Saccharin: Where Do We Go From Here?
“Everything I like is either illegal or fattening” goes a plaintive slogan that adorns many kitchen walls. Nowadays it’s more relevant and less facetious amid the furor over use of saccharin as a sugar substitute.

Twenty years after passing a law requiring FDA to prohibit adding a substance to food if it causes cancer, Congress has had some second thoughts on one substance, saccharin. Noting wide consumer protests against FDA’s plan to ban saccharin because of its cancer-causing potential, Congress has put an 18-month moratorium on any FDA action on saccharin, but has required that the labels on products containing the artificial sweetener state the possible peril to health. In the meantime, FDA will try to determine beyond a doubt the cancer-causing potential of saccharin and whether it’s of any real use in weight control or dealing with diabetes. Saccharin: Where Do We Go From Here? discusses these and related aspects of the problem.

The good and bad aspects of two other substances, both drugs, are also occupying FDA’s attention. The Great Amphetamine Debate is on the question of whether harm from abuses of amphetamines outweighs their acknowledged benefits in medicine. Battling Resistant Bacteria describes work being done by FDA and a Boston hospital laboratory to determine the relationship between extensive use of antibiotics and bacterial resistance that nullifies the therapeutic benefits of these important drugs.

One benefit that isn’t always forthcoming is the promise implied by the labels of 'Hypoallergenic' Cosmetics, the title of an article explaining precautions allergy-prone consumers ought to take in the wake of a court decision that has frustrated FDA’s efforts to make the term mean what it says.

When a court reverses an agency decision it’s often a hint that the agency has bitten off more than it can or ought to chew. FDA has long realized that retail foodstore sanitation is one responsibility it can’t handle without a lot of help from State and local governments. Sanitation Standards for Foodstores tells how FDA is fulfilling its responsibilities by developing a “model ordinance” that can enable States to keep foodstore sanitation standards high and uniform.

Inside Front Cover: What may appear to be a cluster of cotton balls is, in reality, a greatly enlarged picture of Staphylococcus aureus, a type of bacteria that causes skin infections. Unfortunately, these bacteria can develop a resistance to the antibiotics used to combat them. Some of the steps FDA is taking to deal with the growing problem of bacterial resistance is discussed in an article beginning on page 6.
Nutrition Group Warns on Vitamin Overuse

A law passed by Congress in 1976 sharply restricts FDA’s authority to regulate vitamins and minerals. It forbids FDA to set maximum potencies for doses of vitamin and mineral supplements solely because the Agency believes the dosages are greater than the body needs or can use. The law and the long controversy over the use, benefits, risks, and regulation of vitamins and minerals that preceded its passage were the subject of an article in the July-August 1976 issue of FDA Consumer entitled Regulating Vitamins and Minerals. Here's an update.

Taking large amounts of vitamins provides no benefits to the body and can be dangerous, the National Nutrition Consortium has warned.

The Consortium, which is composed of a number of professional societies, said people who take large amounts of vitamins do it out of a sincere interest in nutrition and health but “it is not a wise practice.”

The body does need vitamins, the Consortium said, and “nutritionists have determined on the basis of research the amounts of each vitamin that meet the needs of most healthy persons.” These amounts are called Recommended Dietary Allowances or RDA’s and are similar to the U.S. Recommended Daily Allowances (U.S. RDA’s) used on food labels.

The Consortium said the taking of massive doses of vitamins is based on the “false assumption” that if a small amount of a vitamin is good for you, then a large amount must even be better. “There are important reasons why large amounts of vitamins should not be taken,” the Consortium said.

“The strongest reason is that large doses of certain vitamins, particularly vitamins A and D, are known to be dangerous. Extremely large amounts may cause headaches, blurred vision, damage to the nervous system, and other bad effects. Amounts too small to cause noticeable harm but still in excess of the RDA may interfere with the normal body processes such as nerve transmission, body protein formation, hormone action, or blood circulation. These changes are perhaps even of greater concern because they generally occur without their hazards being observed by the person, much less corrected by a doctor.”

The Consortium also pointed out that a large dose of one vitamin can block the body’s ability to use another vitamin.

Another danger, according to the Consortium, is that when taken in large amounts some vitamins act on the body the way drugs do.

“Under certain circumstances,” the Consortium noted, “doctors prescribe particular vitamins for non-nutritional disorders. Doctors are well aware, however, that drugs often have bad side effects, especially when they are misused.” Most people realize this is true in terms of drugs such as aspirin, the Consortium said, but they forget (or simply do not know) that it can also be true of vitamins, when taken in heavy doses.

The Consortium said that in addition to the possibility of dangerous side effects, taking large doses of vitamins “is a waste of money” because taking more than the body needs provides no benefits. It said excess water-soluble vitamins (vitamin C and all the B vitamins) ”simply pass from your mouth, to the intestines, to the blood, to the kidney, and then out of the body dissolved in urine.”

Fat-soluble vitamins (A, D, E, and K) may be stored in tissues, but the Consortium said this is a hazard rather than a benefit because accumulation of these vitamins in the body can have toxic effects.

The most subtle hazard of vitamin pills is that in taking them some people get a false sense of security about their nutritional health, the Consortium said.

“A person who takes vitamins may think mistakenly that his or her nutritional needs have been cared for and that there is no need to plan appropriate food choices. Again, this assumption is false. Nutritionists continue, even within the last decade, to discover components of food such as vitamins and minerals that are essential to health.”

The Consortium said selection of a variety of types of food that provide enough—but not too many—calories is “the soundest path” to good nutrition.

The Consortium's warning on the dangers of taking large amounts of vitamins came about two weeks before FDA formally revoked regulations in effect since 1973 which required that high doses of vitamins A and D be limited to prescription use only.

The action was taken after extensive litigation ended in a Justice Department decision in September 1977 not to appeal a court ruling invalidating the regulation. The revoking order was effective upon its publication in the Federal Register March 14, 1978.

FDA's regulations requiring prescriptions for capsules and tablets of more than 10,000 International Units (I.U.) of vitamin A and more than 400 I. U. of vitamin D had been in effect since October 1, 1973.

The suit challenging them was brought by the National Nutritional Foods Association and Solgar Company. The appeals court, in ruling June 7, 1977, said in effect that toxicity is not a basis for a product to be a drug rather than a food. It said that if FDA wishes to restrict, because of toxicity, the potency of vitamins offered as dietary supplements, the Agency must rely on the "adulterated food" provisions of the Act, not the "prescription drug" provisions.

The regulations were prompted by reports in the early 1970's of misuse of large doses of both vitamins A and D. Widespread promotion of the vitamins at that time resulted in excessive use for conditions such as acne, night blindness, and arthritis. Neither vitamin is proven effective for these conditions.

Standards Set for Ultrasound Equipment

How high frequency sound waves are used to diagnose and treat illness was described in The Medical Uses of Sound in the March 1977 FDA Consumer. Here's an update.

