart valves create a special problem. In these cases, FDA will, whenever possible, identify the patients who have the



**JOHN DOE  
LABORATORIES**

Somewhere, U.S.A. 12345

**FIRST CLASS M**

These are the model letter, envelope, and post cards which FDA has prepared to indicate how such communications should be handled.

A. B. C. Pharmacy  
Anywhere, U. S. A.

(red print)→

**URGENT: DRUG RECALL**

**JOHN DOE  
LABORATORIES**

Somewhere, U.S.A. 12345

CONTROL DIVISION

Date \_\_\_\_\_

(red print)→

**URGENT: DRUG RECALL**

Re: List 1234, Cyanocobalamin Injection, Lot No. 4321

Recent tests show that the above lot number of this product is not sterile. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot 4321 on hand. If so, discontinue dispensing the lot and promptly return via parcel post, to our New York City Plant; **ATTENTION: RETURNED GOODS**. You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your assistance.

Henry Doe  
Director of Quality Control

**PLEASE FILL OUT AND RETURN**

We do not have any stock of List 1234, Cyanocobalamin injection Lot No. 4321 on hand. ☐

We have requested our accounts to return their stocks of this merchandise to us. ☐

We are returning \_\_\_\_\_ bottles of List 1234, Lot No. 4321

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

**BUSINESS REPLY MAIL**

No Postage Stamp Necessary if mailed in U.S.A.

Postage will be paid by

**JOHN DOE LABORATORIES**  
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Henry Doe  
Director, Quality Control

Firs  
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ol clh  
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Original from

UNIVERSITY OF CALIFORNIA



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**"One important aspect of the recall of a product is that it may trigger the investigation of an entire category of products."**



*The most widely recalled product in recent months has been canned mushrooms. In this photo, Philadelphia District Consumer Safety Officers Kathy Mallon (left) and Joanne Hawkins check mushroom cans.*

defective devices and notify the physicians who implanted them. The patients will be notified by their physicians. Other patients, thousands of whom may be using similar equipment which is functioning perfectly, will be spared the unnecessary uncertainty and fear that would occur if they heard of a recall of the product on a TV newscast or other public announcement.

In all decisions concerning publicity about recalls, the Commissioner of FDA will determine how much or what kind of publicity is consistent with the nature of the hazard and with the numbers of people involved in possible risk.

To illustrate how a product is actually removed from the market, we might follow the course of a Class II recall. Suppose a report reaches

FDA, from a physician or someone else in a health-related field, that a consumer has suffered adverse reactions from an over-the-counter or nonprescription drug. Suppose further that a number of similar complaints are received by FDA, from various parts of the country.

After reviewing information about the adverse reactions suffered by consumers, FDA would then inspect the plant in which the product was manufactured and review all data on the product, including ingredients, production procedures, and containers.

The conclusions might show the drug to be a potential hazard to health, and FDA would then recommend to the manufacturer that the product be removed from the market and that the risk to consum-

ers be publicized.

If the company agreed, it would issue a recall letter notifying its distributors that the product must be removed from consumer channels. FDA's consumer safety officers in the District or Field Office usually offer to assist the firm in arranging the text of telephone calls or composing recall telegrams or letters, so the product can be promptly and effectively removed from the market in accordance with FDA requirements.

The appropriate FDA bureau, in this case the Bureau of Drugs, would issue an official recall number, determine the classification of the recall (I, II, or III), and the District or Field Office would send out detailed information (description of the product, dosage, potency, lot number or other identification, reason for the recall, etc.) that would facilitate removal of the product from the market.

In the case of an over-the-counter drug, a news release might go out from FDA with full information about the name of the product, the name of the manufacturer, the potential hazard or problem, and a warning about using the product. At the same time, a message would go out to FDA District and Regional Offices throughout the country, and State and local health officials are also notified of the recall. The action would also be included in FDA's weekly recall list.

If the recall involved a potential consumer hazard, it would be important for the District Office monitoring the recall to assure that stocks of the product were found and recalled as expeditiously as possible. An agreed-upon time when the recall might be expected to be con-

**"The fact that recalls are now happening more frequently than in the past should be reassuring to consumers. It means that both industry and Government are alert to consumers' interests and more involved with consumer protection."**

cluded would be established with the firm. Later, the District Office would follow through with the recalling company, to confirm how much of the product had been recovered and the ultimate disposition of it, and to ensure that the unsatisfactory product was indeed removed from the market and either reconditioned or destroyed.

Meanwhile, the FDA District staff and other agencies assisting in monitoring the recall would carry out what the Agency calls "effectiveness checks" to make sure distributors, subdistributors, and retail stores were complying with the recall order. This means making sure distributors are holding up any further shipments of the product to retail outlets and that retail stores are no longer selling the product.

If the company has conducted the recall properly, its distributors all know about the recall and have segregated out the product. They have, presumably, notified the stores that buy the product and they, too, have put the merchandise aside, preparatory to sending it back to the distributor.

However, ideal conditions don't always exist. Recall letters may go out late. They may be delayed in the mails. They may be inadvertently overlooked, in spite of their bright red stamp reading "Urgent: Food (or Drug) Recall." The distributor may put off telling his stores, or they may fail to respond. So the consumer safety officer or other official who performs the effectiveness checks is serving a vital function in keeping potentially dangerous products from consumers.

One important aspect of the recall of a product is that it may trigger the investigation of an entire cate-

*On January 17, Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, addressed a national conference on product recall in New York City. This is a short excerpt from Dr. Schmidt's speech:*

"Not only do I believe recall will remain—I think it must!

"I see the technique as an administrative necessity for both of us. In this day of complex technology and massive distributions, the mandatory remedies of injunction, seizure, and criminal prosecution are limited alternatives.

"The need for such a recall system likely will endure as long as man and his machines remain imperfect.

"Speaking as a regulator, I can assure you that while voluntary recall cannot substitute for formal regulation, it undoubtedly redounds to the benefit of cooperative industry through lessened need for a stringent regulatory posture.

"But more than this, there are moral as well as legal imperatives to prevent consumer injury. On the moral side it seems clear that modern industrial leadership—individual as well as corporate—must embrace the concept of responsible citizenship, must accept that responsibility to the consumer goes beyond the mere limits of product liability. If nothing else, public sophistication demands no less.

"On the legal side the courts increasingly insist that responsibility for safe and useful products rests not alone with the inanimate corporation; it extends as well to individual corporate leadership and beyond that to all levels of production and distribution. If the product causes injury, all concerned can be held liable."

gory of products. When one medicated spray is found to be hazardous, for instance, FDA may begin an investigation of other such spray products, and perhaps find that others also contain ingredients—or are packaged in containers—which pose health hazards. In an actual case of recall of a certain brand of decongestant spray last year, FDA later requested the recall of five other aerosol spray products, all of which contained the solvent 1, 1, 1-trichloroethane, a substance that was present in substantial amounts in the product originally found to be hazardous.

Whenever you hear or read about a recall action, and then see the defective product on store shelves, you can perform a public service by calling it to the attention of the store

manager, and by notifying FDA. However, it is important that you be sure of the facts—that you know the exact name, and the lot number, of the product being recalled, since recalls may be of one specific product from a brand line, or one specific lot number of that product.

The fact that recalls are now happening more frequently than in the past should be reassuring to consumers. It means that both industry and Government are more alert to consumers' interests and more involved with consumer protection. Whenever a recall takes place, consumers can know it is happening because FDA and the firm making the recall have found evidence that the product is unacceptable and are using the fastest, most efficient method for removing the product from the market.

# Can Your Kitchen Pass The Food Storage Test?

*The proper storage of foods in the home is essential for food safety.  
Can your kitchen pass this food storage test?*

by Jane Heenan

**I**t'll never happen, but if the Food and Drug Administration were to inspect every family kitchen in the United States for proper storage of foods—most of them probably would flunk.

It takes a concerted effort by homemakers and good planning in the kitchen to avoid many food storage pitfalls. Proper storage of food is essential to assure the products' safety and quality.

Prove it to yourself. Be your own inspector. Check out the "family food firm" in your own kitchen and see what needs to be improved. Make a list of changes that are needed, and then make them.

## Checkpoint One

The first step is a check of cabinets underneath the kitchen sink, or any cabinets through which water pipes, drain pipes, or heating pipes pass. Any food stored there? Sacks of onions or potatoes, or perhaps some liquids or canned goods?

If so, count yourself already in violation of good storage practices.

Foods should never be stored in these cabinets, because they will attract insects and possibly rodents through openings that are almost impossible to seal adequately. Also, possible leakage from the pipes can damage the food products, causing cans, for example, to become overheated or rusty.

It is always a mistake to store anything you may eat alongside

potent household chemicals. Bottles of cleaning chemicals could easily be mistaken for bottles of soda or another food. Imagine a salad dressing of vinegar and denatured alcohol!

Next, take a look at the open surfaces in your kitchen. Any food sitting out? Meat thawing at room temperature? A carton of milk you'll put away "in a minute"?

Foods that should be refrigerated or frozen should be handled always with special care. Bacteria in such foods can multiply rapidly under certain conditions—that is, outside the refrigerator or freezer. Always remember to keep cold foods cold.

Take a look at your breadbox. While bread normally keeps fresher longer at room temperatures than in the refrigerator, in hot humid weather, bread is better protected against mold in the refrigerator.

Next, look at storage areas near heat sources, such as the stove. Foods should not be kept in cabinets above the stove. Even dry mixes, which may be held at room temperature, will not keep well in that area.

## Checking the Stock

Now take a look at foods being held at room temperatures.

The first place to check is the canned goods. Reach all the way to the back of the least accessible shelf. Any dust on the cans? If so, you'd better make some adjustments in your kitchen.

Cans should always be kept

clean and dust-free. Any foreign matter on the tops of cans will be pressed into the food itself during opening.

Pick up each can on the shelf. Does it stick slightly? This could be a sign of leakage, and the can should be returned to the store. Weak seams in the cans can allow gases to build up and force fluid out. This can be a dangerous situation, as toxins (poisons) can be forming.

If you have cans on your shelf that leak, bulge, or are otherwise unusual, be careful! Notify FDA. At the very least, return the can to the store and notify the manufacturer.

By alerting the store, the manufacturer, and FDA, you could be helping protect other consumers. Necessary measures can be taken to locate and remove other cans with the same code number that may also be contaminated.

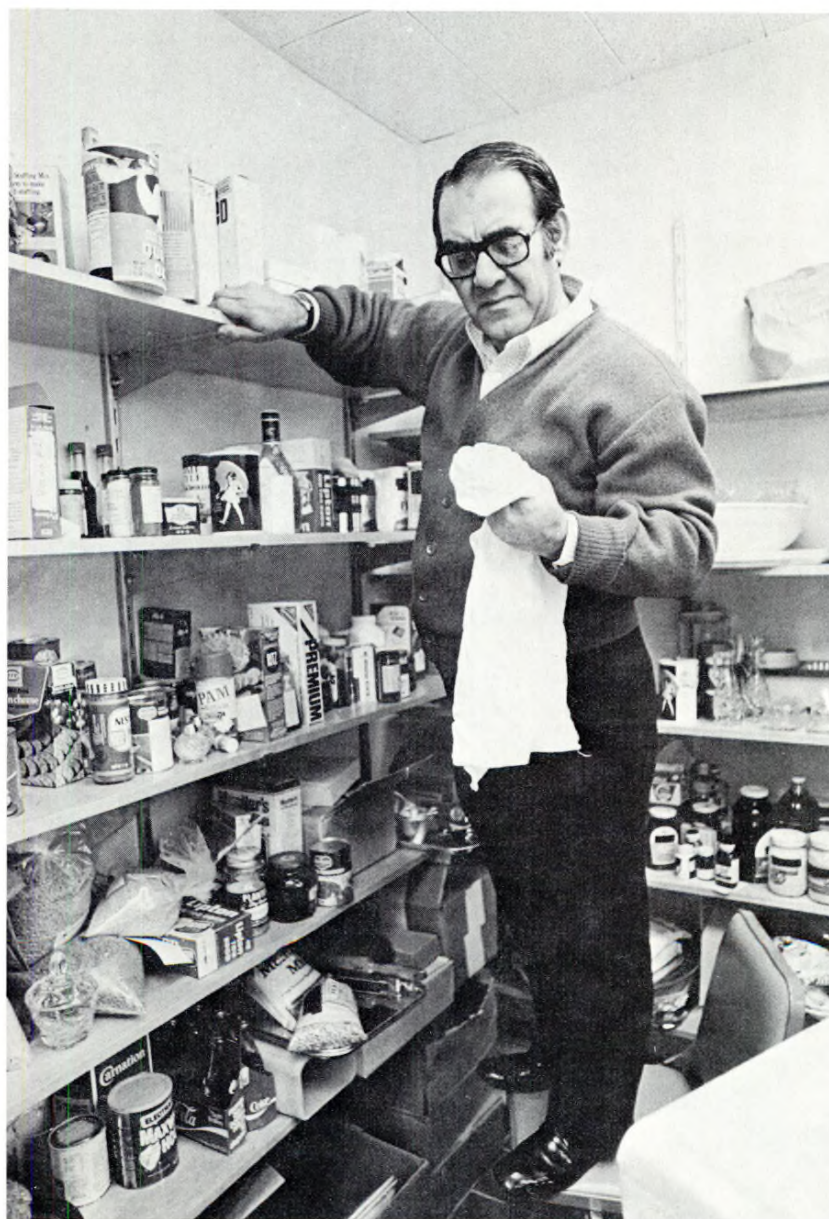
Resist any temptation to taste food that doesn't seem right. You don't even have to swallow the food to be poisoned by the toxins produced by certain types of bacteria. In some cases, even the food's taste is no indicator of safety.

While you're checking through the pantry, reread some of the labels to see if some of the goods should have been refrigerated. Don't assume that all boxed or canned goods may be held at room temperature. For example, canned cheeses such as Brie and Camembert should be kept





*Like most people, he's full of ideas—mostly bad ones. That “perfect” place under the sink is no place for food. Pipes passing through an area can not only leak, but also provide unsealable openings to draw bugs.*



*He's the one who pushed ahead of you at the bargain counter to buy a dented can. Little did either of you know it was no bargain. In buying dented cans, look for seam damage—which may mean the product is contaminated.*

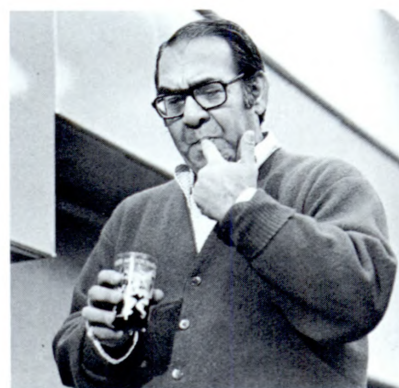
*He never knew that dust on cans should be cleaned off. After all, it doesn't reach the food. Right? Wrong. Harmful bacteria can easily be pushed into the food by a can opener. A neat pantry isn't always clean.*





*The box reads "keep refrigerated." But it's too late now to save the product. And like too many consumers, he's compounded the mistake by storing food near a heat source, in this case over a stove.*

*There's no food like an old food. Begging for medical bills, he uses the taste test to see if foods are still good. Foods that are "over the hill" don't necessarily have to be swallowed to poison you. And the assumption that mold is harmless is equally dangerous.*



under refrigeration even before opening.