The Food and Drug Administration has issued a mandatory safety performance standard to protect people from exposure to incorrect levels of radiation emitted by ultrasonic equipment used in physical therapy.

Ultrasound, a form of energy similar to but higher in frequency than ordinary sound waves, can penetrate body tissues. It is widely used by physicians and physical therapists to produce "deep heating" effects for relief of pain and to promote healing in muscles and joints.

The regulation is the first Federal mandatory safety performance standard for equipment that produces ultrasonic radiation. About 37.5 million ultrasound treatments are administered each year in the United States. About 15,000 ultrasonic therapy units are in use in hospitals, and another 35,000 units are located in other facilities such as physicians' offices and nursing homes. Nine manufacturers of ultrasonic equipment supply a market of $8.5 million annually.

The new standard is being issued because of FDA surveys which showed wide discrepancies between claims made for ultrasonic equipment and actual performance. The Agency found, for example, that many units either delivered too little energy for effective treatment, or too much energy which can cause burns, swelling, and damage to nerve and other sensitive tissues. The standard will assure accurate delivery of ultrasound waves as claimed for the product and indicated by the equipment's controls.

The standard also requires instructions and precautions to assure safe and effective use of equipment.

In addition, the new standard requires manufacturers to provide dealers and distributors with service and repair of information, maintenance schedules, operating and instruction manuals, and assembly and installation directions.

The regulation does not apply to ultrasonic equipment used for surgery, dentistry, or removal of eye cataracts, or to diagnostic ultrasonic equipment. FDA is investigating the need for separate radiation safety regulations for diagnostic equipment using ultrasound.

This final standard was published in the February 17, 1978, Federal Register; it applies to equipment manufactured after February 19, 1979.

X-ray Guidelines Set for Federal Agencies

FDA has estimated that the number of x rays taken each year could be reduced by 30 percent, producing a saving of $2 billion annually in health care costs and at the same time cutting exposure to radiation. How this could be done was described in Reducing X Rays and Health Costs in the December 1977-January 1978 issue of FDA Consumer. Here's an update.

President Carter has issued to all Federal hospitals and clinics guidelines designed to reduce a major source of radiation exposure by discouraging unnecessary uses of diagnostic x rays and assuring that the best available techniques and equipment are used.

The guidelines recommend that general x-ray and fluoroscopic examinations be prescribed only by doctors of medicine or osteopathy and only to obtain diagnostic information. Routine and screening examinations should not be performed except under special circumstances, the guidelines say. For example, many chest x rays and lower back x rays should be eliminated, as well as breast x rays to screen for cancer in women under 50 who have no symptoms or family history of breast cancer. The guidelines also call for protective measures in the x ray of pregnant or possibly pregnant women.
Dental x rays should be prescribed only by doctors of dental surgery or dental medicine on the basis of clinical evaluation or pertinent history, according to the guidelines. Full mouth or bitewing x rays should not be taken as a routine screening procedure.

The guidelines further require that equipment used in Federal facilities meet the Federal Diagnostic X-Ray Equipment Performance Standard and that facilities conduct quality assurance programs, including inspection and maintenance of equipment.

The guidelines call for operators of x-ray equipment to have demonstrated their proficiency in producing quality diagnostic x rays with minimum radiation exposure of the patient. Operators should restrict the size of the x-ray beam and when possible should provide shielding to protect the patient’s reproductive organs or to protect the fetus in women patients who are pregnant or think they might be.

The Administrator of the Environmental Protection Agency (EPA) and the Surgeon General of the Public Health Service jointly recommended the guidelines under EPA’s authority to advise the President on radiation matters affecting health. Agencies covered are the hospitals and clinics of the armed services, Public Health Service, and Veterans Administration. The agencies hope that these facilities, in following the guidelines, will set an example for other medical establishments.

The guidelines were published in the February 1 Federal Register.

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Consumer Forum

**Ingredient Labeling of Food**

Commissioner Kennedy’s interview with Mr. Pines in the February 1978 issue contains misinformation, which was then expanded into an error of fact in the page 3 “teaser.” On page 14, under the question, “Specifically what initiatives need to be taken to improve food labeling,” the Commissioner is reported as stating, “We can’t require ingredient labeling on standardized foods, and even though the FDA knows what’s in the food, that doesn’t help consumers.”

This statement is legally and factually incorrect. Section 401 of the Federal Food, Drug, and Cosmetic Act provides FDA the authority with respect to standardized food to “designate the optional ingredients which shall be named on the label.” FDA has, under this authority, characterized virtually all ingredients in standardized foods as “optional” and thus requires their declaration on the label of standardized foods.

The Commissioner’s statement is, with respect to the standard of identity for mayonnaise, which requires all ingredients to be labeled, unequivocally in error. This kind of misinformation to consumers injures this industry, which has worked closely with the Food and Drug Administration to update the standards for mayonnaise, salad dressing and french dressing to include complete ingredient labeling.

This organization has long supported declaration of ingredients for standardized foods. In fact, voluntary label declaration of ingredients was adopted by this Association in 1971, and Food and Drug was notified of this policy in July of that year.

The statement in the February issue does a disservice to FDA, industry and the consumer particularly since FDA, supported by this and other industries, has been at work in bringing about full ingredient labeling. Errors such as those in FDA Consumer can only confuse and mislead consumers who have come to respect this FDA activity and to recognize the growing number of fullylabeled products.

Robert H. Kellen
President, The Association for Dressings and Sauces
Atlanta, Georgia

*The law forbids FDA to require the listing of ingredients that are mandatory on the labels of standardized foods. FDA can and has designated essentially all the ingredients in many standardized foods as optional and therefore required that they be listed on the label. But this method of achieving full ingredient labeling is procedurally complicated, time consuming, and expensive. This procedure has not been undertaken for some standardized foods and many of their ingredients do not have to be listed on the label. Commissioner Kennedy did not specifically identify mayonnaise as a food that does not require ingredient labeling. Mayonnaise was cited, however, in the This Month column on page 1 as an example of a food that does not require full ingredient labeling. This statement is incorrect; all the ingredients in mayonnaise must be listed on the label.*
Battling Resistant Bacteria

Antibiotics have produced some remarkable results in the fight against disease. But now scientists are finding more and more strains of bacteria that have become resistant to these important drugs. With the help of a Boston research team, FDA is compiling data on trends in bacterial resistance and is seeking ways to prevent the problem from becoming worse because of overuse of antibiotics.

by Annabel Hecht

In May 1977 a strain of a pneumonia-causing bacteria (Streptococcus pneumoniae) that was resistant to four antibiotics—penicillin, ampicillin, cephalothin, and chloramphenicol—was isolated from five young patients at a hospital in Durban, South Africa. Two months later, thousands of miles away in Minneapolis, Minnesota, another strain of the same bacteria, resistant to penicillin, was found in the blood of a five-year-old girl.

Health officials were concerned, so the stories made news. But these were not isolated incidents, nor were they unique. What happened to these children has happened before with other kinds of bacteria in other places and at other times. Why did it happen? Is it the result of too much of a good thing—the overuse of antibiotics?

The Food and Drug Administration is concerned about the growing problem of bacteria becoming resistant to antibiotics. One outcome of this concern is FDA's recent proposals to prohibit the routine use of some antibiotics in animal feed as a means of promoting the growth of livestock. Continuous long-term use of small amounts of antibiotics in animal feed can cause bacteria in the animals that eat the feed to become resistant to the antibiotics. This resistance can be transferred to bacteria that cause diseases in people, making the antibiotics less effective for the treatment of these diseases.

FDA's concern actually goes back more than two decades to the time when the resistance to antibiotics of certain disease-causing bacteria was just emerging as a global problem. Although such resistance had long been known, the significance of the problem was not widely appreciated until the late 1940's when large numbers of hospital patients developed an infection due to Staphylococcus aureus that did not respond to antibiotic treatment.

At that time it was generally believed that any resistant strain of bacteria would be resistant only to one type of antibiotic. Then, in the late 1950's, Japanese scientists isolated strains of bacteria harboring resistance to a number of antibiotics—resistance that could be transferred from one bacterium to another. This important discovery indicated that the problem was more serious than thought earlier.

Resistance to antibiotics in bacteria is determined by what is called R (for resistance) factors in the bacteria's genes. The genes that carry resistance factors are transferred from one type of bacteria to another by cell-to-cell contact.

One especially disturbing aspect of bacterial resistance is that R factors can be transmitted to disease-causing bacteria from harmless germs that are always with us in our intestinal tracts. Thus, if a person ingests some harmless bacteria which are resistant to antibiotics, this resistance can be transferred to the normal intestinal bacteria. If the person is then infected with disease-causing intestinal bacteria the resistance may be transferred to them, making treatment with some antibiotics ineffective. Since disease-causing bacteria of the intestines are a major cause of life-threatening bacterial diseases, the medical and public health implications of drug resistance are of considerable concern.

The first reports in the United States of bacteria carrying R factors came in late 1966. Since then, R factors have come to be recognized as responsible for most of the clinically important antibiotic resistance in U.S. hospitals. Widespread use of antibiotics outside hospitals has contributed to the growth of resistant bacteria.

As more and more reports of resistant bacteria surfaced in other countries, FDA initiated conferences to explore the need for studies of the long-term effects of antibiotics and took a number of steps to reduce public exposure to these drugs. The first step was to prohibit residues of antibiotics in food from animals fed such drugs—that is, in meat, dairy products, and eggs. Another step was to disallow the use of antibiotics as a preservative for fish and poultry. But the primary concern about the development of bacterial resistance remained the human use of antibiotics.

Although it was known that overuse of antibiotics could contribute to increased resistance, it was also clear that withholding antibiotics in cases thought to involve bacterial infection resulted in considerable risk to the patient. For these reasons, FDA saw the need to identify and alter practices in the use of antibiotics which might contribute to the prevalence of bacterial resistance. The key lay in the widespread study of resistance patterns and their changing trends, but the necessary laboratory tests for such a survey appeared to be prohibitively expensive.

Then in the late 1960's, researchers at Peter Bent Brigham Hospital and the Harvard Medical School in Boston found a way to make greater use of the information from the antibiotic susceptibility tests which are conducted routinely in hospital laboratories. Bacteria are said to be susceptible to antibiotics that are effective against them. The susceptibility test involves
Before a susceptibility test is carried out it is necessary to know what kind of germs the antibiotic in the test disc will be fighting. Here, Elaine Gilleece, technologist in the Peter Bent Brigham Hospital Microbiology Laboratory, prepares to run biochemical tests to identify bacteria in the laboratory dishes stacked in front of her.

A closeup view of susceptibility test discs (left) shows the effectiveness of four antibiotics against a particular bacterium. The large clear zone points to a highly effective antibiotic. The smaller zone indicates only mild effectiveness and no zone at all means those antibiotics will not be useful in fighting this germ. After the bacterium have had sufficient time to grow, Microbiologist Lorna Mitchell (below) measures the clear area or "zone of growth inhibition" around each test disc. The size of each ring will be recorded in the laboratory's computer.
What microbiologists have learned from measuring the zones of activity around the antibiotic susceptibility discs is fed into the laboratory computer (above) by data manager John Farrell. The information then can be analyzed and reproduced by the computer in various forms, including a printout (right) showing worldwide patterns of bacterial resistance to antibiotics.
tiny paper discs each impregnated with a different antibiotic. The discs are placed on a culture medium which has been inoculated with bacteria from a patient. Growth of bacteria susceptible to a given antibiotic will be slowed or stopped in the area around that disc. Resistant bacteria will continue to grow. By measuring these growth patterns, a microbiologist in a hospital laboratory can tell which antibiotic will be effective in treating the disease caused by that bacteria.

What the Boston researchers did was to develop a system for using a computer to store and analyze the information from these tests. FDA's Bureau of Drugs saw the potential of the new system for improving the regulation of antibiotics and asked the researchers if the computer program could be adapted to FDA's needs. It could, and in 1970 a contract was awarded that has given FDA a ready means of keeping an eye on these life-saving drugs.

FDA regulates antibiotic susceptibility discs by testing and certifying them on a batch-by-batch basis and by developing standard procedures for their use. Initially the computer program was used to establish accurate standards for susceptibility testing and to monitor quality control—that is, to assure that the tests were being done properly so data from different hospitals could be compared. Test information was collected from a number of hospitals throughout the country and run through the computer. To date, some 24 hospitals have participated in this surveillance program. In some cases, differences in interpretation of test results have led to re-examination of the test methods and to changes in FDA's regulations.

Some changes have come about in other ways. For instance, when ampicillin-resistant strains of a bacterium (Hemophilus influenzae) that causes meningitis began to emerge in 1973, the Peter Bent Brigham researchers did a study to determine why the resistance was not being detected by the disc test. Because this disease often proves fatal to infants, immediate treatment with an alternative drug is vital. The resistance factor proved to be a particular enzyme which could not always be detected by the standardized test. A way was found to change the test so it would detect the resistance.

Over the years the computer system has been used not only to monitor susceptibility testing methods for errors, but has been further developed to study overall trends in bacterial resistance and new mechanisms of resistance.

During the past five years the Peter Bent Brigham researchers have been studying antibiotic resistance in a number of hospitals in Europe. To their surprise they have found that patterns of resistance are quite different in Europe than in the United States. For instance, resistance to individual antibiotics was three times higher in a Paris hospital than at Peter Bent Brigham. Furthermore, the percentage of bacterial strains resistant to seven or more antibiotics was ten times higher in Paris. The seriousness of this situation is evident, since a disease caused by multiple resistant bacteria would be nearly untreatable.

The same patterns were found in hospitals in Belgium, Holland, Germany, and Spain. Pilot studies in Brazil have shown even higher bacterial resistance to ampicillin and chloramphenicol, suggesting a situation which is different from that in either Europe or North America.