And a double-check with every purchase of grated Parmesan cheese is necessary; some containers call for refrigeration after opening and others don't. If you've made a mistake and failed to refrigerate something that should be, throw the product away.

You may also find honey and syrup that's been opened but remains in your pantry. Syrups are better protected from mold in your refrigerator. If crystals form in refrigerated honey or syrup, simply place the containers in hot water before use.

Peanut butter also belongs in the refrigerator after opening, and it can stand at room temperature for a short while to soften before use.

Before your pantry inspection is complete, check on storage of

nuts. Unshelled nuts held at room temperature up to about 6 months are no problem in your kitchen. But other nuts, because of their high fat content, should be stored in airtight containers in the refrigerator or freezer to delay rancidity. If they have become moldy, throw them out.

You may also find in your pantry or perhaps atop the stove a can of bacon drippings. This, along with margarine and butter of course, belongs in the refrigerator—always!

#### **Your Biggest Problem**

Now for the toughest part of your inspection—the refrigerator. You'll probably find more problems here than in any other area. Why? Because you've expected it to do things it was never meant to do.

You may have thought the refrigerator would destroy most harmful bacteria in food. Wrong.

Refrigeration will retard the growth of the bacteria found in food, and keep them from multiplying. Their ability to spread or produce a poison is greatly inhibited by refrigeration, but bacteria or poison present in a food may still be there even after refrigeration.

The same is true for freezing. Freezing does not kill bacteria in food, it simply stops their spreading. The bacteria will become active and again continue to spread as the food is thawed. Such foods should be prepared as soon as possible after thawing.

But with many foods you will still have rapid deterioration even in the refrigerator. Broths, gravies, stuffings, chicken salad, potato salad, poultry, fish, liver, kidneys, brains, and giblets are some of the foods that should be used within 1 or 2 days of home storage.

So your first check is to see



that foods aren't being held too long. Look inside covered dishes, sniff beverages, open bags and bins. Throw out questionable items as well as products you really don't plan to use.

With the most obvious part of your refrigerator survey out of the way, you still have several points to check before further considerations about the stored items themselves.

Do you have an accurate thermometer in your refrigerator and freezer? Chances are there's no thermometer at all—probably only a regulator allowing for general setting of "colder" or

"warmer." Good thermometers made especially for refrigerator and freezer use may easily be purchased and should be used.

In the normal home refrigerator, a temperature of 45 degrees Fahrenheit may be adequate to hold food 3 or 4 days; but if items are to be kept longer, they should be refrigerated at 40 degrees or lower. In the freezer compartment, foods to be held for long periods should be kept at zero degrees, but you'll probably find this not maintained throughout the compartment. A thermometer is really your safety map of the refrigerator. Without it, you're

missing an important part of quality control for your kitchen, and, in strictest terms, you don't pass inspection.

Next, check around the motor and refrigerating unit. Lint and dirt on these parts cut off the air supply, overwork your refrigerator, and reduce efficiency.

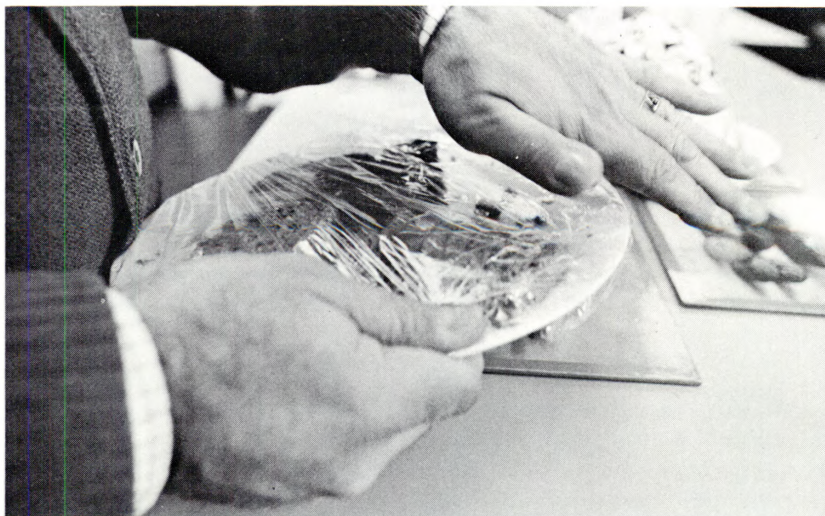
Look at the gaskets (the rubber insulation) around the doors. They should be flexible. Stiff, cracked, and damaged insulation allows air seepage. Make a test with a dollar bill. Hold it halfway in the door, shut the door, and see if you can easily pull the bill out. If so, the gasket is allowing air to



*It's a bad habit, and it means he'll probably wind up dribbling milk down his shirt. But the real problem is that bacteria from his mouth will contaminate the milk.*

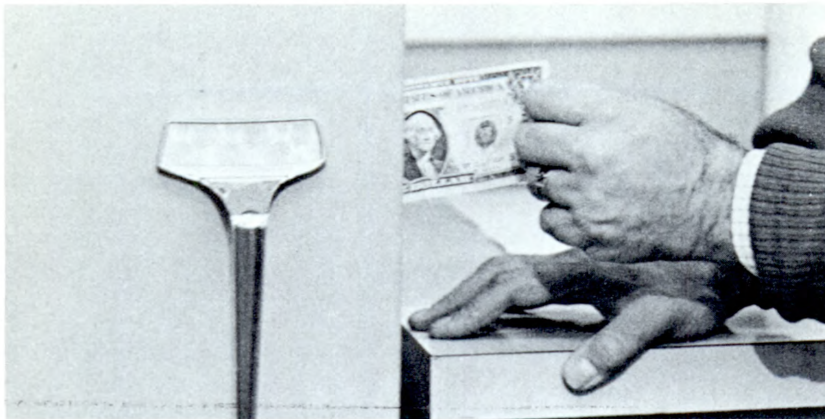


*A study in how NOT to refrigerate food, our friend stacks, spills, crams, and tilts products and uses one criterion: just get the door shut. This makes for quick spoilage, forgotten items, and poor cooling patterns.*



*Carefully covering those last treasured bites of dessert, he doesn't realize they'd keep in moisture far better if transferred to the smallest possible container, where wrapping could be almost airtight.*





*Doing something right, for a change, he tests the refrigerator gaskets to see that the door shuts tightly. If the dollar bill can be slipped out easily, then it's time to replace the rubber insulation around the door.*

*He shows promise! He's finally bringing himself to throw away any old or leftover foods with "off" color, taste, or odor. Any food that has been around for awhile or set out at room temperature merits checking.*

escape and should be repaired.

Next, check your freezer. Frost buildup of one-fourth inch or more actually serves as insulation AGAINST keeping foods frozen well.

And one final, simple check for the refrigerator itself. Is it clean? Enough said!

#### **Inspect for Good Management**

How you manage foods in cold storage—how you wrap them, where you place them, when you use them—is important for the safety and quality of every item. Your check list of things to change after this inspection could very well include management techniques.

First, check for these procedures on wrapping:

Fresh meat should be wrapped loosely, just enough to allow air to circulate but not enough to let the product dry out.

The rule is reversed for leftovers: they should be covered tightly.

Raw poultry should be unwrapped, placed on a dish, and covered. Giblets must be wrapped and stored separately. Also, stuffing must never remain in meat and poultry; warm dark cavities are ideal areas for growth of dangerous toxins.

All containers should be closed or covered.

Leftover egg yolks should be covered with cold water and refrigerated with a cover. (They should be used within 2 to 4 days.) Whites don't need the water.



## Storing Chart

### STORAGE PERIOD (To maintain its quality)

PRODUCT	STORAGE PERIOD	
	Refrigerator 35° to 40° F.	Freezer 0° F.
	DAYS	MONTHS
FRESH MEATS		
Roasts (Beef and Lamb) ....	3 to 5	8 to 12
Roasts (Pork and Veal) ....	3 to 5	4 to 8
Steaks (Beef) .....	3 to 5	8 to 12
Chops (Lamb and Pork) ....	3 to 5	3 to 4
Ground and Stew Meats ....	1 to 2	2 to 3
Variety Meats .....	1 to 2	3 to 4
Sausage (Pork) .....	1 to 2	1 to 2
PROCESSED MEATS		
Bacon .....	7	1
Frankfurters .....	7	½
Ham (Whole) .....	7	1 to 2
Ham (Half) .....	3 to 5	1 to 2
Ham (Slices) .....	3	1 to 2
Luncheon Meats .....	3 to 5	} Freezing not recom- mended
Sausage (Smoked) .....	7	
Sausage (Dry and Semi-Dry).....	14 to 21	
COOKED MEATS		
Cooked Meats and Meat		
Dishes .....	1 to 2	2 to 3
Gravy and Meat Broth.....	1 to 2	2 to 3
FRESH POULTRY		
Chicken and Turkey .....	1 to 2	12
Duck and Goose .....	1 to 2	6
Giblets .....	1 to 2	3
COOKED POULTRY		
Pieces (Covered with Broth)	1 to 2	6
Pieces (Not Covered) .....	1 to 2	1
Cooked Poultry Dishes .....	1 to 2	6
Fried Chicken .....	1 to 2	4



### In Case of Emergency

If power fails or the freezer stops operating normally, try to determine how long before the freezer will be back in operation.

A fully loaded freezer usually will stay cold enough to keep foods frozen for 2 days if the cabinet is not opened. In a cabinet with less than half a load, food may not stay frozen more than 1 day.

If normal operation cannot be resumed before the food will start to thaw, use dry ice. If dry ice is placed in the freezer soon after the power is off, 25 pounds should keep the temperature below freezing for 2 to 3 days in a 10-cubic-foot cabinet with half a load, 3 to 4 days in a loaded cabinet.

Place the dry ice on cardboard or small boards on top of packages, and do not open freezer again except to put in more dry ice or to remove it when normal operation is resumed.

Or move food to a locker plant, using insulated boxes or thick layers of paper to prevent thawing.

For freezing, all items should be wrapped tightly in moisture-resistant materials, such as freezer paper or foil.

Where you put the food is important for three reasons: 1) Some should be kept colder than others; 2) Food placement affects air circulation and efficiency of the refrigerator; 3) Foods that should be used quickly need to be in full view so they're not easily forgotten.

The coldest part of the refrigerator is the area nearest the freezing compartment. Milk,

meats, and most leftovers should be in that area.

Foods should not be stacked, and refrigerator shelves should never be covered with foil or any material that keeps down air circulation.

Produce should be held in the lower compartments to prevent crystallization.

Food should also be arranged, both in the freezer and the refrigerator, so that the oldest is used first. This is important for safety as well as flavor, texture, and nutrition.

### How Did You Do?

You may have found several areas where you've used improper storage methods. And you may say to yourself, "It can't be so bad, because what I've done hasn't killed me yet!"

But this response is a cop-out.

How many times have you or members of your family said, "I don't feel very good. It must have been something I ate."???

Jane Heenan writes for FDA's Consumer Education and Information Staff.

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# News Highlights

## Legislation Suggested to Expand FDA Authority in Many Areas

The Administration has transmitted to the Congress proposed legislation to strengthen and expand FDA authority.

Titled The Food, Drug, and Cosmetic Amendments of 1974, the proposed legislation is designed to improve FDA's ability to ensure the safety and quality of food, drugs, cosmetics, and devices.

Enactment of the legislation would give FDA access to complaint files, processing records, quality control records, and similar information. It would give the Agency power to require recordkeeping and reporting of industry data and actions, such as recalls. Additionally, it would give the Agency detention and subpoena power, and would increase penalties for violating the Food, Drug, and Cosmetic Act.

Major provisions of the proposed legislation would:

- *Broaden FDA's inspection authority.* The legislation would give FDA full access to formulas and complaint files, quality control and processing records. This authority would apply to all products under FDA's jurisdiction.
- *Require recordkeeping and reporting.* FDA now has this authority only for new drugs. The legislation would extend it to other products regulated by FDA. With it, FDA could, for example, require manufacturers to report recalls of merchandise or submit existing safety or product experience data.
- *Give FDA authority to administratively detain products.* Currently, FDA has no authority under the Federal Food, Drug, and Cosmetic Act to hold a suspected product. In some cases, such products have been distributed before legal action could be taken. The legislation would allow FDA to hold the product for up to 20 days, while appropriate legal action was initiated.
- *Increase fines for criminal violations.* The maximum fine for violation of the Federal Food, Drug, and Cosmetic Act would be increased from \$1,000 to \$10,000 for the first offense and from \$10,000 to \$25,000 for subsequent or fraudulent violations.
- *Authorize issuance of subpoenas.* This provision would give FDA the power to subpoena witnesses or

documents related to matters under investigation or review.

- *Require the listing of the quantity of active ingredients on nonprescription drugs.* Currently, such labels are required to declare quantities for only certain active ingredients.
- *Make registration of foreign drug firms mandatory.* Registration and reporting requirements currently imposed on U.S. drug manufacturers would be extended to foreign drug establishments.
- *Prohibit the exportation of uncertified antibiotics.* This provision eliminates an ambiguity in present law which suggests that it may be lawful to export uncertified human antibiotics.

The proposed bill would also repeal the Filled Milk Act of 1923 and the restrictions on the sale of filled cheese in the Internal Revenue Code.

In addition, legislation presently before the Congress, and supported by the Administration, would require food plant registration and mandatory labeling of ingredients in standardized foods.

## FDA Outlines Procedures For Cyclamate Petition

FDA has outlined procedures it will follow in reviewing a petition for reapproval of the use of cyclamate, a nonnutritive sweetener, as a food additive.

As its initial action, FDA announced February 12 the formal filing of the petition, and the public availability of scientific data submitted in support of the food additive by Abbott Laboratories, North Chicago, Illinois.

In announcing the review procedures, Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, said:

"Use of nonnutritive sweeteners is of great interest to both the public and scientific community. For this reason, we are charting, as precisely as we can, the course we intend to follow during our review of cyclamate. These procedures are designed to allow the greatest public and scientific participation throughout the decision-making process."

FDA has assigned a team of toxicologists, nutri-



tionists, and chemists to evaluate the data which has been submitted. It is anticipated that this preliminary evaluation will be completed in March. If required, FDA will request additional clarifying data from the petitioner.

When the data are complete, FDA will refer the petition to the Food Protection Committee of the National Academy of Sciences for its evaluation also. This committee is presently reviewing the safety of saccharin.

Following FDA's evaluation of a recommendation from the Academy, FDA will publish its intended action as a proposal for public comment.

"We realize these procedures will require time—probably into 1975," said Dr. Schmidt. "But we will not act until all scientific issues and opinions are fully considered."

Cyclamate has been available for some 30 years. Because it was on the market before Congress passed current premarketing requirements, it was not subjected to the type of safety testing required of newer food additives. It was not, however, used extensively in food until the 1960's when the popularity of diet foods and drinks increased greatly. Intensive testing followed on the heels of increased usage.

In 1969, Abbott Laboratories, the major cyclamate producer, submitted to FDA results of an animal feeding study which showed that animals fed cyclamate had developed bladder tumors. An FDA study resulted in similar findings.

After evaluation of all available data, FDA concluded that safety questions existed which could not be resolved on the basis of existing scientific evidence. The product was then banned.