The Brigham research team plans to extend its international studies to include more hospitals in Europe, Latin America, Africa, India, Asia, and Australia to learn more about why these differences are occurring. It may be a natural phenomenon that is happening faster in some areas than in others. Or the answer may lie in the way antibiotic drugs are being used in various parts of the world.

In the United States, most antibiotics must be prescribed by a doctor. But in many parts of Europe, Latin America, Asia, and Africa they are available over the counter or are freely dispensed by paramedical personnel. The relatively high resistance noted in French patients early in their hospital stay suggests that they brought the resistance factor in with them from the community and that the resistance developed because of widespread overuse of antibiotics.

With only a few families of antibiotic drugs available, and cross-resistance within families high, the choices for treatment are already limited. Thus, it is important that strategies be developed to minimize the development of resistant strains of bacteria such as are now being isolated around the world. With the help of data from Peter Bent Brigham Hospital's computer program, that is what FDA is trying to do.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.
The Great Amphetamine Debate

by Annabel Hecht

The question is how to control the widespread abuse of a group of stimulants known as amphetamines without unduly interfering with their use for legitimate medical purposes. FDA is considering withdrawing its approval of the use of these drugs for weight control, an approach that has drawn a variety of reactions from health professionals, the pharmaceutical industry, and others interested in the issue.

Medically speaking they are called anorectics and are used primarily to treat people who are trying to lose weight. In street parlance they are known by a variety of names—A, bennies, chalk, greenies, hearts, jellybeans, L.A. turnabouts, speed, splash, uppers, whites—and they are used as stimulants. But like Shakespeare’s rose, under any name they are all the same—amphetamines—and they are among the most frequently abused drugs in the United States.

There is general agreement that amphetamines are abused. There is no clear consensus, however, on how to prevent such abuse. The Food and Drug Administration is considering revoking its approval of the use of these drugs for weight control, but continuing to permit their use in the treatment of narcolepsy, a relatively rare condition that causes uncontrollable sleepiness, and minimal brain dysfunction which causes children to be hyperactive. In addition, FDA is considering a special patient brochure to explain the limited usefulness of amphetamines and warn about their potential for abuse.

FDA is considering these actions because information provided by the National Institute of Drug Abuse (NIDA) and the Drug Enforcement Administration (DEA) indicates that abuse of amphetamines continues despite efforts by the Federal Government to limit their use. In addition, FDA has no evidence that amphetamines are better for weight control than many other drugs for which there is not the same evidence of abuse.

FDA’s proposals were challenged by a number of speakers at a public hearing on amphetamines held by FDA last December. More than two dozen people, including physicians in private practice, Federal and State officials, social science researchers, and pharmaceutical industry representatives spoke at the daylong hearing. Some questioned the validity of the NIDA and DEA data, maintaining that amphetamine abuse is going down. They said amphetamines are useful in treating obesity and depression (an unapproved use) and claimed that abuse of the drug is not related to its legal availability. The abuse problem, they argued, stems from illegal producers and so-called “script doctors” who write prescriptions for or directly dispense large quantities of amphetamines every year, often without proper examination of the patient.

Speakers at the hearing who supported tighter controls said obesity is a chronic problem that cannot be solved by amphetamines, or any drugs, which have only a short term effect. They also pointed out that other available drugs have the same effect without the potential for abuse.

FDA cannot stop doctors from prescribing amphetamines for weight control because the Agency does not regulate the practice of medicine. If the agency withdraws its approval of amphetamines for use in treating weight control, however, drug manufacturers no longer would be permitted to claim that it is effective for that purpose in the labeling and advertising for the drug to which physicians are exposed.

Deletion of weight control as an approved use also would lead to decreased prescribing and sharply reduced production quotas for the drug. Because amphetamines already are subject to certain restrictions under the Controlled Substances Act, DEA has authority to set production quotas based on recommendations from the Department of Health, Education, and Welfare. DEA has estimated that if weight control were no longer an approved use the production quota for amphetamines could be cut from the present level of more than 500 million dosage units a year to about 64 million.

A number of States have imposed restrictions on the use of amphetamines for weight control. For the past seven years Maryland has limited these drugs to the treatment of narcolepsy, hyperactivity in children, and certain research and special uses. These limitations have had no apparent ill effects on the health of patients in Maryland, according to a physician representing the Maryland State Medical Society at the FDA hearing. Wisconsin recently instituted similar restrictions.

If FDA moves to restrict use of amphetamines, it will not be the first time the Agency has taken action against these drugs. Amphetamines have been subject to misuse almost since their discovery and FDA has been combating this abuse for more than 25 years.

Amphetamines were developed in the early 1930’s. Their first major use was as an ingredient in Benzedrine inhalers, formerly a nonprescription product used to clear clogged nasal passages. The effectiveness of amphetamines in treating narcolepsy and hyperactivity in children came to light in the mid-1930’s. In 1939 narcolepsy patients reported they did not get hungry after they took amphetamines, and the drug soon was being used as an appetite suppressant.

With the outbreak of World War II,
amphetamines found their way to the battlefront, on both sides. The Germans and Allies used amphetamines in an attempt to increase the efficiency of their troops and to prevent sleep. Use of the drug by Japanese workers to stimulate production on the homefront eventually led to an abuse problem of major proportions after the war. Large stockpiles of amphetamines were being sold in Japan over the counter for "elimination of drowsiness and repulsion of the spirit." Strict controls on production, a massive education program, and strict penalties eliminated the problem in the 1950's.

Amphetamine abuse became a post-war problem in the United States as well. Some users learned how to extract the drug from Benzedrine inhalers, creating a problem so serious that Congress considered legislation to make the inhaler a prescription item. This proved unnecessary because the major manufacturer substituted an equally effective drug which had no stimulant effect. FDA banned the use of amphetamine in inhalers in 1959, but because of a loophole in the law one such device was on the market until 1965.

Far more serious was the growing problem of amphetamine abuse fed by illegal sales of the drug. In the 1950's FDA mounted an intensive campaign to stop this trafficking. Amphetamines were being dispensed not only by pharmacists and physicians, but illegally by lunch counter and tavern operators, filling station attendants, and proprietors of massage parlors. The 1953 FDA Annual Report describes the "speak-easy" atmosphere in which some women obtained amphetamines after saying the password "tops."

Illegal sales of amphetamines to truckdrivers were of particular concern because of the fear that overuse of the stimulants would result in accidents. FDA inspectors spent many months tracking down the source of these supplies, which often were roadside truck stops.

Despite congressional debate on ways to control amphetamine abuse, no action was taken until enactment of the Drug Abuse Control Amendments of 1965. This law gave FDA stronger authority to regulate the manufacture and distribution of dangerous drugs. A separate FDA Bureau of Drug Abuse Control was created in 1966. In its two years of existence, the Bureau carried out over 2,000 criminal investigations, made more than 1,300 arrests, and handled about 300 criminal cases. As a result of some 1,100 accountability investigations, nearly 600 million dosage units of both stimulant and depressant drugs were removed from the marketplace because accurate records had not been kept on their distribution as required by the 1965 law.

The Bureau of Drug Abuse Control was merged with the Treasury Department's Bureau of Narcotics in 1968 to form the Bureau of Narcotics and Dangerous Drugs (BNDD) in the Department of Justice. In 1973 this Bureau became the Drug Enforcement Administration (DEA).

Meanwhile, in 1970, Federal regulation of drugs subject to abuse was strengthened by passage of the Controlled Substances Act. Under this act dangerous drugs may be placed in one of five regulatory categories (called schedules) according to their potential for abuse. Schedule I drugs are those which have a high potential for abuse and no currently accepted medical use in this country. Schedule II includes drugs that have accepted medical uses but also are subject to significant abuse. The greatest restrictions are placed on Schedule I and II drugs.

Of the 12 weight-control drugs on the market, only the three amphetamines (amphetamine, dextroamphetamine, methamphetamine) and phentermine are regulated under Schedule II of the Controlled Substances Act. This means that prescriptions for these drugs must be signed by the practitioner and cannot be refilled (a new prescription must be written each time); special order forms issued by DEA have to be used for all sales other than those to patients who have prescriptions; manufacturers and wholesalers are required to take stringent precautions to prevent theft or diversion of drugs from their facilities; production is limited to Government-established quotas; and the drugs may not be imported or exported across U.S. boundaries without permission from DEA.

In 1972, as part of a review of the effectiveness of all prescription drugs, FDA conducted a study to determine if patients on weight-reducing drugs lost more weight than patients taking a placebo (a pill containing no active ingredient). The study showed that all weight-reducing drugs, including the amphetamines, were of some short term benefit in a weight-reducing program, although their effect was considered trivial.

As a result, FDA changed the approved labeling for amphetamines to emphasize that they have a potential for abuse and to limit their approved use to narcolepsy, minimal brain dysfunction, and short term therapy in obesity when used in combination with diet and exercise. FDA also recommended to DEA that production quotas for amphetamines be reduced.

Between 1971 and 1973 the number of amphetamine prescriptions dropped dramatically and the amount produced decreased. FDA believes, however, that available information indicates that the abuse of amphetamines continues at an unacceptably high level. According to surveys by the National Institute of Drug Abuse and data collected by DEA, drugs intended for weight reduction are commonly used for nonmedical purposes and among this class of drugs amphetamines have the highest rate of abuse. The DEA data also showed that in about 25 percent of the reported cases of amphetamine abuse the drug was obtained through legitimate prescriptions. The rest of the cases involved amphetamines either bought on the street or stolen.

According to DEA information amphetamines most often are diverted from legitimate purposes through theft or by health professionals who sell them without prescriptions or prescribe them for nonmedical purposes. DEA has information on physicians who have ordered more than 3 million amphetamine dosage units per year. Others are prescribing amphetamines for long periods of time even though the drug is not effective for long term weight reduction. A substantial amount of illegal diversion of amphetamines occurs through the operation of clinics devoted entirely to the treatment of obesity—often called "fat clinics."

FDA is reviewing all the data on amphetamine abuse, including the testimony at the December hearing. The Agency allowed 30 days following the hearing for interested parties to submit additional written comments. Once the review of all this material is completed FDA will decide whether to withdraw approval for the use of amphetamines in the treatment of obesity or to take other actions to reduce abuse of the drug.

Annabel Hecht is a staff writer with FDA's Office of Public Affairs.
‘Hypoallergenic’
Cosmetics

A Federal court has struck down an FDA regulation requiring cosmetic manufacturers to conduct tests to back up any claim that a product is “hypoallergenic.” The decision means the term has no real meaning in the marketplace, but the list of ingredients now required on cosmetics can help consumers determine if there is any significant difference between “hypoallergenic” products and competing brands that don’t make this claim.

by Margaret Morrison

Ever since the days when “She’s lovely, she’s engaged, she uses Ponds” became one of the best known advertising slogans in America, cosmetics manufacturers have pursued consumers with promises of everything from new beauty to a new lifestyle. Indeed, with cosmetics—perhaps more than with any other type of product—promotion is the key to sales success. Recognizing this, manufacturers have used a wide variety of appeals to break into or increase their share of this lucrative market.

For many years companies have been producing products which they claim are “hypoallergenic” or “safe for sensitive skin” or “allergy tested.” These statements imply that the products making the claims are less likely to cause allergic reactions than competing products. But there has been no assurance to consumers that this actually was the case.

For the past four years the Food and Drug Administration has been working to clear up this confusion of claims by establishing testing requirements that would determine which products really are “hypoallergenic.” But late last year the U.S. Court of Appeals for the District of Columbia ruled that FDA’s regulation defining “hypoallergenic” was invalid. This means there is now no regulation specifically defining or governing the use of the term “hypoallergenic” or similar claims. And because of the lengthy procedural steps required to establish a new regulation that is likely to be the situation for some time to come.

Where does that leave consumers? Consumers concerned about allergic reactions from cosmetics should understand one basic fact: There is no such thing as a “nonallergenic” cosmetic—that is, a cosmetic that can be guaranteed never to produce an allergic reaction.

But are some cosmetics less likely to produce adverse reactions than competing products?

By and large, the basic ingredients in so-called “hypoallergenic” cosmetics are the same as those used in other cosmetics sold for the same purposes. Years ago some cosmetics contained harsh ingredients that had a high potential for causing adverse reactions. But these ingredients are no longer used. FDA knows of no scientific studies which show that “hypoallergenic” cosmetics or products making similar claims actually cause fewer adverse reactions than competing conventional products.

FDA’s ill-fated regulation on “hypoallergenic” cosmetics was first issued as a proposal in February 1974. It said that a cosmetic would be permitted to be labeled “hypoallergenic” or make similar claims only if scientific studies on human subjects showed that it caused a significantly lower rate of adverse skin reactions than similar products not making such claims. The manufacturers of cosmetics claiming to be “hypoallergenic” were to be responsible for carrying out the required tests.

Numerous comments on the proposal were received from consumers, consumer groups, and cosmetic manufacturers. Some people urged a ban on the use of the term “hypoallergenic” on grounds that most consumers don’t have allergies. Others suggested that the term be banned because allergic individuals cannot use “hypoallergenic” products with any assurance of safety. A number of cosmetic manufacturers complained about the requirement for product comparison tests to validate claims of hypoallergenicity.

In responding to the comments, FDA pointed out that the proposed regulation was not intended to solve all problems concerning cosmetic safety. The primary purpose of the regulation, the Agency said, was to clear up confusion about the term “hypoallergenic” and to establish a definition that could be used uniformly by manufacturers and understood by consumers.

FDA issued its final regulation on “hypoallergenic” cosmetics on June 6, 1975. Although the final regulation did require comparative tests, procedures for carrying out the tests were changed to reduce the costs to the manufacturers.

The new regulation was quickly challenged in the U.S. District Court for the District of Columbia by Almay and Clinique, makers of “hypoallergenic” cosmetics. The two firms charged that FDA had no authority to issue the regulation, but the court upheld FDA.