"The earlier decision to ban cyclamate was made on the basis of the best scientific information of the time, and was made in accord with clear provisions of the Food, Drug, and Cosmetic Act," said Dr. Schmidt. "If newer, more extensive data now offer convincing scientific evidence of the safety of cyclamate, we are legally obligated to, and will approve its return to the market."

Abbott's petition consists of 440 papers bound into 16 volumes. It is available for public review in the Office of the Hearing Clerk, Room 6-86, 5600 Fishers Lane, Rockville, Maryland.

#### **Hearing Slated April 1 On Iron in Bread Rule**

FDA scheduled a hearing for April 1 to resolve the issue of whether additional iron should be added to some flour and bread products.

The action was in response to objections filed by individuals, including five physicians, to an FDA order which would have increased iron levels in these products beginning April 15, 1974. The FDA order was stayed until January 1, 1975, pending the outcome of the hearing.

Objections by the physicians were based primarily on concerns that added dietary iron could create a health hazard for persons suffering from iron storage disorders such as hemochromatosis, and that it could mask diagnosis of other disorders or contribute to the development of other diseases.

FDA originally proposed to increase enrichment levels of iron and other nutrients in flour and bakery products on December 3, 1971. Although most comments supported the proposed increases in the other essential nutrients, there was some opposition expressed to increasing the iron content.

At FDA's request, the Federation of American Societies for Experimental Biology (FASEB) and the Council on Foods and Nutrition of the American Medical Association reviewed the safety question thoroughly. They concluded that the increased iron consumption from enriched bread and flour would not jeopardize the health of normal individuals, nor would it increase the incidence of hemochromatosis or other disorders.

Deficiency of iron in the American diet was noted by the White House Conference on Food, Nutrition and Health (1969) and the Ten-State Nutrition Survey (1968-70) conducted by the Department of Health, Education, and Welfare. Both of these projects produced recommendations urging that corrective steps be taken.

The sole issue considered at the hearing is whether it is safe to increase the levels of iron in certain flour and bread products.

#### **Chocolate Candy Balls Recalled; Salmonella Contamination Suspected**

FDA has announced the recall of foil-wrapped chocolate balls labeled as Regent Solid Milk Chocolate, and distributed in this country by Triumph Candy Corp., Englewood Cliffs, New Jersey. The manufacturer is Regent Chocolates Limited, St. Hyacinthe, Quebec, Canada. The product has been associated with salmonella illness.

The recall was initiated as a result of investigations by public health agencies of 47 cases of *Salmonella Eastbourne*, a form of the infection which had been rare in this country. Evaluation by the Center for Disease Control indicated that foil-wrapped chocolate balls were the cause. In addition, the New Jersey Health Department has identified this particular type of salmonella in a sample of this brand of chocolate balls.

The solid chocolate round balls involved in the recall were individually wrapped in multicolored Christmas-like foil and distributed nationally.

FDA advises consumers who may have these products to return them to the store where purchased.

Salmonella illness is characterized by fever, nausea, vomiting, and diarrhea. The illness generally disappears within 24 to 48 hours.

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# Regional Reports

## REGION I

A U.S. marshal seized 1,840 unlabeled 100-pound bags of rice at Van Brode Milling Co., Clinton, Massachusetts, where they became insect contaminated while held under insanitary conditions. The complaint, brought by the **Boston Field Office**, further claimed that because the bags were unlabeled, the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, and the common or usual name of the food, all required by FDA, were not known.

## REGION II

**New York District's** Import Investigations Branch is currently inspecting all imported canned mushrooms. Mushrooms fall into the category of low-acid canned foods which—if improperly preserved or canned—are conducive to the growth of spores that can cause botulism, a rare but often fatal form of food poisoning. Thus far 337 lots of the imported mushrooms, valued at over \$1¼ million, have been checked by FDA investigators. The inspection was triggered by the recent FDA nationwide survey of all domestic mushroom plants and warehouses after botulinum spores or toxin was found in some canned mushrooms and products in which such mushrooms were used.

Cooperation between the New York and Philadelphia Districts helped to correct a problem found recently on the Penn Central commuter train running into New York City. FDA's Interstate Travel Sanitation personnel working out of the New York District have been concentrating on railcar sanitation inspections because more people appear to be using the trains since the cutback in automobile and airline travel. While checking the drinking water supply in the bar car of the commuter train, the inspectors found the sample of water collected to be quite dark in appearance. They alerted the general foreman of the car department and recommended that the potable water tanks be flushed. Several days later when the inspectors rechecked, nothing had been done. FDA's preliminary laboratory tests had shown the water contained mold. At New York District's request, FDA's Philadelphia District asked Penn Central's main office in Philadelphia to instruct the railroad's New York personnel to flush and sanitize the water tanks as requested. When the New York FDA inspectors made followup checks, the prob-

lem had been corrected.

When Elkins-Sinn, a drug firm in Cherry Hill, New Jersey, was notified that a pharmacist in a Chicago hospital had found a vial of the company's Procaine HCL in a unit carton labeled "Sodium Chloride," the company immediately initiated a recall of the two involved lots of Procaine HCL Solution U.S.P. 2% and Sodium Chloride Injection U.S.P. Bacteriostatic 30 ml. **Newark District** consumer safety officers in an in-depth inspection at Elkins-Sinn found there had been a label mix-up in the company's printing shop. The Procaine HCL carton labels were printed immediately after the Sodium Chloride carton labels, on the same day, and apparently the procedures used to protect the integrity of the labels were not adequate.

Consumer Affairs Officer Gloria Martini, Newark District office, recently presented two lectures for the "Bachelor Living" classes at a high school in Fairlawn, New Jersey. The course is offered for senior boys and parallels the Home Economics classes for girls, covering various aspects of food preparation, housekeeping, budgeting, and home safety. Mrs. Martini spoke to two assemblies of approximately 75 boys each on how to prepare food safely in the home.

**Buffalo District** detained a shipment of Black Diamond Canadian Farmer Cheese from Ontario, Canada, because it was in violation of both the Fair Packaging and Labeling Act and the Food, Drug, and Cosmetic Act. The mandatory labeling was missing. The shipment of cheese was valued at over \$400.

## REGION III

In the **Philadelphia District**, Michael M. Bogos, treasurer and manager of B. Bogoslafsky's Bakeries, Inc., Philadelphia, was sentenced in U.S. Court for the Eastern District of Pennsylvania. The Government had charged both Mr. Bogos and the firm with shipping adulterated food into interstate commerce, after it had been prepared and held under insanitary conditions, causing it to become insect and rodent contaminated. Judge A. Leon Higginbotham, Jr., sentenced Mr. Bogos to 3 years in jail, suspended the sentence, placed him on a year's probation, and fined him \$150. The court did not sentence the bakery, for it had closed its doors last October and gone bankrupt.

In FDA's Philadelphia District a Government-seized

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Diapulse device was destroyed following a motion of judgment of condemnation by default, granted by Judge R. Dixon Herman of the U.S. Court for the Middle District of Pennsylvania. The Government asked for the motion when the claimant, Donald McCabe, D.O., Harrisburg, Pennsylvania, failed to answer written interrogatories. The Government alleged that instructions with the device did not contain adequate directions for safe use by laymen.

#### REGION IV

The first FDA mobile laboratory in Region IV's eight-State area has begun its tour of duty in Florida. The \$20,000 traveling lab, equipped with its own electrical generator and water supply, is one of only 15 FDA labs of this type in the country. Coordinated by the **Orlando Section** office and manned by two FDA consumer safety officers, the lab will run tests to detect food filth and contamination of imported foods entering Florida ports. About 72 percent of all imports arrive at Tampa, Miami, and Jacksonville. In the past, all lab work had to be sent to FDA's regional laboratory in Atlanta. Now the new van will save analysis time and allow for increased examinations of imports.

#### REGION V

The Environmental Protection Agency (EPA) recently informed FDA's **Cincinnati District** that several food-producing farms are located within a few hundred feet of a Northwest Ohio industrial plant which has been emitting fumes containing beryllium residues in excess of EPA air quality standards. There was concern that the foods produced on the farms might be contaminated by residues of beryllium, a poisonous substance. Cincinnati District sampled and analyzed the foods and found the results negative for beryllium.

#### REGION VI

At Houston, FDA's **Dallas District** detained 163,699 pounds of coffee, valued at \$64,010 and imported from Indonesia, because of mold and insect contamination, and 1,053,360 pounds, valued at \$487,112 and imported from the Ivory Coast, because of insect contamination.

Representatives of El Centro College and television station KERA-TV, both Dallas, were taken on a tour of FDA's Dallas District laboratories by Juan A. Tijerina, consumer affairs officer, to plan a half-hour program for a TV course titled *Man and Environment*. The program was shown eight times between November 25 and December 1 and will be shown over a week beginning April 14 this year. About half the program

was taped during a tour in which Jerry L. Henderson, District program manager and consumer affairs coordinator, discussed the different laboratory analyses and answered questions about the work.

#### REGION VII

A Nebraska warehouse corporation and two officials were fined by Judge Warren Urbom of the U.S. District Court for Nebraska, Lincoln, for permitting rodent infestation of stored foodstuffs. The Nash-Finch Co., Lincoln, pleaded guilty to all four counts of an indictment brought on charges by FDA's **Kansas City District** and was fined \$50 on each count. John T. Mower, branch manager, and Jay T. Phipps, warehouse supervisor, pleaded nolo contendere to one count each and were fined \$25 each.

A complaint by a consumer who found a fly in a bottle of Pepsi Cola started an investigation by FDA's St. Louis Resident Post. Consumer safety officers visited the manufacturer, Union Bottling Works, doing business as Pepsi Cola Co. of St. Louis, and found extraneous matter in filled bottles of soft drinks at the plant. FDA laboratory tests confirmed the presence of mold and insect parts. The company was notified of poor sanitary conditions found at the plant and promptly ceased operation, placed a hold on finished products at the plant, and recalled all distributed products. The plant voluntarily destroyed 8,000 cases of soft drinks and carried out a thorough cleanup and repair of equipment before resuming production.

The Government seized 307 hundred-pound bags of long grain rice, valued at \$9,670, in the B & L Drayage warehouse, St. Louis, after an inspection by consumer safety officers at Kansas City District's St. Louis Resident Post revealed contamination by birds. The presence of bird excreta contamination was confirmed by FDA laboratory analysis. Seizure had already been ordered when the warehouse received a new lot and this was seized also because the same conditions existed in the warehouse—birds flying around the new lot and bird droppings on the burlap bags of rice.

The Springfield Grocery Co., Springfield, Missouri, was fined \$200 on one count of a five-count information charging adulteration of stored flour, cornmeal, beans, and candy, after pleading guilty. Magistrate Dennis J. Stewart of the U.S. District Court for Western Missouri also fined Suzanne M. Tynes, president, and Joseph M. Helfrecht, treasurer, \$100 each on one of five counts, and suspended these fines. The remaining four counts against the corporation and the individuals were dismissed. The charges were brought by FDA's Kansas City District.



Inspections by FDA's Kansas City District of two Missouri warehouses resulted in corrective actions. A St. Louis warehouse converted over 9 tons of insect-infested soy flour, grits, and proteins, valued at \$4,279, to animal feed. A Poplar Bluff warehouse voluntarily destroyed over 3 tons of flour and other cereal products, valued at \$467, found contaminated by rodents.

## REGION VIII

A Denver company that makes salads found itself in two kinds of trouble from FDA for processing its product under insanitary conditions. After an inspection of the Vincent Bar-None Co., Inc., plant by Al Shain, FDA Denver District consumer safety officer, Mr. Shain's list of insanitary conditions noted was given for review to W. G. Biggs, Region VIII interstate travel sanitation consultant, on detail as acting supervisory investigator. Mr. Biggs immediately recognized the company as a supplier to airline caterers and railroad commissaries. Whereupon FDA immediately invoked the provisions of the Interstate Quarantine Regulations, prohibiting the use of the company by interstate carriers as a supplier of salads.

## REGION IX

Among 30 detentions by FDA's San Francisco District at the port of San Francisco was a lot of cocoa beans, totaling 770,627 pounds and valued at \$462,376, found contaminated with excessive residues of the pesticide chemical DDT. The lot had originated in Ecuador but had been exported from The Netherlands.

The San Francisco District detained 34 lots of various patent medicines with a total value of \$9,000 at the port of Honolulu on charges they were new drugs without approved New Drug Applications. The drugs, from the Peoples Republic of China, ranged from powdered antelope horn to tablets containing known therapeutic agents.

The Consumer Affairs Office at San Francisco District is working with the California Federated Womens' Clubs, with a membership of 60,000, in a public education program for prevention of *Salmonella* infection. Individual programs conducted by the federation's 740 clubs include placement of printed information in public libraries, work with Parent-Teacher Association groups, and arrangement of public meetings for disseminating information to those attending. The District feels the combined Federal and volunteer effort is proving a success.

Guilty pleas were entered and sentencing imposed in two prosecutions in the U.S. Court for the Central District of California, Los Angeles, resulting from in-

spections and sampling by FDA's Los Angeles District.

Florence Manufacturing Co., Los Angeles, a maker of pasta products, pleaded guilty to three counts of maintaining an insect-infested plant, and was fined a total of \$600 by Magistrate James J. Penne. Joseph R. Esposito, vice president, pleaded guilty to one count and was fined \$100.

Central Fish & Oyster Co., Los Angeles, and David E. Harvey, production manager and secretary, each pleaded guilty to one of three counts charging that breaded fish sticks held at the plant were contaminated by rodents and processing was done under insanitary conditions. Judge Robert J. Kelleher dismissed two counts against each defendant and fined the corporation \$250 on the remaining count. He suspended sentence against Mr. Harvey and placed him on 2 years' probation.

A California company and one of its officials have been enjoined from further manufacture, interstate distribution of, and distribution after receipt of raw materials for the drug Afrodex received in interstate commerce. Afrodex is a new drug for which the company, ICN Pharmaceuticals, Inc., Covina, does not have an approved New Drug Application. The drug is promoted primarily for treatment of male impotence.

Bruce Delvin, group vice president of the company, was also named in the permanent injunction restraint by Judge Harry Pregerson of the U.S. Court for the Central District of California, Los Angeles. FDA's Los Angeles District moved for the injunction because the company was continuing to distribute Afrodex after seizure of the drug had been adjudicated in Texas by a Federal court.

An Arizona farmer and a produce processing and distributing partnership and one of its partners have been found guilty of violative shipment of lettuce containing excessive residues of the pesticide parathion as a result of investigations and sampling by FDA's Los Angeles District. Rala Singh, owner of Rala Singh Farms, Glendale, pleaded nolo contendere to one count; the partnership of Hamilton Farms, Eloy, and R. E. Schlittenhart, a partner in Hamilton Farms, each pleaded guilty to one count. Each was fined \$250. Four other counts against each defendant were dismissed by Magistrate Richard C. Gormley of the U.S. Court for the District of Arizona, Phoenix. The case involved five shipments of lettuce grown in 1970 by Mr. Singh and purchased, packed, and shipped by Hamilton Farms.

The contested seizure of a Diapulse device was resolved in favor of the Government by Judge Malcolm M. Lucas of the U.S. Court for the Central District of California, Los Angeles. The seizure, resulting from charges by FDA's Los Angeles District, was made because of inadequate directions on the label for safe use

by laymen. Dr. Lawrence L. Cunningham, Los Angeles, claimant for the device, had held that a trial was required because there is a difference of medical opinion concerning the use of the device, citing one case in which the Government's motion for summary judgment had been denied.