The firms then appealed to the U.S. Court of Appeals for the District of Columbia, which ruled that the regulation was invalid. The appeals court held that FDA’s definition of the term “hypoallergenic” was unreasonable because the Agency had not demonstrated that consumers perceive the term “hypoallergenic” in the way described in the regulation.

As a result of the decision, manufacturers may continue to label and advertise their cosmetics as “hypoallergenic” or make similar claims without any supporting evidence. Consumers will have no assurance that such claims are valid.

However, cosmetics users who know they are allergic to certain ingredients can take steps to protect themselves. FDA regulations now require the ingredients used in cosmetics to be listed on the product label, so consumers can avoid substances that have caused them problems.

Margaret Morrison is a staff writer with FDA’s Office of Public Affairs.
Sanitation Standards
For Foodstores

Regulation of the Nation’s more than 250,000 foodstores can be handled most effectively by State and local agencies. To help them do a better and more uniform job, FDA has developed a “model ordinance” on sanitation practices in retail foodstores.

by Harold Hopkins

FDA has proposed a “model ordinance” to help State and local government agencies provide better protection for consumers against insanitary conditions and practices in retail foodstores.

The proposed ordinance is not mandatory. It was developed by FDA as a guideline for States and localities to use in establishing their own retail foodstore sanitation regulations.

In offering the proposed ordinance, FDA said that although under the law the Agency is obliged to regulate food held for sale after shipment in interstate commerce, it recognizes the primary jurisdiction of State and local governments over food retailers and will continue to concentrate on assuring the safety and sanitation of food before it reaches retailers. There are over 250,000 retail foodstores and their regulation is too much for FDA to handle, so this job must remain with States and localities, the Agency said.

FDA in 1969 took over the Public Health Service responsibility for helping State and local agencies establish and maintain food protection programs and began drawing up the proposed ordinance in 1973. In 1974 the Association of Food and Drug Officials, an organization of local, State, and Federal officials who have regulatory responsibilities for food and drugs, proposed retail foodstore standards. These standards were compatible with the Federal Food, Drug, and Cosmetic Act, but they didn’t include compliance procedures and sanctions. The FDA proposal does include enforcement procedures.

The FDA model retail foodstore ordinance was drawn up after consultation with representatives of the retail foodstore industry, food equipment manufacturers, regulatory agencies, the U.S. Department of Agriculture, and others interested in a uniform document with practical and enforceable sanitary requirements.

FDA already has distributed proposed model ordinances to help States and localities regulate restaurants and other food service establishments and the vending of food and beverages. The sanitation and food handling requirements included in the model ordinance for retail stores are somewhat equivalent to FDA’s blanket Good Manufacturing Practice Regulations for food warehouses and processing plants. Aside from general sanitation requirements, the retail store proposal goes into considerable detail on the handling of “potentially hazardous food,” that is, milk products, eggs, meat, poultry, fish, shellfish, edible crustaceans, and other ingredients that are in a form capable of rapid growth of infectious or poisonous microorganisms. It also calls for prior approval by States of the building plans for new retail food facilities and for alterations to existing structures.

The ordinance’s headings cover food protection, storage, preparation, display, and transportation; health, clothing, and sanitation practices of employees; design, installation, location, and sanitization of equipment and utensils; adequacy of sanitary facilities and controls, including water supply, sewage, plumbing, toilet and handwashing, garbage and refuse, and insect and rodent control.

Requirements for construction and maintenance of physical facilities cover floors, walls and ceilings, cleaning facilities, lighting, ventilation, dressing rooms and lockers, poisonous materials, and general premises.

The ordinance provides for a system of permits for retail foodstore operation and for withdrawal or withholding of permits where violations of the ordinance are involved. It provides for inspection of each store at least every six months, and would permit inspectors to examine the store’s records on food and supplies bought, used, or sold. The inspection report would be public and would be made available to any person who requested a copy. The inspection would be based on a point system with weighted points for violations significant to health. The ordinance establishes deadlines for corrections of violations, and provides for closing down the store in case of imminent threats to health or failure to correct violations.

FDA published a notice in the October 25, 1977 Federal Register stating that copies of the proposed ordinance were available for comment. The Agency now is reviewing the comments received and then will adopt a final model ordinance.

Harold Hopkins is editorial director of FDA Consumer.
The 18-month moratorium imposed on FDA's proposed ban on saccharin provides time to gather and study new evidence but it doesn't solve the problem. Saccharin's ultimate fate depends on a number of factors, among them additional information that may be developed on the substance's safety and possible congressional action on how food additives should be regulated.

Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals.

Americans will become quite familiar with these words. A law passed by Congress late in 1977 requires that this warning appear prominently on all foods containing the artificial sweetener saccharin. The law, whose primary purpose was to impose an 18-month moratorium on FDA's proposed ban of saccharin, provides time to study existing evidence, to gather new information, and to consider the impact that a ban would have. It does not, however, solve the problem or answer the questions that have been raised about saccharin.

FDA proposed its saccharin ban on April 15, 1977, following the completion of a study by the Canadian government which showed that saccharin, when fed to rats, caused bladder tumors. The Canadian results confirmed those from earlier studies, including one conducted by FDA.

The proposed ban would have eliminated the use of saccharin in foods and beverages, in cosmetics likely to be ingested, and in drugs as a nonmedical ingredient to improve taste. FDA proposed to allow continued marketing of saccharin as a single-ingredient drug available without prescription, provided that manufacturers prove it is medically effective for such uses as controlling diabetes or obesity.

FDA reasoned that if saccharin were available only as a single-ingredient drug with a warning label people would have to make a conscious decision to use it; but that if it were to continue to be used as just another ingredient in diet sodas, foods, lipstick, or mouthwash, many consumers would be exposed to it without full knowledge or consent. FDA's proposal would have reduced consumption of saccharin by about 90 percent.

In response to an unprecedented public outcry—FDA received more than 100,000 comments, most opposing the ban—Congress, in November 1977, passed the 18-month moratorium.

The moratorium legislation calls for a number of specific studies to assess the health benefits and risks of saccharin. FDA is contracting with the National Academy of Sciences to compile current information on the risk to public health from cancer-causing substances in the food supply and to examine the possibility that any health hazard from saccharin is caused by impurities in the saccharin rather than by the artificial sweetener itself. FDA will conduct tests to clarify evidence that saccharin causes cancer in animals.

In addition, FDA and the National Cancer Institute (NCI) are conducting a nationwide study to determine saccharin's precise role in causing bladder cancer in humans. The study, which began in March 1978 and will cost about $1.4 million, is being conducted in five States—New Jersey, Connecticut, Iowa, New Mexico, Utah—and four metropolitan areas—Detroit, San Francisco-Oakland, New Orleans, and Atlanta.

NCI will interview about 3,000 people with newly diagnosed bladder cancer and 6,000 randomly chosen individuals living in the same areas. They will be asked about their eating habits and other aspects of their behavior.