A total of \$60,000 worth of stored food products has been seized by the Government from California Milling Corp., Phoenix, Arizona, because of extensive evidence of rodent activity and rodent-defiled foods found during an inspection by FDA's Los Angeles District. At FDA's request, the State of Arizona had placed the entire warehouse under embargo pending Federal seizure of the food products involved.

## REGION X

FDA's **Seattle District** has detained five lots of imported frozen froglegs and shrimp, a total of over 65,000 pounds valued at more than \$120,000, because of *Salmonella* contamination. The two shipments of froglegs, detained at Tacoma, were from Japan. Of three shipments of shrimp detained at Seattle, two were from Thailand and one from Hong Kong.

The Government has seized 14,102 pounds of frozen white halibut which FDA's Seattle District charges consists in part of decomposed fish. Seizure was made at a cold storage warehouse in Bellingham, Washington. The halibut originated in Alaska.

## FDA Offices

*Phone numbers listed are those of the consumer affairs officers. District offices are indicated in large type. Cities that have both regional and district, section, or field offices are indicated by one asterisk. Two asterisks indicate other cities with consumer affairs officers.*

**\*ATLANTA** 880 W. Peachtree St.,  
N.W.

Atlanta, Ga. 30309

(404) 526-3162

**\*\*Orlando, Fla.** 32801

(904) 377-2282

**BALTIMORE** 900 Madison Ave.

Baltimore, Md. 21201

(301) 962-3396

**\*\*Falls Church, Va.** 22046

(703) 557-0389

**\*\*Richmond, Va.** 23240

(804) 782-2565

**\*BOSTON** 585 Commercial St.

Boston, Mass. 02109

(617) 223-5857

**\*\*E. Hartford, Conn.** 06108

(203) 244-2529

**BUFFALO** 599 Delaware Ave.

Buffalo, N.Y. 14202

(716) 842-6925

**\*\*Albany, N.Y.** 12207

(518) 472-6045

**\*CHICAGO (Regional) Rm.**

A-1945

175 W. Jackson Blvd.

Chicago, Ill. 60604

(312) 353-1046

(District) Main Post Office Bldg.

Rm. 1222/433 W. Van Buren St.

Chicago, Ill. 60607

(312) 353-7126 and 353-5244

**CINCINNATI** 1141 Central Pkwy.

Cincinnati, Ohio 45202

(513) 684-3500

**\*\*Cleveland, Ohio** 44114

(216) 522-4844

**\*DALLAS** Suite 470-B,

500 S. Ervay

Dallas, Tex. 75201

(214) 749-2384

**\*\*419 S. Main, Rm.** 301

San Antonio, Tex. 78204

**\*DENVER** New Customhouse

Bldg.

Rm. 500/20th & California Sts.

Denver, Colo. 80202

(303) 837-4917

**DETROIT** 1560 E. Jefferson Ave.

Detroit, Mich. 48207

(313) 226-6260

**\*\*110 Michigan, N.W.**

Grand Rapids, Mich. 49502

(616) 456-2340

**\*\*Indianapolis, Ind.** 46204

(317) 633-8580

**\*KANSAS CITY** 1009 Cherry St.

Kansas City, Mo. 64106

(816) 374-5623

**\*\*1709 Jackson St., Rm.** 108

Omaha, Nebr. 68102

(402) 221-4676

**\*\*St. Louis, Mo.** 63101

(314) 622-5021

**LOS ANGELES** 1521 W. Pico

Blvd.

Los Angeles, Calif. 90015

(213) 688-3771

**MINNEAPOLIS** 240 Hennepin

Ave.

Minneapolis, Minn. 55401

(612) 725-2121

**NEW ORLEANS U.S.**

Customhouse

Rm. 222/423 Canal St.

New Orleans, La. 70130

(504) 527-2420

**\*NEW YORK** 850 3rd Ave.

Brooklyn, N.Y. 11232

(212) 788-1454

**NEWARK** Rm. 831/970 Broad

St.

Newark, N.J. 07102

(201) 645-3265

**\*PHILADELPHIA U.S.**

Customhouse

Rm. 1204/2nd & Chestnut Sts.

Philadelphia, Pa. 19106

(215) 597-4374 and 597-5857

**\*SAN FRANCISCO** Federal

Office Bldg.

Rm. 544/50 Fulton St.

San Francisco, Calif. 94102

(415) 556-2062

**SAN JUAN** P.O. Box 4427

Old San Juan Station

San Juan, P.R. 00905

(809) 622-0443

**\*SEATTLE** Federal Office Bldg.

Rm. 5003/909 First Ave.

Seattle, Wash. 98104

(206) 442-5258



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## State Actions

### Herbicide Contaminates

#### Blueberries

A 1973 blueberry crop was ruined on three farms in southwestern Michigan by two utility companies applying the herbicide picloram to their rights-of-way adjoining the farms, the Michigan Department of Agriculture reports. The herbicide was applied in spring 1972 and damaged some of the bushes along the rights-of-way, but analysis at that time revealed no herbicide residue on berries from undamaged bushes. The department theorized that the high water table in the area later permitted lateral movement of the herbicide within the fields to cause the 1973 damage.

#### Oregon Sues 'Reducers'

The Oregon Department of Justice's Consumer Protection Division has filed a complaint in Clackamas County Circuit Court charging six persons and four corporations with multiple misrepresentations in selling body-wrap treatments for weight reduction. The complaint seeks permanent injunction against all the alleged misrepresentations, rescission of all contracts with clients and refund of all monies paid, and nearly \$900,000 in civil penalties.

The charges involved the Slender Wrap body reducing facility which operated at Lake Oswego for about 6 months in early 1973 and discontinued operations at the end of July. The division, according to Lee Johnson, attorney general, charges that the defendants represented that their "magic formula" body wrap could remove fat from the body by a process of osmosis, but that the so-called magic formula was nothing more than epsom salts, which can at best only remove some water from the body. The complaint charges the defendants misrepresented the treatment's effectiveness and the price and guarantee and failed to warn consumers who may

have various medical ailments that would be adversely affected by the sauna and wrap treatment. The division said that although the practices have ceased, it is taking action to ensure that the defendants do not return to Oregon to resume "their fraudulent business practices" and to recover money paid by Oregonians for "this useless body-wrap process."

In a letter to Raymond V. Mlecko, director of the Compliance Branch at FDA's Seattle District office, James L. Carney, division chief counsel, expressed appreciation to FDA for cooperation and assistance to the division in evaluating the Slender Wrap reducing claims.

#### Flour Embargo

The Puerto Rico Health Department embargoed because of heavy insect contamination two lots of all-purpose flour manufactured by Molinos de Puerto Rico, Cantano, Puerto Rico. The flour was in possession of the Puerto Rico Department of Social Services, Mayaguez. It will be held under embargo pending analysis of samples taken from the two lots by FDA's San Juan District investigators.

#### California Label Law

The State of California has amended its Food, Drug, and Cosmetic Act to require ingredient declarations on all food items composed of two or more ingredients. It goes into effect on July 8, 1974. The regulation affects most processed foods and standardized products.

#### Salvager Shut Down

The Denver Health Department has ordered the closing of Walk Brokerage, a local food salvage dealer, because of gross insanitation on the company premises. The U.S. Department of Agriculture discovered the condition while tracing some uninspected meat and notified FDA.

Joint inspection by the Denver Health Department and FDA found vast infestation by rodents, including gnawed bread, meat, and other products. They also found that the company's freezer had been operating improperly, resulting in the thawing, refreezing, and rethawing of much frozen food. The whole warehouse and its contents were judged to be in a deplorable state of insanitation. The department ordered disposal of 100,000 pounds of unfit foods at the dump and permitted salvaging only of canned goods in sealed cases showing no evidence of rodent contamination, the rest to be dumped unless the company can come up with a satisfactory means of sanitizing.

#### North Carolina Embargo

Inspectors of the North Carolina Department of Agriculture have obtained embargoes of flour and other materials at two companies after one joint inspection with FDA's Atlanta District and one inspection performed under an FDA contract.

The State embargoed 14,000 pounds of flour and 31,000 pounds of salt for rodent infestation and 3,550 pounds of flour for insect contamination after the joint inspection of the Statesville Flour Distribution Warehouse, Charlotte. The State inspectors embargoed 1.5 tons of flour and sweet dough mix infested with insects after an inspection of Colonial Stores Warehouse, Raleigh. The contaminated flour later was converted to animal feed.

#### Short-Weight Shrimp

Two lots of Sea Est brand glazed, peeled, cleaved shrimp have been embargoed by the Florida State Department of Agriculture because of short weight. The lots, shipped by the New England Shrimp Co., Malden, Massachusetts, to Tampa and Jacksonville, were found to be 10 to 20 percent short in weight.

# Seizures and Postal Service Cases

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

A total of 35 actions to remove from the consumer market products charged to be violative was reported in December. These included 26 seizures of foods: 1 involved charges concerning poisonous and deleterious substance, 23 involved charges concerning contamination, and 2 involved charges concerning economic and labeling violations. Other seizures included 1 of food additive, 4 of drugs (including 2 of veterinary and medicated feed), and 5 of medical devices.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>FOOD/Poisonous and Deleterious Substance</b>		
Sprouter Kits, Biosnack/Tulsa, Okla. 12/12/73	Samen Mauser/Zurich, Switzerland (M)	Contain the added poisonous and deleterious substance <i>Bacillus cereus</i> ; false and misleading labeling suggesting articles will supply one with health and well-being. Labeling fails to bear statement of the quantity of contents; common or usual name of the food (some); and declaration of ingredients.
<b>Contamination, Spoilage, Insanitary Handling</b>		
Basil leaves, Bulgarian/Countryside, Ill. 10/18/73	Sokol & Co./Countryside, Ill. (D)	Rodent contaminated.
Beans, California blackeye/Barceloneta, P.R. 11/29/73	Casera Foods, Inc./Barceloneta, P.R. (D)	Held under insanitary conditions; insect contaminated.
Catsup, Shurfine tomato/Wichita, Kans. 12/7/73	Fettig Canning Co./Elwood, Ind. (M, S)	Decomposed.
Coriander, Moroccan/Madison, Wis. 11/2/73	Sokol & Co./Countryside, Ill. (S)	Held under insanitary conditions; insect contaminated.
Corn, whole, shelled, white/Phoenix, Ariz. 11/7/73	R & S Mexican Foods, Inc./Phoenix, Ariz. (D)	"
Flour, cornmeal, salt/Caneyville, Ky. 11/13/73	Otis Bryant & Son Milling Co./Caneyville, Ky. (D)	Held under insanitary conditions; rodent contaminated.
Garlic/Laredo, Tex. 12/6/73	David M. Slaughter & Sons, Inc./Laredo, Tex. (D)	Held under insanitary conditions; insect contaminated.
Nuts, mixed/Seattle, Wash. 10/29/73	The Commission Co./Seattle, Wash. (D)	Held under insanitary conditions.
Oats, Triangle rolled/Fresno, Calif. 11/14/73	Robb-Ross, Inc./Fresno, Calif. (D)	" ; rodent contaminated.
Peaches, Argo Yellow Cling Whole/Hopkins, Minn. 12/21/73	Del Monte Corp./Oakland, Calif. (S)	Contain foreign material resembling paint chips.
Peanuts, Alexandria, La. 12/18/73	Noah's Potato Chip Co., Inc./Alexandria, La. (D)	Held under insanitary conditions; rodent contaminated.
shelled, Hartford, Ala. 11/21/73	Anderson's Peanuts/Hartford, Ala. (M, S)	Held under insanitary conditions; insect and rodent contaminated.
Pro-Nuts/Monroe, N.C. 11/16/73	Trophy Brands, Inc./Monroe, N.C. (D)	Held under insanitary conditions; rodent contaminated.

PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>Contamination, Spoilage, Insanitary Handling (cont'd)</b>		
Rice/Canton, Mass. 12/3/73	Van Brode Milling Co., Inc./Canton, Mass. (D)	Held under insanitary conditions; insect contaminated. Fails to bear label containing name and place of business of the manufacturer, packer, or distributor; accurate statement of the quantity of contents; and common or usual name of the food.
Mac's Finest Long Grain; Adolphus Long Grain/St. Louis, Mo. 11/27/73	B & L Drayage Co., Inc./St. Louis, Mo. (D)	Held under insanitary conditions; bird contaminated (Adolphus).
extra fancy long and medium grain/Fresno, Calif. 11/26/73	Marbo Quality Foods, Inc./Fresno, Calif. (D)	Held under insanitary conditions; rodent contaminated.
Salt/Mosinee, Wis. 10/16/73	DuBay Finer Foods/Mosinee, Wis. (D)	Held under insanitary conditions.
Sardines, canned/Shreveport, La. 11/13/73	R.B. & C.G. Stevens Co./Jonesport, Maine (M, S)	Prepared and packed under insanitary conditions; decomposed; swollen cans.
Shrimp, fresh, frozen/Dover, Fla. 11/9/73	Treasure Isle, Inc./Dover, Fla. (D)	Prepared and packed under insanitary conditions.
Spices, various, and dates/Brooklyn, N.Y. 12/10/73	Action Warehouse, Inc./Brooklyn, N.Y. (D)	Held under insanitary conditions; insect contaminated (spices); decomposed (dates).
Sugar, brown, and flour/Des Moines, Iowa 11/23/73	Acric Wholesale Grocery Co., Inc./Des Moines, Iowa (D)	Held under insanitary conditions; rodent contaminated.
pure cane, granulated/Memphis, Tenn. 9/25/73	Manufacturer and shipper unknown.	"
Tomatoes, canned/Cincinnati, Ohio 11/29/73	Milroy Canning Co., Inc./Milroy, Ind. (M, S)	Decomposed substance.
<b>Economic and Labeling Violations</b>		
Popcorn/Lawrence, Kans. 11/19/73	T-N-T Food Products/Lawrence, Kans. (D)	Net quantity of contents statement on principal display panel area not in conformity with the Fair Packaging and Labeling Act.
Tea/Nashville, Tenn. 12/5/73	Colonial Coffee Co./Nashville, Tenn. (D)	Net quantity of contents declaration not in conformity with the Fair Packaging and Labeling Act.
<b>FOOD ADDITIVE</b>		
"Seventeen" (special dietary food)/Detroit, Mich. 12/28/73	General Research Laboratories/Van Nuys, Calif. (M, S)	Contains amygdalin, an unsafe food additive not in conformity with regulations. False and misleading vignette and statement suggesting amygdalin is a nutrient with special dietary properties; inadequate directions for use (the treatment and prevention of cancer). Inadequate warnings; use may be dangerous to health.
<b>DRUGS/Human Use</b>		
Lipohep Injection/Gravette, Ark. 11/15/73	Medwick Labs/Melrose Park, Ill. (M, S)	New drug without effective approved New Drug Application.
Sulfamethazine No. 100 Medicated/Oxford, Kans. 12/10/73	Neese & Sons, Inc./Ankeny, Iowa (M, S)	New drug without effective approved New Drug Application; contains less than labeled potency; label fails to bear accurate statement of net quantity of contents in terms of weight.
<b>Veterinary/Medicated Feed</b>		
Rx Veterinary Drugs, various/Ipswich, Mass. 10/10/73	Vet Pro, Inc./Ipswich, Mass. (D)	Inadequate directions; sold to user without prescription.
Stilbolol-10 diethylstilbestrol premix/ Kissimmee, Fla. 9/24/73	Mid State Feed Mill/Kissimmee, Fla. (D)	New animal drug without effective New Animal Drug Application.
<b>MEDICAL DEVICES</b>		
Diapulse/Lakeland, Fla. 11/8/73	Diapulse Corp. of America/New Hyde Park, N.Y. (M)	False and misleading claims to be effective as a treatment for infections, fractures, bursitis, arthritis, etc.; inadequate directions for safe use by laymen.
Brownwood, Tex. 10/15/73	A.L. Tarlton, D.C./Brownwood, Tex. (D)	False and misleading claims to be effective as a treatment for tissue and bone healing, infections, bursitis, arthritis, etc.; inadequate directions for safe use by laymen.