Of the 3,000 bladder cancer victims, three-fifths will be 65 years old or
older, three-fourths will be male, and most will be white. Patients younger than 21 or older than 85 will not be eligible. NCI will analyze the data to determine the effects of saccharin on bladder cancer.

The study also will develop information on the effects on bladder cancer of cyclamate (another artificial sweetener, banned by FDA in 1970), drinking water, filter cigarettes, and certain rare occupational exposures.

The NCI-FDA study is not specifically required by the moratorium law. It stems from a recommendation by a special task force consisting of FDA and NCI scientists, which urged in December 1977 that a study be conducted on a large number of people to determine the association between saccharin and bladder cancer.

FDA's decision to propose a saccharin ban, and especially the scientific studies associated with that decision, have given rise to a number of questions, the answers to which are fundamental to public understanding of the saccharin issue. Let's look at some of these questions:

**Question:** Didn't FDA act to ban saccharin only because the Agency is bound by the strict, inflexible provisions of the Delaney Clause?

**Answer:** It is true that the section of the Food, Drug, and Cosmetic Act known as the Delaney Clause was the legal trigger for FDA's proposed action against saccharin. This clause unequivocally prohibits approval of any food additive that causes cancer in man or animals. When the Canadian study confirmed earlier suspicions that saccharin causes cancer in animals, the Delaney Clause clearly required FDA to act.

It is not true, however, that the Agency acted only on the basis of the Delaney Clause. General provisions of the Food, Drug, and Cosmetic Act require that food additives be safe. And with the accumulated evidence against saccharin, FDA's judgment would have had to be that saccharin is not safe for continued use in food. The Agency would therefore have moved to end the general use of saccharin in foods even without the Delaney Clause.

Canada, which does not have a law similar to the Delaney Clause, successfully banned saccharin despite political and public outcry similar to that which stopped such an action in the United States.

**Question:** Wasn't FDA's decision to ban saccharin based on just one study?

**Answer:** The Canadian study was merely the final brick in a mounting wall of evidence against saccharin. FDA's decision was based on a series of studies dating back to 1971, when an investigation by the Wisconsin Alumni Research Foundation produced the first clear signal that the sweetener caused cancer. In the Wisconsin study, seven of 15 male rats fed saccharin as 5 percent of their diets for two years developed bladder tumors.
Although the Wisconsin study did not provide evidence sufficient to justify a ban, it and other studies prompted FDA, as early as 1972, to impose limits on the amount of saccharin that could be used in food products. The World Health Organization, among other groups, adopted similar limitations. In addition, since 1972 FDA has required products containing saccharin to carry a label cautioning that they should be used only by people who must restrict their intake of ordinary sweets.

A study completed by FDA in 1973 again indicated that saccharin in the diets of test rats could cause cancer. The Agency asked the National Academy of Sciences' National Research Council to review the evidence about saccharin as a cancer-causing substance. In late 1974, the Council concluded that available test data did not establish conclusively whether saccharin itself causes cancer. It was possible, the Council suggested, that orthotoluenesulfonamide (OTS), an impurity found in commercial saccharin, could have caused the tumors.

The Canadian government already had begun, in February 1974, a study designed to settle this point. That study was completed in March 1977. It found that of 200 animals fed OTS-free saccharin, 21 developed bladder tumors. None of the rats fed OTS alone developed tumors. Particularly significant was the discovery of more cancers among second-generation rats who had been exposed to saccharin while in their mothers' wombs. This raised serious questions about the possible effects of saccharin on humans during the fetal stage and in childhood.

FDA concluded that this study was well conducted and demonstrated that saccharin, not the OTS impurity, caused cancer. The Canadian study clarified the results of earlier ones and led FDA to prepare, as required by law, a ban on saccharin in food.

**Question:** Since animals in the tests were fed much larger proportions of saccharin than people would ever eat, how can the test results be valid for determining whether saccharin causes cancer in humans?

**Answer:** Exposure of test animals to high doses is the most valid way that scientists know to predict whether a chemical may cause cancer in people. Such tests are realistic and reliable. They are essential to identify, for example, a substance that may cause cancer in only one out of every 20,000 Americans. That may be a rare occurrence statistically, but it translates into more than 10,000 additional cancer victims.

Practical reasons require that test animals be given doses far larger than humans are ever likely to receive. It is impossible to breed, raise, sacrifice, and examine test animals fast enough to identify a substance that in normal consumption might cause one case of cancer out of 20,000 animals. The only practical way to test such substances
is to use fewer animals and, to compensate, give them higher doses of the substance being tested.

There is no way to tell from high-dose animal tests exactly how many people might get cancer from a lower dose. But there are reliable methods for estimating the maximum number who might be affected. FDA scientists calculate that even moderate use of saccharin—the amount present in one large diet soft drink—if ingested daily over a lifetime by every American might lead to as many as 1,200 additional cases of bladder cancer per year.

This system of using animal results to predict cancer risk for humans is imperfect but it works. Tests similar to those used for saccharin have shown that all but one of the 30 or so chemicals known to cause cancer in people also cause it in animals. So, when a chemical tested in high doses on a limited number of animals causes cancer, scientists are concerned because they know that if a high dose of something causes cancer in a significant number of animals, a low dose probably will cause cancer in some people.

It is clear that there is a strong relationship between the amount of a cancer-causing substance in our air or water or food supply and the number of people who will get cancer. The higher the exposure, the more cancers that will result. If the amount of a cancer-causing substance present in the environment is reduced, the number of cancers will drop. But it is not true that if a cancer-causing substance—for example in a food additive—is reduced to a low enough concentration no one exposed to it will get cancer. It has never been proved that there is a safe level of human exposure for any cancer-causing chemical.

**Question: Is there any evidence that saccharin causes cancer in humans?**

**Answer:** There is as yet no proof of a cause-effect relationship but a study conducted by the Canadian counterpart of the U.S. National Cancer Institute has provided statistical evidence of an association between saccharin use and cancer in humans. Scientists compared artificial sweetener use in 480 men who had bladder cancer and in a carefully matched control group without bladder cancer. They found that the men who consumed saccharin had a significantly higher incidence of bladder cancer than the men who did not. The higher the consumption of saccharin, the greater were the chances for getting bladder cancer, the study showed. Similar studies in the United States, however, have not produced the same results.

The joint FDA-NCI study being carried out as part of the effort to gather more information during the moratorium should further clarify the relationship between saccharin and bladder cancer in humans.

**Question:** Isn't it a fact that too much of almost any substance will cause cancer?

**Answer:** No. The National Cancer Institute reported in 1969 that of 120 suspicious pesticides and industrial compounds fed to mice in high doses, only 11 definitely produced tumors. Relatively few compounds have been shown to cause cancer in high-dose testing. But animal tests do show beyond reasonable doubt that saccharin is among the substances that cause cancer in test animals and therefore may be hazardous to humans.