PRODUCT, PLACE & DATE SEIZED	MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)	CHARGES
<b>MEDICAL DEVICES (cont'd)</b>		
Beaver, W. Va. 10/15/73	Manufactured for Diapulse Corp. of America/New Hyde Park, N.Y.	Inadequate directions for use by laymen.
Havre, Mont. 11/12/73	Diapulse Corp. of America/New Hyde Park, N.Y. (M)	Inadequate directions for use by laymen.
Specific Adjusting Machine/Albuquerque, N. Mex. 11/21/73	Son of James W. Young, D.C./Menlo Park, Calif. (M); James W. Young, D.C./Menlo Park, Calif. (S)	Inadequate directions for use and inadequate warnings.

**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)

- October 2, 1973: **Slim and Trim**, Box 376, Encino, California 91316. Advertising and sale by mail of the Vitamin E Diet representing that vitamin E is an integral part of a weight loss plan.
- October 19, 1973: **E-Diet**, Box 376, Encino, California 91516. Advertising and sale by mail of the Vitamin E Diet representing that vitamin E is an integral part of a weight loss plan.
- October 29, 1973: **Shang-Ri-La Imports**, 17430 South Drive Highway, Miami, Florida 33157. Advertising and sale by mail of a product called "Lose Weight Sensibly Program" represented to be an effective means of losing weight.
- October 29, 1973: **Shang-Ri-La Imports**, 17430 South Drive Highway, Miami, Florida 33157. Advertising and sale by mail of a product called "Please" represented to be effective as a smoking deterrent.
- October 31, 1973: **New Hair Vitamin E**, Post Office Box 603, Delray Beach, Florida 33444. Advertising and sale by mail of a product called "New Hair" represented to be effective in preventing baldness.
- October 31, 1973: **Shang-Ri-La**, 17430 South Dixie Highway, Miami, Florida 33157. Advertising and sale by mail of a product called "Genseng" represented to be effective as a sex stimulant.
- October 31, 1973: **Snowbird Products, Inc.**, P.O. Box 1988, Zephyr Cove, Nevada 89448. Advertising and sale by mail of the U.S. Women's Ski Team Diet represented to be effective in causing a weight loss of 20 pounds in 2 weeks.
- November 5, 1973: **Myers Products**, P.O. Box 9313, Fort Lauderdale, Florida 33310. Advertising and sale by mail of a product called "get it up" represented to be effective as a sex stimulant.
- November 5, 1973: **Myers Products**, P.O. Box 9313, Fort Lauderdale, Florida 33310. Advertising and sale by mail of a product called "keep it up" represented to be effective as a sex stimulant.
- November 7, 1973: **Frederick's of Hollywood**, 6610 Hollywood Boulevard, Los Angeles, California 90025. Advertising and sale by mail of the Professional Swedish Thermal Massage Machine represented to be an effective device for weight loss.
- November 9, 1973: **Vita-Slim**, 1739 Country Club Dr., Cherry Hill, New Jersey. Advertising and sale by mail of Diet Plan in conjunction with diet capsules that allegedly fills your stomach to curb your appetite.
- November 15, 1973: **Sibley Pharmacy**, 280 E. 147th Street, Harvey, Illinois 60426. Advertising and sale by mail of a product called "Siblex diet tablet" represented to be effective in curbing the user's appetite.

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

- October 16, 1973: Against **Eve McElvain Methods**, 1001 Glendale Boulevard, Los Angeles, California 90026. Advertising and sale by mail of White Magic and Blue Mystique, instructions for making a tonic represented to be effective as a weight loss program.
- November 15, 1973: Against **Gift House Products**, 4500 N.W. 135th Street, Miami, Florida 33054. Advertising and sale by mail of a product called "Super-E Penetrating Cream" represented to be effective as a wrinkle remover.
- November 16, 1973: Against **Brentwood Research**, 1800 North Highland, Los Angeles, California 90028. Advertising and sale by mail of Report 43 and the Brentwood Method, instructions for making a tonic represented to be effective as a weight loss program.
- November 16, 1973: Against **Cornell Research Corp.**, 797½ North Main Street, Akron, Ohio 44310. Advertising and sale by mail of a product called "Metab-A Slim" represented to be an effective diet pill by turning fat into water.
- November 16, 1973: Against **Lydia Feldman**, 8228 Sunset Boulevard, Los Angeles, California 90046. Advertising and sale by mail of My Secret, instructions for making a tonic represented to be effective as a weight loss program.

# Notices of Judgment

## NOTICES OF JUDGMENT on Seizure Actions

### FOOD/Poisonous and Deleterious Substances

#### Lettuce, at Chelsea, Dist. Mass.

Charged 1-30-73: when shipped by Bruce Church, Inc., Yuma, Ariz., the article contained the pesticide chemical 1-methoxycarbonyl-1-propen-2-yl dimethylphosphate in excess of the prescribed tolerance; 402(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 58864; S. No. 14-864 G; N.J. No. 1)

#### Salmon, frozen, at Seattle, W. Dist. Wash.

Charged 4-4-73: when shipped by Shoshoni, Inc., Grand Rapids, Mich., the article contained the nonconforming food additive DDT (a pesticide chemical) and its related degradation products; the article contained decomposed fish; and the article's label statement "For Export Only" was false and misleading as being contrary to fact; 402(a)(2)(c), 402(a)(3), 403(a). Default decree ordered destruction. (F.D.C. No. 58984; S. Nos. 74-863 6 D; N.J. No. 2)

### FOOD/Contamination, Spoilage, Insanitary Handling

#### Beans, dried, at Eaton, S. Dist. Ind.

Charged 12-14-72: while held by Meridian Foods, Inc., Eaton, Ind., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 58683; S. Nos. 38-789/92 F; N.J. No. 3)

#### Breader, Star Chef & Colonial Farms frozen breaded mushrooms, and batter mix, at Oxford, E. Dist. Pa.

Charged 4-10-73: while held by The Oxford Corp., Oxford, Pa., the breader contained rodent filth, and the batter mix contained insect filth—402(a)(3); and the breader and batter mix were held under insanitary conditions, and the breaded mushrooms had been prepared and packed under insanitary conditions—402(a)(4). Default decree ordered destruction. (F.D.C. No. 59079; S. Nos. 84-146/50 G; N.J. No. 4)

#### Buttermilk powder, flour, and nonfat dried milk, at Honolulu, Dist. Hawaii.

Charged 3-2-73: while held by H & W Distributors, Inc., Honolulu, Hawaii, the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for reconditioning. (F.D.C. No. 58869; S. No. 75-566 F; N.J. No. 5)

#### Candies, at Phoenix, Dist. Ariz.

Charged 2-9-73: while held by Ponca Wholesale Mercantile Co., Phoenix, Ariz., the articles were held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58849; S. No. 47-014 F et al.; N.J. No. 6)

#### Cashew kernels, blanched, at San Francisco, N. Dist. Calif.

Charged 3-6-73: while held for sale, the article contained insects; 402(a)(3). Consent decree authorized release to Hirschfelder Co., San Francisco, Calif., for salvaging. (F.D.C. No. 58959; S. No. 91-285 G; N.J. No. 7)

#### Catsup, 3 seizure actions, at Muskegon, W. Dist. Mich.

Charged 12-14-72, 1-8-73, and 1-11-73: when shipped by Fettig Canning Corp., Elwood, Ind., the article, labeled in part "Shurfine Tomato Catsup . . . Distributed by Shurfine Central Corp., Northlake, Ill.," contained decomposed tomato material; 402(a)(3). Consent decrees ordered destruction. (F.D.C. Nos. 58685, 58766, 58808; S. Nos. 98-421 F, 98-423 F, 98-422 F; N.J. No. 8)

#### Catsup, Vine Ripe, at Beaver Dam, E. Dist. Wis.

Charged 3-27-73: when shipped by Fettig Canning Corp., Elwood, Ind., the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 59042; S. No. 60-047 G; N.J. No. 9)

#### Cocoa bean sweepings, at Philadelphia, E. Dist. Pa.

Charged 3-2-73: while held by Ben Rosenberg, Inc., Philadelphia, Pa., the article was held under insanitary conditions; 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58946; S. No. 83-001 G; N.J. No. 10)

#### Cornmeal, flour, and dried pinto beans, at Paintsville, E. Dist. Ky.

Charged 6-26-73: while held by Paintsville Grocery Co., Inc., Paintsville, Ky., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 59333; S. Nos. 3-574 80 G, 3-703 4 G; N.J. No. 11)

#### Cornmeal mix, hominy grits, and flour, at South Milwaukee, E. Dist. Wis.

Charged 11-18-71: while held by W. Sucharski, Inc., South Milwaukee, Wis., the articles contained insect filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57646; S. Nos. 35-193 5 E, 35-198 9 E; N.J. No. 12)

#### Fennel seed and lupini beans, at Denver, Dist. Colo.

Charged 10-15-71: while held for sale, the fennel seed contained rodent filth, and both articles contained insects; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 57562; S. Nos. 63-569/70 E; N.J. No. 13)

#### Filberts, shelled, at Trenton, Dist. N.J.

Charged 2-13-73: while held by Mrs. Erzak's Foods, Inc., Trenton, N.J., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58859; S. No. 63-981 G; N.J. No. 14)

#### Flatbread and gingersnap cookies, at New York, S. Dist. N.Y.

Charged 3-21-73: while held by Reliable Kirschbaum Warehouse Corp., New York, N.Y., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 58879; S. Nos. 57-325 F, 58-400 F; N.J. No. 15)

#### Flour, at Casper, Dist. Wyo.

Charged 4-6-73: while held for sale after storage at Pioneer Markets, Inc., Casper, Wyo., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59105; S. No. 45-182 G; N.J. No. 16)

#### Flour, at Charlotte, W. Dist. N.C.

Charged on or about 2-21-73: while in transit in a rodent-infested railcar, the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to Southern Railway Co., Charlotte, N.C., for salvaging. (F.D.C. No. 58881; S. No. 1-503 F; N.J. No. 17)

#### Flour, at Des Moines, S. Dist. Iowa.

Charged 2-8-73: while held for sale, the article contained rodent filth; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 58868; S. No. 50-203 G; N.J. No. 18)

#### Flour, at Detroit, E. Dist. Mich.

Charged 3-30-73: while held by Tarnow Bakery, Detroit, Mich., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59081; S. Nos. 40-365 6 G; N.J. No. 19)

#### Flour, at Lansing, N. Dist. Ill.

Charged 2-8-73: while held by Conrad Kern Co., Lansing, Ill., the article contained rodent filth and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58884; S. No. 22-381 G; N.J. No. 20)

#### Flour, at Orlando, M. Dist. Fla.

Charged 1-9-73: while held by Famous Bakeries, Inc., Orlando, Fla., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree ordered destruction. (F.D.C. No. 58718; S. No. 84-523 F; N.J. No. 21)

#### Flour, cornmeal, and donut mix, at Detroit, E. Dist. Mich.

Charged 12-6-72: while held by Bedell Flour Co., Inc., Detroit, Mich., 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. 58609; S. No. 36-782 F et al.; N.J. No. 22)

#### Flour, donut mix, and donut dusting sugar, at Long Branch, Dist. N.J.

Charged 3-7-73: while held by Baldanza Bakery, Inc., Long Branch, N.J., the articles contained insect and/or rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58912; S. No. 63-470 F et al.; N.J. No. 23)

#### Flour and flour mix, at Union City, N. Dist. Calif.

Charged 11-27-72: while held by Cheney Bros. Food Products, Inc., Union City, Calif., the flour contained rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58573; S. Nos. 75-070/2 F; N.J. No. 24)

#### Flour and rice, at South Boston, Dist. Mass.

Charged 3-6-73: while held by Abbey Warehouse Corp., South Boston, Mass., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58883; S. No. 14-541 G; N.J. No. 25)

#### Flour and sunflower seeds at South Boston, Dist. Mass.

Charged 3-15-73: while held by Abbey's Warehouse Corp., South Boston, Mass., the flour contained rodent filth, and the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58983; S. No. 15-909 G; N.J. No. 26)

#### Lentils, dried, split peas, rolled oats, shelled peanuts, millet, and soybeans,

at Culver City, C. Dist. Calif.

Charged 4-2-73: while held by Erehwon Trading Co., Inc., Culver City, Calif., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to Erehwon, Inc., of Boston, Mass., for salvaging. (F.D.C. No. 59096; S. Nos. 52-366/7 G et al.; N.J. No. 27)

#### Milk, nonfat, dried, at Thomaston, M. Dist. Ga.

Charged 3-30-73: while held for sale, the article was held under insanitary conditions whereby it may have become contaminated with mold; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59094; S. Nos. 5-124 5 G; N.J. No. 28)

#### Mung beans, at Chicago, N. Dist. Ill.

Charged 8-21-73: while held by Great China Food Products Co., Chicago, Ill., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). (F.D.C. No. 59428; S. Nos. 24-951/2 G; N.J. No. 29)

#### Mustard bran, at Nashville, M. Dist. Tenn.

Charged 3-27-73: while held by Dale's Foods, Nashville, Tenn., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59083; S. No. 3-426 G; N.J. No. 30)

#### Orange juice, at Detroit, E. Dist. Mich.

- Charged 1-8-73: while held for sale, the article contained a decomposed substance and was in rusty, swollen, and leaking cans; 402(a)(3). Consent decree authorized release to Kenneth C. Evans, t/a Ken Evans Food Distributor, Detroit, Mich., for salvaging. (F.D.C. No. 58738; S. No. 37-991 F; N.J. No. 31)
- Peanuts, shelled**, at Charlotte, W. Dist. N.C.  
Charged 2-26-73: while held for sale, the article contained insects; 402(a)(3). Consent decree authorized release to Dothan Oil Mill Co., Dothan, Ala., for salvaging. (F.D.C. No. 58911; S. No. 6-435 F; N.J. No. 32)
- Peanuts, unshelled**, at Greenville, E. Dist. N.C.  
Charged 11-7-72: when shipped by Gold Kist Peanut Co., Ashburn, Ga., the articles, which had been involved in a fire, were unfit for food by reason of a strong odor of smoke, blackened shells, scorched nuts, empty shells, and miscellaneous debris; 402(a)(3). Consent decree authorized release to Keel Peanut Co., Inc., Greenville, N.C., for salvaging. (F.D.C. No. 58484; S. No. 5-467 F; N.J. No. 33)
- Pecan pieces**, at Miami, S. Dist. Fla.  
Charged 3-5-73: when shipped by Dasher Pecan Co., Valdosta, Ga., the article contained *E. coli*; 402(a)(3). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 58956; S. No. 584 G; N.J. No. 34)
- Peanuts, shelled, Mansura**, at Memphis, W. Dist. Tenn.  
Charged on or about 3-26-73: when shipped by Central Pecan Shelling Co., Mansura, La., the article contained *E. coli*; 402(a)(3). Consent decree ordered destruction. (F.D.C. No. 59093; S. Nos. 2-090/1 G; N.J. No. 35)
- Rice**, at Colma, N. Dist. Calif.  
Charged 4-10-73: while held by Quality Foods, Inc., Colma, Calif., the articles contained rodent filth and were held under insanitary conditions; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 59120; S. Nos. 90-647/51 G; N.J. No. 36)
- Sage, coriander seed, and dried chilis**, at Los Angeles, C. Dist. Calif.  
Charged 2-23-73: while held by Tampico Foods (Jesus Martinez), Los Angeles, Calif., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for reconditioning. (F.D.C. No. 58910; S. Nos. 49-365/7 F; N.J. No. 37)
- Salmon slices, smoked, canned**, at St. Paul, Dist. Minn.  
Charged 8-10-73: while held for sale, the article contained decomposed salmon; 402(a)(3). Consent decree authorized release to Gourmet Foods, Inc., St. Paul, Minn., for export to the original foreign supplier. (F.D.C. No. 59421; S. Nos. 59-837 G, 60-435 G; N.J. No. 38)
- Salt and flourmill food component**, at Henderson, E. Dist. N.C.  
Charged 10-25-72: while held by Sanford Milling Co., Henderson, N.C., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 58424; S. Nos. 6-673/4 F; N.J. No. 39)
- Soups of various kinds**, at Bridgeport, Dist. Conn.  
Charged 9-28-71: when shipped by Bon Vivant Soups, Inc., Newark, N.J., the articles, labeled in part "Bon Vivant Cream Vichyssoise Soup (or other kind of soup) . . . Packed by Bon Vivant Soups, Inc., Newark, N.J.," "Ancora Clear Green Turtle Soup (or other kind of soup) . . . Bon Vivant Soups, Inc., Newark, N.J.," and "S. S. Pierce Red Label Vichyssoise Cream Soup (or other kind of soup) . . . Packed for S. S. Pierce Co., Boston, Mass.," were unfit for food in that some cans had been found to be defective and abnormal, and in that the manufacturing procedures used did not assure proper sealing of the cans or adequate heat treatment of the sealed can to prevent contamination and spoilage, and the articles had been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health; 402(a)(3), 402(a)(4). Default decree ordered destruction. (F.D.C. No. 57505; S. Nos. 29-016 E, 5-318 E; N.J. No. 40)
- Soybean cakes**, at New York, S. Dist. N.Y.  
Charged 2-27-73: when shipped by Quong Hop & Co., San Francisco, Calif., the article had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58905; S. No. 71-222 G; N.J. No. 41)
- Sugar, jelly, ketchup, mustard, and relish**, at Norfolk, E. Dist. Va.  
Charged 2-16-73: while held by Norfolk, Baltimore, & Carolina Lines, Inc., Norfolk, Va., the articles were held under insanitary conditions; 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 58927; S. Nos. 10-343/54 G; N.J. No. 42)
- Tomato juice**, at Fort Wayne, N. Dist. Ind.  
Charged 3-6-73: when shipped by Beckman & Gast Canning Co., St. Henry, Ohio, the article, labeled in part "Hillcrest Tomato Juice . . . Distributed by Wesco Foods Company, Cincinnati, Ohio," contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 58954; S. No. 39-706 G; N.J. No. 43)
- Tomato juice, Naas**, at St. Louis, E. Dist. Mo.  
Charged 2-22-73: when shipped by NAAS Foods, Inc., Geneva, Ind., the article contained decomposed tomato material; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 58930; S. No. 47-809 G; N.J. No. 44)
- Wafers, wheat, Venus, and cheese sticks, Venus**, at Des Plaines, N. Dist. Ill.  
Charged 2-7-73: when shipped by Venus Wafers, Inc., Quincy, Mass., the articles had been prepared, packed, and held under insanitary conditions; 402(a)(4). Default decree ordered destruction. (F.D.C. No. 58877; S. Nos. 21-843/5 F; N.J. No. 45)
- Wheat**, at Julesburg, Dist. Colo.  
Charged 2-9-73: while held by Farmer's Grain Co., Julesburg, Colo., the article contained rodent filth and was held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 58874; S. No. 34-091 F; N.J. No. 46)
- FOOD/Economic and Labeling Violations**
- Candy, Chocolate Peanut Clusters**, at St. Louis, E. Dist. Mo.  
Charged 4-6-73: while held by St. Louis Peco Flake Co., St. Louis, Mo., the article, which had been packaged by the dealer from bulk, was in violation of the Fair Packaging and Labeling Act, since the principal display panel lacked a quantity of contents declaration; 15 U.S.C. 1453(a)(2). Consent decree authorized release to the dealer for relabeling. (F.D.C. No. 59129; S. No. 47-703 G; N.J. No. 47)
- Carbonated beverages, Happy Sparkle Lemon Sour and Black Jack Tom Collins Mixer Sour**, at East Ellsworth, W. Dist. Wis.  
Charged 4-12-73: when shipped by Jacob Ries Bottling Works, Inc., Shakopee, Minn., the articles failed to declare the optional ingredient sodium benzoate as prescribed by the definition and standard of identity for such beverages; 403(g)(2). Default decree authorized donation to charitable institution. (F.D.C. No. 59133; S. No. 60-587 G; N.J. No. 48)
- Cookies, gingerbread**, at St. Louis, E. Dist. Mo.  
Charged 6-1-73: when shipped by Crystal Cookie Corp., San Fernando, Calif., the article was in violation of the Fair Packaging and Labeling Act, since the principal display panel of the individual cookie packages lacked a statement of the identity of the commodity and lacked a quantity of contents statement; 15 U.S.C. 1453(a)(1), 1453(a)(2). Consent decree ordered destruction. (F.D.C. No. 58257 A; S. No. 47-709 G; N.J. No. 49)
- Corn kernels**, at Los Angeles, C. Dist. Calif.  
Charged 2-28-73: when shipped by Crispy Corn Co., Bellingham, Wash., the article, labeled in part "Clover Club Jumbo Corn . . . Distributed by Clover Club Foods Co., . . . Kaysville, Utah," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not separated from other printed label information appearing below the declaration, and the quantity of contents statement, appearing on the principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Default decree ordered destruction. (F.D.C. No. 58933; S. No. 53-141 G; N.J. No. 50)
- Salmon, smoked**, at Minneapolis, Dist. Minn.  
Charged 2-26-73: when shipped by Specialty Seafood Co., Anacortes, Wash., the article, labeled in part "Specialty Brand Smoked Barbecued Salmon . . . Packed for International Packing Co., . . . Minneapolis, Minn.," was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not in the bottom 30 percent of the principal display panel area, and the quantity of contents statement, appearing on the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high; 15 U.S.C. 1453(a)(2), 1453(a)(3)(C)(i). Consent decree authorized release to International Packing Co., Minneapolis, Minn., for relabeling. (F.D.C. No. 58932; S. No. 60-361 G; N.J. No. 51)
- Sauces for spaghetti, Chef-a-Roni**, at Attleboro, Dist. Mass.  
Charged 3-6-73: when shipped by Eastern Food Industries, Inc., East Greenwich, R.I., the ingredient statement was not prominently placed on the articles' labels with conspicuousness, since the statement was printed in gold ink on a gold-colored background—403(f); and the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents statement, appearing on the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high; and the quantity of contents declaration was not separated from other printed label information appearing above the declaration—15 U.S.C. 1453(a)(3)(C)(i), 1453(a)(2). Default decree authorized donation to charitable institutions. (F.D.C. No. 58872; S. Nos. 14-621/2 G; N.J. No. 52)
- Shrimp, raw, breaded, frozen**, at Biloxi, S. Dist. Miss.  
Charged 4-2-73: when shipped by Hudson Mercantile Corp., Hattiesburg, Miss., the article lacked the name and place of business of the manufacturer, packer, or distributor, and lacked an accurate statement of the quantity of contents; and the article's label lacked the name of the food as specified by the definition and standard of identity for frozen, raw, breaded shrimp; 403(e)(1&2), 403(g)(2). Consent decree authorized release to Ramon & Henry Guitierrez, t/a United Seafoods of Biloxi, Miss., for relabeling. (F.D.C. No. 59089; S. No. 1-145 G; N.J. No. 53)
- Shrimp, raw, breaded, frozen**, at Scranton, M. Dist. Pa.  
Charged 4-26-73: when shipped by National Shrimp Processors, Inc., Brownsville, Tex., the article, labeled in part "Chicken of the Sea Shrimp Miniatures . . . Dist. by Ralston Purina Company, St. Louis, Mo., Ingredients . . . Sodium Tripolyphosphate," failed to conform to the definition and standard of identity for frozen, raw, breaded shrimp, because the article tested less than 50 percent shrimp material and because the shrimp material contained sodium tripolyphosphate, a food additive not permitted as an ingredient; and the article's label lacked the name of the food, as specified by the definition and standard of identity; 403(g)(1), 403(g)(2). Default decree authorized donation to charitable institution. (F.D.C. No. 59146; S. No. 85-513 G; N.J. No. 54)
- Sorghum and cane molasses sirup with added citric acid**, at Waxahachie, N. Dist. Tex.  
Charged 1-18-73: when shipped by Norris Brothers, West Monroe, La., the article, labeled in part "Little Mary Sorghum-Molasses Ingredients: Sorghum, Cane Molasses and Citric Acid . . . Distributed by T. W. Burleson and Son, Inc., Waxahachie, Texas," had been substituted for sorghum molasses, the article was offered for sale under the name of another food, i.e., sorghum molasses, and the name of the article was false and misleading—402(b)(2), 403(a), 403(b); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not placed in the bottom 30 percent of the principal display area, the quantity of contents declaration was not separated from other printed label information appearing above and below the declaration, and the quantity of contents declaration was expressed as "Net Wt. 1 Lb. 14 Oz." instead of "Net Wt. 30 Oz. (1 Lb. 14 Oz.); and the quantity of contents statement, appearing on the principal display panel area of more than 5 square inches, was in a type size less than 1/8 inch high—15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Consent decree authorized donation to charitable organization. (F.D.C. No. 58759; S. No. 32-078 F; N.J. No. 55)
- Taco shells, Pancho Villa**, at St. Paul, Dist. Minn.  
Charged 2-7-73: when shipped by Raymond Distributing Co., Inc., Superior, Wis., the article was short weight (approx. 5.5 percent); 403(e)(2). Consent decree authorized release to Gourmet Foods, Inc., St. Paul, Minn., for relabeling. (F.D.C. No. 58885; S. No. 59-922 G; N.J. No. 56)
- Turnip greens, frozen, and other frozen vegetables**, at Memphis, W. Dist. Tenn.  
Charged 4-26-72: when shipped by Morrison Grain Co., Salina, Kans., the articles, labeled in part "Fresh Delight Brand . . . Chopped Turnip



Greens for "Chopped Turnip Greens With Diced Turnips" or "Whole Leaf Spinach" . . . Packers and Distributors Delta Food Processing Corporation, Moorhead, Miss., "Stilwell Brand Stilwell Frozen Foods, Inc., Stilwell, Oklahoma . . . Packers and Distributors Chopped Mustard Greens," and "Capitol Foods Sliced Squash . . . Capitol Foods Company Distributor . . . Atlanta, Ga.," were short weight (approx. 2.54-4.98 percent)—403(e)(2); and the articles were in violation of the Fair Packaging and Labeling Act, since the quantity of contents of the spinach and both kinds of turnip greens was not placed within the bottom 30 percent of the principal display panel area; all the articles except the mustard greens were labeled as "Net Weight: 3 Lbs." or "Net Weight 2½ Lb." instead of "Net Wt. 48 Oz. (3 Lbs.)" or "Net Wt. 40 Oz. (2 Lbs. 8 Oz.)"; and the quantity of contents statements of all the articles except the mustard greens, appearing on principal display panel areas of more than 25 square inches, were in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(2), 1453(a)(3)(A)(i), 1453(a)(3)(C)(i). Consent decree authorized release to the dealer for bringing into compliance with the law. (F.D.C. No. 57960; S. Nos. 1-770/4 F; N.J. No. 57)

**Turnips with potatoes and carrots, mashed, frozen, Horn & Hardart, at Philadelphia, E. Dist. Pa.**  
Charged 11-29-72: while held by Blue Grass Food Services, Inc., Philadelphia, Pa., who had manufactured the article in part from turnips shipped in interstate commerce, the name of the article, "Frozen Mashed Turnips," in the setting in which it was presented was false and misleading, since the article also contained substantial amounts of potatoes, carrots, and "vegetable stock," and the label lacked the common or usual name of each ingredient, since the declared "vegetable stock" was not the common or usual name of any ingredient; 403(a), 403(i)(2). Consent decree authorized release to the dealer for relabeling. (F.D.C. No. 58507; S. No. 69-024 F; N.J. No. 58)

**Vanilla flavoring, imitation, Como, and other flavorings and spices, at Nashville, Tenn.**  
Charged 3-13-73: while held by Cumberland Manufacturing Co., Nashville, Tenn., who had manufactured the flavorings and had repacked the spices, the articles were short weight; 403(e)(2). Default decree authorized donation to charitable organizations. (F.D.C. No. 58949; S. No. 7-374 F; N.J. No. 59)

#### VITAMINS/SPECIAL DIETARY FOODS

**Caramel corn, at Mount Kisco, S. Dist. N.Y.**  
Charged on or about 5-3-72: when shipped by Howard Food Companies, Inc., Methuen, Mass., the labeling of the article, labeled in part "Sweet'N Low . . . Caramel Corn 'Sweet'N Low is America's #1 Sugar Substitute . . . No Salt Added—No Butter Fats Eat All You Want—As Often As You Want! . . . Ingredients Corn Syrup Solids, Pure Unsalted Vegetable Margarine . . . Distributed by Sweet'N Low Confections Inc., New York," contained false and misleading claims about being sweetened with "Sweet'N Low" sugar substitute in place of ordinary sweeteners, and about being of value in weight control diets and about being consumed in any amount desired by dieting individuals—502(a); the labeling lacked required information for food represented for special dietary use—403(j); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration, appearing on the principal display panel area of more than 25 square inches, was in a type size less than 3/16 inch high—15 U.S.C. 1453(a)(3)(C)(i). Consent decree ordered destruction. (F.D.C. No. 58000; S. No. 67-375 F; N.J. No. 60)

**E Power candy bars, at Phoenix, Dist. Ariz.**  
Charged 12-5-72: when shipped by Carolyn's Candies, Inc., Los Angeles, Calif., the article's name and the label statement "Vitamin E 400 Intl. Units" falsely and misleadingly represented and suggested that vitamin E provided energy and stamina, and that such a candy bar was necessary and useful in supplementing the diet with vitamin E—403(a); and the article was in violation of the Fair Packaging and Labeling Act, since the quantity of contents declaration was not located on the principal display panel—15 U.S.C. 1453(a)(2). Default decree ordered destruction. (F.D.C. No. 58594; S. No. 46-941 F; N.J. No. 61)

**Neo-Life Pro-Nibs tablets, Neo-Life Minute Meal powder, and Neo-Life 90 Plus Instantized High Protein food, at Fremont, Dist. Nebr.**  
Charged 6-14-68: when shipped by Neo-Life of America, San Lorenzo, Calif., the Minute Meal powder had had the valuable constituents vitamin B<sub>1</sub>, vitamin B<sub>2</sub>, and vitamin C in part omitted or abstracted; and the labeling of the Minute Meal was false and misleading as to the declared vitamin content and contained false and misleading claims that the article was a significant source of protein for the diet when used in place of an ordinary meal—402(b)(1), 403(a); the labeling of the Pro-Nibs tablets contained false and misleading claims for promoting health and energy in people of all ages and conditions and of being a significant source of protein for the diet; and the article failed to bear the required special dietary use information, such as the number of available calories, the percent of the nonnutritive constituent calcium cyclamate, and the word "nonnutritive" in juxtaposition with the name calcium cyclamate—403(a), 403(j); and the labeling of all the articles contained false and misleading claims to promote proper glandular function, assimilation of food, and rebuilding processes of the body; that the articles contained all known vitamins, minerals, and trace elements from natural and organic sources; that they were truly nutritive food supplements; and that, when used as directed, the articles were significant sources of protein containing all essential amino acids for the diet; and that the article Minute Meal was a balanced meal, low in calories; and the articles failed to bear the common or usual name of each ingredient, since calcium cyclamate was not declared and since other ingredients were not declared by their common or usual name—403(a), 403(i)(2). The articles were claimed by Clara Smith, Fremont, Nebr., who denied the charges. The parties served written interrogatories on each other and litigated the answers thereto. Subsequently, a consent decree of condemnation ordered destruction. (F.D.C. No. 55465; S. No. 30-415 C et al.; N.J. No. 62)

#### FOOD ADDITIVE

**Cherries, Maraschino, Blanke Baer, at Omaha, Dist. Nebr.**  
Charged 4-19-73: when shipped by Blanke Baer Fruit & Flavor Co., St. Louis, Mo., the article contained the nonconforming color additive Ponceau SX, in that the article contained in excess of 150 ppm of such red color. 402(c). Default decree ordered destruction. (F.D.C. No. 59139; S. No. 50-144 G; N.J. No. 63)

#### DRUGS Human Use

**Aminophylline tablets, U.S.P. at Mansfield, N. Dist. Ohio.**  
Charged 3-1-73: while held for sale after manufacture by C. M. Bundy Co., Cincinnati, Ohio, who manufactured the article from ingredients shipped in interstate commerce, the article's strength differed from and its quality fell below U.S.P. standards, since the article failed the U.S.P. test for ethylene diamine; 501(b). Default decree ordered destruction. (F.D.C. No. 58908; S. No. 26-711 F; N.J. No. 64)

**Beef peptone combination injection, at Brooklyn Park, Dist. Md.**  
Charged on or about 3-30-73: when returned to D-M Pharmaceuticals, Inc., Rockville, Md., from Albuquerque, N. Mex., the article, labeled in part "Prosan Injection . . . manufactured for Sandia Pharmaceuticals, Inc., Albuquerque, N.M. . . . Beef Peptones," was a new drug without an effective approved New Drug Application, and the package insert contained false and misleading claims to the effect that because of the Beef Peptone constituent, the article was generally recognized as a rational, safe, and effective treatment for stimulating the antibody-forming and detoxifying mechanisms of the body, and that the article was safe and effective for the relief of pain in inflammatory neuritis, relief of pain and healing of lesions in herpes zoster ophthalmicus, relief of pain associated with tabes dorsalis, when, in fact, the article was not generally recognized by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as rational, safe, and effective treatment for such purposes; 502(a), 505(a). Default decree ordered destruction. (F.D.C. No. 58940; S. No. 10-823 C; N.J. No. 65)

**Digoxin tablets, U.S.P., at Danbury, Dist. Conn.**  
Charged on or about 12-17-71: when returned to Davis-Edwards Pharmacal Corp., Danbury, Conn., from Philadelphia, Pa., circumstances of the article's manufacture, processing, and the packing and holding failed to conform to current good manufacturing practice, and the article's strength and quality differed from and fell below U.S.P. standards, since the article failed the U.S.P. test for content uniformity; 501(a)(2)(B), 501(b). Default decree ordered destruction. (F.D.C. No. 57329; S. No. 5-014 E; N.J. No. 66)

**Heptron heparin sodium, choline, and vitamin combination, at St. Louis, E. Dist. Mo.**  
Charged 2-22-73: when shipped by Myers-Carter Laboratories, Glendale, Ariz., the article was a new drug without an effective approved New Drug Application, and the labeling of the article contained false and misleading claims in that the listing in the labeling of the article of heparin sodium, choline chloride, cyanocobalamin, folic acid, and niacinamide as ingredients of the article and the statement "Indications: Wherever impaired lipid metabolism exists or is suspected as in hypertension, diabetes mellitus, xanthomatosis, hypothyroidism, angina pectoris, myocardial infarction, and certain diseases of the liver and kidney associated with atherosclerosis" represented and suggested that each such ingredient of the article was of value for the article's intended use and that there was substantial scientific evidence that the article was safe and effective under the specified conditions of use; 502(a), 505(a). Default decree ordered destruction. (F.D.C. No. 58919; S. No. 43-688 F; N.J. No. 67)

**Lidocaine hydrochloride with epinephrine injection for dental block and infiltration, at Bellwood, N. Dist. Ill.**  
Charged 4-10-73: when shipped by Litton Dental Products Co., Toledo, Ohio, the strength of the article, labeled in part "Lidocaine 2% with Epinephrine Lidocaine HCl . . . Manufactured in Switzerland by: Pharmatam Ltd. . . Exclusive Distributors for USA: MPL, Inc., Chicago, Ill.," differed from, and its quality and purity fell below, the U.S.P. standards; 501(b). Default decree ordered destruction. (F.D.C. No. 59077; S. No. 23-050 F; N.J. No. 68)

**Lidocaine hydrochloride for dilution with Add-A-Jet injector, 6 seizure actions, at Venice, M. Dist. Fla.; Columbia, W. Dist. Mo.; Fort Lauderdale, S. Dist. Fla.; Lynchburg, W. Dist. Va.; Philadelphia, E. Dist. Pa.; and Exeter, Dist. N.H.**  
Charged 3-26-73, 3-27-73, 3-30-73, 3-19-73, 4-4-73, 3-19-73: when shipped by International Medication Systems, Ltd., South El Monte, Calif., the article was a new drug without an effective approved New Drug Application and without notice of claimed investigational exemption; 505(a). Default decrees ordered delivery to FDA and/or destruction. (F.D.C. Nos. 59014, 59037, 59055, 59059, 59061/2; S. Nos. 3-189 G, 48-922/3 G, 531 G, 12-725 G, 82-186 G, 15-193 G; N.J. No. 69)

**Mykocert medicated vaginal tampons, at Chicago, N. Dist. Ill.**  
Charged 1-26-71: while held by Beutlich, Inc., Chicago, Ill., after manufacture locally for the dealer from 9-aminoacridine hydrochloride which had been shipped in interstate commerce, the article's box label contained false and misleading claims as a treatment of most vaginal infections caused by gram-positive and gram-negative organisms; and the article's labeling lacked adequate directions for use and was not exempted therefrom, since the article was a new drug without an effective approved New Drug Application, and no notice of claimed investigational exemption was on file; 502(a), 502(f)(1). The article was claimed by the dealer who denied the charges. The parties served written interrogatories on each other which were subsequently answered by each party. The Government filed a motion for summary judgment. Thereafter, the case came on before the court on the motion for summary judgment with the stipulation by all parties that should the court decide that it could not or did not wish to dispose of the case within the limitations of the summary judgment rule, that the court might decide the case on the merits, taking into consideration the affidavits, depositions, interrogatories, and other information on file, as refined and distilled by oral argument. In finding for the Government, the court said:

"The seeming complexity of this action diminishes, once the critical issue around which the entire case revolves is isolated. The drug here in question consists of a tampon impregnated with 14 mgs. of the chemical ingredient 9-aminoacridine hydrochloride and a 'binder' of 14 mgs. of polyvinylpyrrolidone which Beutlich markets as a prescription drug for the alleviation of various vaginal infections. The tampon is inserted in the conventional manner and its intended purpose is to slowly release the medication onto the infected area. The Government in its 21 U.S.C. § 352(a) argument contends that purpose falls short of accomplishment and that the labeling statements in regard to its adequacy and effectiveness are therefore false and misleading in violation of the statute. Though not in any way conceding any part of

these allegations the Government's briefs concentrated on the second part of its argument in regard to the 21 U.S.C. § 352(f)(1) violations. "There are five conceivable defenses that claimant could have raised to the Government's § 352(f)(1) grounds for forfeiture.

"The fifth and final avenue and the one chosen by claimant is that Mykocert is not a 'new' drug as defined in 21 U.S.C. § 321 and 21 CFR § 130.1 and that even though § 352(f)(1) is inapplicable because of the drug's prescriptive nature the non-newness of the drug exempts it from any of the requirements of the previously mentioned alternatives such as application or filing with the Federal [Food and] Drug Administration. Thus the entire crux of the case is dependent on the one critical decisive issue as whether Mykocert is or is not a new drug.

"In applying the statutes, regulations and cases to our set of facts we find the Government's position to be the correct one.

"Claimant's contention that Mykocert is not a new drug can only succeed if it is recognized by experts in the field as safe and effective. There are two possible alternatives that would substantiate claimant's assertions. Either a Mykocert type drug in its exact form, dosage, and application must be recognized by experts (even though that drug may be marketed under a different name) or each of the component parts of Mykocert must be recognized with the critical caveat that the combination of these parts does not in any way create a new drug under 21 CFR § 130(h).

"It is clear from the affidavits, documents and all other evidence that though there are other dosages and forms of application for the type of drug here involved there is however no general recognition under any construction of that test for Mykocert in its exact form.

"Literature on Mykocert in its exact form is virtually nonexistent, no less a body of literature, and there is no expert opinion available as to the general recognition of a 14 mg. dosage of 9-aminoacridine applied in a tampon form and claimant therefore cannot succeed with the contention that a Mykocert type drug itself is recognized. Without going into great detail the few affidavits that address themselves to Mykocert itself rather than to its component parts are inadequate, since they focus on safety and effectiveness rather than general recognition and furthermore are by practitioners prescribing the drug for patients rather than experts in the field. (See 294 F. Supp. 1307 Supra at 1309-10.)

"In addition it is difficult for this Court to acknowledge the general recognition of Mykocert when the chairmen of the Obstetrics and Gynecology Departments at Chicago Medical School; State University of New York, Downstate Medical Center; Northwestern University Medical School; and Loyola University Medical Center all swear that Mykocert is not generally recognized. While we do not express an opinion as to whether a 'mere' conflict in expert opinion constitutes lack of general recognition, it cannot be denied that the affidavits of five of the leading doctors in the field which deny general recognition creates more than a 'mere' conflict. It is inconceivable that a drug such as this could be considered generally recognized in the face of such learned non-recognition.

"Yet even if these experts claim that Mykocert is not generally recognized in its present state, claimants might still attempt to salvage Mykocert by using the other avenue available by asserting that absence of recognition, for Mykocert as such is irrelevant given the fact that its component parts are generally recognized. Claimant does in fact place great faith in this contention by directing a vast amount of literature to the effectiveness and recognition of tampons and aminoacridines generally for use on infections. In order for this argument to succeed Mykocert in its present state must be similar enough in form, dosage, purpose, and application to the general usage of aminoacridines so as to be within the genre 'aminoacridine' and the general recognition attributed to that genre. If Mykocert deviates in any substantial degree from previous forms of aminoacridine usage then it cannot rely on the general recognition of its component parts. The regulations in fact indicate that combinations of 'old' drugs may be a 'new' drug as is stated in 21 CFR 130.1(h)(1) through (5). See Supra, pages 6 and 7.

"Simply stated under the drug laws the whole of a drug may be greater or 'newer' than all of its parts.

"How critical this factor becomes to our case is evidenced in the fact that the vast majority of claimants' affidavits and documents are directed at the recognition of the component parts of Mykocert rather than to the exact form and dosage of Mykocert. There is a vast amount of literature on aminoacridines, affidavits on the efficacy of and recognition of aminoacridines and literature on tampon usage and claimant adds up the general recognition of tampon usage and 9-aminoacridine usage and comes up with a total of non-newness. Thus if we determine that Mykocert is more than just the component parts of tampons and aminoacridines, claimant is practically foreclosed from succeeding based on its almost total reliance on affidavits directed at the component parts rather than the whole.

"In adding up the tampon and aminoacridine usage we do not come up with a total of Mykocert. In view of the fact that the 14 mg. dosage of Mykocert is a much larger dosage than used in other aminoacridine medications for vaginal infections; given the tampon form of application which is unlike gel tablet and cream form of application of vaginal infection medication; that the element of polyvinylpyrrolidone is added as a chemical binder, we hold that Mykocert is a new drug as defined in 21 CFR § 130.1(h)(5) i.e. 'The newness of a dosage or method or duration of administration or application [constitutes newness]

even though when used in other dosage, or method of duration or administration on application . . . is not a new drug.'

"We believe that the new dosage and form of application creates greater risks and questions of safety and effectiveness than previously recognized forms of medication for vaginal infections and given the delicate area of its application—warrants a finding of 'newness.'

"To summarize, then, we are satisfied that based on all the documents and evidence submitted there is no general recognition among qualified experts that Mykocert as such is safe and effective and that claimant cannot rely on the recognition of its component parts since the combination is a new drug within the meaning of the regulations. Mykocert is therefore a new drug and not exempt from the statutes under which forfeiture by the Government was accomplished.

"Judgment will be entered for the United States." (F.D.C. No. 56959; S. No. 26-459 D; N.J. No. 70)

Phenobarbital combination liquid, at Floral, M. Dist. Ala.

Charged 2-5-73: while held for sale, the strength of the article fell below its purported strength, since it contained approximately 71 percent of the declared phenobarbital; 501(c). Default decree ordered destruction. (F.D.C. No. 58873; S. No. 6-654 F; N.J. No. 71)

#### DRUGS/Veterinary

Dr. Brittner's calcium gluconate tablets and Dr. Brittner's Cough Suppress dextromethorphan combination tablets, at Pennsauken, Dist. N.J. Charged 8-23-73: while held by Animal Specialties, Inc., Pennsauken, N.J., who had repacked the article from bulk tablets, the articles were new animal drugs, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of such drugs; 501(a)(5). Consent decree ordered destruction. (F.D.C. No. 58206; S. Nos. 54-976 F, 54-979/80 F; N.J. No. 72)

Oxytetracycline powder accompanied by bottles of a diluent base for injection, at Rushville, S. Dist. Ill.

Charged 2-20-73: while held by Schuyler Laboratories, Rushville, Ill., whose printed flyers promoted the sale of the powder and diluent, the article consisting of the powder and the diluent was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the article, and the labeling lacked adequate directions for mixing and use in each condition and in each species of animal for which the article was intended; 501(a)(5), 502(f)(1). Consent decree authorized release to dealer for destruction of labels and accompanying labeling and bringing into compliance. (F.D.C. No. 58907; S. No. 22-121 G; N.J. No. 73)

Vasp medicated premix, at Fort Dodge, N. Dist. Iowa.

Charged 3-15-73: while held by Quality Plus Products, Fort Dodge, Iowa, who manufactured the article using drug components received in interstate commerce, the article was a new animal drug, and no approval of a New Animal Drug Application was in effect with respect to the use and intended use of the article; 501(a)(5). Default decree ordered destruction. (F.D.C. No. 58924; S. Nos. 50-201/2 G; N.J. No. 74)

#### MEDICAL DEVICES

Aire-N-Aqua bath device, at Colorado Springs, Dist. Colo.

Charged 2-23-73: when shipped by Anaco, Inc., Brainerd, Minn., the accompanying leaflets contained false and misleading claims for arthritis, bursitis, rheumatism, neuritis, muscle soreness, varicose veins, backache, nervous tension, hemorrhoids, traumatic sprains, strains, contusions, synovitis, bone injuries, post fractures, circulatory disturbances, inflammation, edema, ulcers, arteriosclerosis, peripheral vascular diseases, painful joints, scar tissue, adhesions, peripheral nerve injuries, post-poliomyelitis spasm, and for toning and conditioning muscles, controlling weight, and providing better mental and physical health; 502(a). Default decree ordered destruction. (F.D.C. No. 58886; S. No. 33-639 F; N.J. No. 75)

Diapulse electromagnetic energy generators, 12 seizure actions, at Lancaster, C. Dist. Calif.; Oakland, N. Dist. Calif.; Redondo Beach, C. Dist. Calif.; Cambridge, S. Dist. Ohio; Larned, Dist. Kans.; Unionville, E. Dist. Mich.; Harrisburg, M. Dist. Pa.; Stockton, Dist. Kans.; Smith Center, Dist. Kans.; Cimarron, Dist. Kans.; Hays, Dist. Kans.; and Glendale, C. Dist. Calif.

Charged on or about 12-14-72, 12-13-72, 12-6-72, 12-22-72, 12-11-72, 11-20-72, 11-30-72, 11-28-72, 11-30-72, 11-28-72, 12-14-72: when shipped after manufacture for Diapulse Corp. of America, New Hyde Park, N.Y., and while held for sale, the articles' labeling lacked adequate directions for lay use for their intended purposes, and adequate information for use by licensed practitioners could not be prepared; 502(f)(1). Default decrees ordered destruction or, in the Kansas seizure actions, rendering inoperable and donation to an educational institution. (F.D.C. Nos. 58517, 58531/2, 58538, 58549/55, 58560; S. Nos. 47-683 F, 74-243 F, 47-686 F, 25-959 F, 40-397/8 F, 38-173 F, 66-464 F, 42-343 F, 42-342 F, 42-349 F, 42-354 F, 45-819 F; N.J. No. 76)

E Z Breathe electrostatic air filter cabinet, at Winchester, W. Dist. Va.

Charged on or about 12-31-70: when shipped by M-Tron Industries, Yankton, S. Dak., the article's labeling contained a number of false and misleading statements including the statement "E Z Breathe" which represent and suggest that the article was adequate and effective to filter the air in a 15 x 15 foot room in 14-18 minutes; to totally remove all particles from the air, even bacteria and viruses; to make a room healthier; to make the air free from smoke, pollen, dust, and household spray; to make breathing easier, especially for people with breathing problems, pollen irritation, or general congestion; to reduce the discomfort of asthma, hay fever, and other respiratory diseases, and by removal of smoke, dust, and household sprays to reduce the cause of suffering for patients with asthma, emphysema, and allergies; 502(a). The article was claimed by the shipper who denied the charges. The Government served written interrogatories on the claimant. Thereafter, a consent decree authorized release to the claimant for relabeling. (F.D.C. No. 58679; S. No. 12-957 D; N.J. No. 77)

Firm O Matique battery-powered vibrator pads for face, throat, and breasts, and pink "firming" cream, at Beaumont, E. Dist. Tex.

Charged 5-31-72: when shipped by Peel-O-Matique Corp., Inc., Los Angeles, Calif., the articles' labeling contained false and misleading claims to firm the body; provide a firmer, healthier, more attractive appearance; renew the firmness of youth in a woman's face, chin, and breasts; restore and build muscles and muscle elasticity; create better circulation; tighten and firm soft and sagging skin tissues, saggy breasts, double chins, and flabby jaws; tone the muscle fibers that support the breasts, and develop and strengthen these muscles to return them to their natural shape and firmness—502(a); the pink cream lacked an accurate statement of the quantity of contents, lacked the name of each active ingredient, lacked adequate directions for use, lacked warnings against unsafe use, and was a new drug without an approved New Drug Application—502(b)(2), 502(e)(1)(A)(ii), 502(f)(1), 502(f)(2), 505(a). The articles were claimed by the shipper, who denied the charges. The Government served written interrogatories on the claimant. After the claimant answered the interrogatories, the Government moved for summary judgment. Thereafter, a consent decree ordered destruction. (F.D.C. No. 58048; S. Nos. 31-710/12 F; N.J. No. 78)

Massage-A-Bath bath device, at Davenport, S. Dist. Iowa.

Charged 2-27-73: when shipped by Anaco, Inc., Brainerd, Minn., the accompanying leaflets contained false and misleading claims for arthritis, bursitis, rheumatism, neuritis, muscle soreness, varicose veins, backache, nervous tension, hemorrhoids, traumatic sprains, strains, contu-

sions, synovitis, bone injuries, post fractures, circulatory disturbances, inflammation, edema, ulcers, arteriosclerosis, peripheral vascular diseases, painful joints, scar tissue, adhesions, peripheral nerve injuries, and postpoliomyelitis spasm, and for toning and conditioning muscles, controlling weight, and providing better mental and physical health; 502(a). Default decree ordered destruction. (F.D.C. No. 58887; S. No. 38-927 F; N.J. No. 79)

**Tights, body suits, shirts, and stretch garment for neck and chin**, at Columbus, S. Dist. Ohio.

Charged 2-13-73: when shipped by True Form Foundations, Inc., Darby, Pa., the labeling of the articles, labeled in part "Skin Gym by Subtract . . . New York, N.Y." and "Chin Gym by Subtract . . . New York, N.Y.," contained false and misleading claims for the tights, body suits, and shirts for toning and beautifying the body with gentle massage-like action, in shaping the body, in working isometrically to tone, firm, and beautify the body, in improving the posture, in shaping the body when one sleeps, and for the Chin Gym garment for firming the chin and neckline, in providing gentle massage, in working isometrically to remove wrinkles, and in working isometrically to firm the body. Default decree ordered destruction of Chin Gym garments and other articles for relabeling. (F.D.C. No. 502(f)(1), 502(f)(2); S. Nos. 33-985 F; N.J. No. 80)

**Saf T Labs portable oxygen kits**, at Bloomfield, Dist. N.J.  
Charged on or about 12-21-72: when shipped by Safety Laboratories, Inc., Miami, Fla., the article's labeling lacked adequate directions for use for its intended purposes by untrained laity, and such directions could not be written, and the labeling lacked adequate warnings against unsafe use; 502(f)(1), 502(f)(2). Default decree ordered destruction. (F.D.C. No. 58537; S. No. 55-942 F; N.J. No. 81)

#### NOTICES OF JUDGMENT ON Criminal Actions

##### FOOD

**Parnell Green, t/a Green Livestock Co.**, Layton, Dist. Utah.

Charged 5-22-72: when shipped, beef steers contained the new animal drug diethylstilbestrol, and the use of the drug did not conform to any effective approved New Animal Drug Application, since the drug had not been withdrawn from use in the beef steers 7 days before slaughter; 402(a)(2)(D). Guilty plea; imposition of sentence suspended and probation. (F.D.C. No. 57978; S. No. 33-985 F; N.J. No. 82)

**Alfred M. Lewis, Inc.**, Las Vegas, Dist. Nev.

Charged 10-2-67: alphabet macaroni, elbow macaroni, salad macaroni, yellow corn flour, and yellow cornmeal were held in a building accessible to insects and were contaminated with insects; 402(a)(3), 402(a)(4). The corporation pleaded not guilty and moved to suppress all food stuffs, evidences of any contamination, and records taken during the FDA inspection of the corporation's warehouse. The district court ruled as follows:

"Motion to suppress is granted. The search could not be conducted without a warrant, unless consent to search was given. The Court finds consent to search was not given."

The Government appealed the granting of the motion to suppress. In reversing the district court and denying the motion to suppress, the Court of Appeals for the 9th Circuit said:

"Inspection of food warehouses is a necessary incident to such holding of food. Inspections are authorized under 21 U.S.C. § 374(a), (d) under certain specified conditions. It is undisputed this inspection was carried out in accord with the letter and spirit of the statute. Thus it was a 'reasonable time,' and both 'credentials' and a 'written notice' were presented by Mr. Chin to Mr. Riddle, the warehouse manager. Permission to inspect was granted by Mr. Riddle, not only without limitation or condition, but wholeheartedly and with Mr. Riddle's full and active cooperation, as authorized by his employer, and as instructed by that employer. 'It was at a reasonable time and within reasonable limits and in a reasonable manner.'"

"We cannot imagine a clearer factual case of the giving of a consent to an inspection which reflected an understanding (uncoerced and unequivocal) that the warehouse owners knew their rights and gladly cooperated in such inspection."

"The 'search,' or more properly 'inspection,' in this case occurred on September 13, 1966. The *See* and *Camara* cases, . . . were decided June 5, 1967. The trial judge held them retroactive. Both cases relate to the exclusion of evidence."

"Assuming that *See* and *Camara* accomplish a change in the law as to the right to search in FDA cases, and if we assume arguing that the search in this case was rendered unreasonable under the new rule, still that was not the rule at the time the search took place. The search at that time was therefore not unreasonable. . . ."

"Finally, in *United States v. Hammond Milling Co.*, . . . consent to an inspection such as here occurred was held to have been validly given, though not actually expressed. In *Hammond*, the corporate officers made no objection to and intimated no reluctance toward such an inspection. There the Fifth Circuit panel distinguished *United States v. Blalock*, . . . which held that one cannot intelligently surrender a right which he does not know he has. Agreeing with the soundness of that principle, the *Hammond* opinion points out that in the *Blalock* bank robbery case the search was at a time that the investigation had reached the accusatory stage. . . . In summation, the *Hammond* panel said:

"In the case at bar, the defendants had not been charged with a crime at the time of their voluntary consent to the inspection nor had the investigation attained the accusatory stage. Accordingly, we conclude that the defendants need not have been aware of their rights in order to consent to a survey of the premises." (413 F.2d at 611.)

"This circuit has approved the same rule, where there had been voluntary presentation of evidence to revenue agents, with no stealth, trickery, fraud or misrepresentation involved on their part, where defendant was without counsel, and where the defendant had not been warned of his rights. . . ."

"In this connection we note with approval *United States v. Thriftmart, et al.*, 9 Cir., 429 F.2d 1006, decided by a panel of this court on

July 7, 1970, wherein the distinction between an administrative search and a criminal search is made. Here, of course, there was an administrative search similar to that in *Thriftmart*.

"We reverse the order suppressing evidence and remand for further proceedings in the trial court."

The case came on for trial before the district court, and the corporation was found guilty and was fined \$5,000, plus costs. The Government submitted charges based on the actual costs to the Government. The corporation moved to retax costs on the grounds that there was no authority to assess costs of inspecting the warehouse, costs for analysis of food samples, costs for more than one round-trip airline fare from Los Angeles to Las Vegas for one witness who testified on May 5 and May 11, 1971, costs for attendance and services in a representative capacity (rather than a witness), costs for witnesses for days other than days of actual testimony, etc. The court sustained the costs of inspection and cost for analysis, sustained the two round-trip airline fares, retaxed a number of the other contested costs, and granted the reduced total of \$702 costs. (F.D.C. No. 54252; S. Nos. 50-103 F; N.J. No. 83)

#### NOTICE OF JUDGMENT ON Injunction Action

**Fay Candy Co., Raymond F. Underwood, president, and Richard J. Prasser**, production vice president, Skokie, N. Dist. Ill.

Charged 6-1-71 in complaint for injunction: that the defendants operated a candy-making plant at Skokie, Ill., for the production of soft jelly candies, candy lozenges, and hard candy, that FDA analysis revealed a number of wood fragments between 1 mm and 8 mm in size in the defendants' soft jelly candy, that the soft jelly candy was unfit for food because of the wood chips, that the soft jelly candy and the rest of the candy from the plant was prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health, and that the defendants were well aware that their activities were in violation of the law; 402(a)(3), 402(a)(4). A consent decree of permanent injunction permanently enjoined the violations complained of and enjoined the introduction into interstate commerce of any soft jelly candy until a number of specified conditions concerning the production of candy had been met and until all soft jelly candy on hand had been segregated under FDA supervision. (Inj. No. 609; S. Nos. 1-092 '3 D et al.; N.J. No. 84)

#### NOTICE OF JUDGMENT ON Miscellaneous Action

**IMS 4% lidocaine hydrochloride for dilution (Add-A-Jet & Flex-O-Jet systems)**, South El Monte, C. Dist. Calif.

Charged 2-21-73 in complaint for declaratory judgment and injunction, by IMS Limited, t/a International Medication Systems Ltd., against HEW Secretary Caspar W. Weinberger and FDA Commissioner Charles C. Edwards: that the plaintiff had since 1969 been engaged in manufacturing and distributing 4% lidocaine hydrochloride; that the drug was packaged in the delivery systems known as Add-A-Jet and Flex-O-Jet, which systems comprised a vial and a vial injector; that FDA had requested the plaintiff to halt distribution and recall the articles; that FDA's allegation that the design of the articles and their labeling represented and suggested that the medication was intended for intravenous use was wholly incorrect; that FDA's allegation that the only accepted intravenous use of lidocaine hydrochloride was the treatment of cardiac arrhythmias was irrelevant to the articles' labeling in that there was no mention of "intravenous," "cardiac," or "arrhythmias" in the labeling; that lidocaine hydrochloride was first synthesized in 1943, had been continuously used and sold with the same label claims since prior to October 10, 1962, and was not a new drug; that the drug constituted a very substantial part of the plaintiff's business; that, if the plaintiff was forced to discontinue the sale of the drug by FDA seizure or injunction, the plaintiff would be irreparably harmed; and that, accordingly, the plaintiff was entitled to an injunction restraining FDA. The defendants moved to dismiss the actions, or in the alternative for summary judgment, on the grounds that the complaint failed to state a claim upon which relief could be granted; that the case was inappropriate for declaratory judgment; that, as to seeking to enjoin multiple seizure of the article, the action was moot, since multiple seizures had already been instituted across the United States; and that the plaintiff's pleadings, affidavits, and exhibits established that the drug was an unapproved new drug and a misbranded drug. Pursuant to stipulation between the parties, the defendants were granted an extension of time to answer or otherwise plead, because of a hearing in a companion case. Thereafter, the plaintiff having adopted new labeling for its lidocaine hydrochloride which rendered the issues moot, the case was dismissed. (Misc. No. 219; N.J. No. 85)

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

Published by direction of the Secretary of Health, Education, and Welfare.  
Alexander M. Schmidt, M.D., Commissioner of Food and Drugs  
Washington, D.C., March 1, 1974



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