**Question:** Since tests show that saccharin is only a weak carcinogen, is such drastic action as a ban justified?

**Answer:** A panel of scientists who studied saccharin for the Congressional Office of Technology Assessment said saccharin was a relatively weak carcinogen. "Weak," however, refers to the number of cancers caused, not to the seriousness of the cancer. Cancer caused by a "weak" carcinogen is no less deadly.

The Office of Technology Assessment panel also pointed out that the potential risk of this weak carcinogen could be large if many people are exposed to it. Unquestionably, many people are exposed to saccharin. Some 6 million pounds of the artificial sweetener are used in the United States annually, three-quarters of it in diet soft drinks and most of the rest in dietetic foods and table sweeteners used in place of sugar. The Office of Technology Assessment study estimated that if 200 million people drank...
one can of diet soda per day, anywhere between 600 and 15,000 additional cancers a year would result.

**Question:** Since no other artificial sweeteners are permitted in food, isn't saccharin essential for people who need to control their weight?

**Answer:** There is no evidence that saccharin is beneficial for weight control. In fact, one animal study indicates that saccharin may actually increase appetite. The panel which reported to the Office of Technology Assessment concluded that saccharin's impact on weight control is largely psychological.

On the other hand, many people do depend on it for weight control and believe strongly in its value for this need.

A related issue involves the importance of saccharin to diabetics, for whom control of sugar intake is a medical necessity. But the need to control sugar intake does not necessarily mean that saccharin is essential to the medical management of diabetes.

When this question was discussed at a National Academy of Sciences forum on artificial sweeteners, a physician pointed out that most doctors probably would agree that "it is possible to manage diabetics and the obese patient without saccharin." He added, however, that the availability of saccharin or another artificial sweetener makes the patient's life "a good deal more tolerable" and that it is particularly helpful to doctors in managing juvenile diabetics who find it especially difficult to restrict their intake of sweets.

Saccharin's benefits for diabetics and its usefulness—real or psychological—in weight control are legitimate and important issues that should be carefully and sympathetically examined during the moratorium.

Regardless of why people use saccharin—for weight control, because it helps them deal with a medical problem, or perhaps simply because they want soda pop without sugar—the moratorium assures that saccharin will be available through mid-1979. But what about after the moratorium? Will it be available for general use as a food additive? Will its use be restricted only to cases of medical need? Will it be banned?

The answers to these questions depend in large measure on what information is developed during the moratorium and on what action—if any—Congress takes.

Congress could alter the Delaney Clause and change other provisions of the food additives law to permit FDA to consider benefits as well as risks in determining whether to approve a food additive. Under present law FDA must base its decision solely on whether an additive is safe for its intended use. On the basis of the evidence now available it would be difficult to make a favorable risk-benefit judgment on saccharin because the risk—cancer—is extreme while the benefit—usefulness in weight control—is questionable.

It is possible that before the moratorium is over a safer alternative to saccharin will be developed and approved by FDA. That probably would take most of the heat out of the saccharin issue. In 1976 FDA rejected a petition from Abbott Laboratories seeking permission to market the artificial sweetener cyclamate. Cyclamate was the most popular artificial sweetener until it was banned by FDA in 1970 because of questions about its safety. At the request of Abbott and the Calorie Control Council, FDA held a hearing on the Agency's denial of the petition to market cyclamate. The Commissioner of Food and Drugs will make a final ruling on cyclamate after all the evidence presented at the hearing is evaluated.

Another artificial sweetener, aspartame, was approved by FDA in 1974 but was never marketed. Approval was withdrawn by FDA after the Agency found significant deficiencies in the animal test data submitted by the manufacturer to prove that the product was safe for human use. An objective third party, the University Association for Research in Education, is reviewing the test data. No further action on the aspartame marketing request will be taken until the results of this review are submitted to FDA.

There is considerable industry interest in development of new artificial sweeteners and petitions for approval of new products may be submitted to FDA at any time.

Another possibility is that the new studies being carried out during the moratorium will contradict the studies that show that saccharin causes cancer. If that occurs, FDA would have to reconsider its proposed ban.

If, however, new data confirm previous studies, the artificial sweetener will be back in the news and—barring a change in the law—FDA will be obligated to move ahead with its proposed ban.

It has been suggested that when a risk is associated with a popular product like saccharin the best course of action is to require a warning label and let consumers decide for themselves whether they want to use the product. But when the risk involved is cancer, that is not an easy course to follow. Public opinion polls show that Americans fear cancer more than any other calamity—even war—and with good reason. Each day 1,000 Americans die from cancer. Each day 1,600 new cases of cancer are detected. And scientists now agree that the majority of cancers, perhaps as many as 80 or 90 percent, are caused by substances in our environment—substances in the food we eat, the air we breathe, the water we drink, and the products we make and use.

It is in this context that the final decision about saccharin will be made. Whatever the outcome, the saccharin controversy does have its beneficial side. It has drawn public attention to the whole process of regulating environmental hazards—from methods scientists use for testing potential carcinogens to the consumer protection laws and how they work. Saccharin has influenced people to look at some of the products they use in a new light, causing them to focus not only on the benefits but the risks as well.

This growing awareness is valuable because scientists will continue to raise hard questions, not only about new and exotic products but about old friends such as saccharin. And when scientific questions are raised, the people must decide where to draw the line between the individual desire for free choice and the collective need for protection where the choices are complex.
Charge of False Claims Brings Bread Seizure

U.S. marshals in Cleveland, acting in cooperation with FDA and the Ohio Department of Agriculture, seized more than 20,000 cartons of No Hunger Bread, a bread mix being sold nationally by mail order.

The complaint filed by FDA in Federal District Court in Cleveland alleged that No Hunger Bread is illegal and grossly deceptive under both the food and drug sections of the Food, Drug, and Cosmetic Act.

According to the complaint, among the many claims made for the bread mix which are false and misleading are the following:

- The product is effective in preventing heart attacks, cancer, various diseases of the colon, appendicitis, phlebitis, constipation, hemorrhoids, varicose veins, and obesity.
- The product is a hunger depressant.
- The mix produces a bread that is nutritionally superior to whole wheat bread.

FDA has concluded that the mix will make whole wheat bread containing a small amount of fruit oil.

No Hunger Bread has been advertised nationally through full-page ads in newspapers since the beginning of the year. The mix, which sells for $10, is sufficient to make four loaves of bread.

The cartons were seized at a parcel distribution service and at a mail-order house in Cleveland. No Hunger Bread lists as the distributor American Health Foods, 4626 Cleveland Avenue, N.W., Canton, Ohio.

The mixes, which were seized March 2, were embargoed on February 27 and 28 by the Ohio Department of Agriculture after a joint investigation with FDA. The embargo gave FDA time to prepare the necessary papers asking the Federal court to order the marshals to seize the goods.

Warning Issued on Mislabeled ‘Laetrile’

The Food and Drug Administration has been advising cancer patients, physicians, and Customs officials that 4,500 tablets labeled as amygdalin (the “generic” name for Laetrile) have been found to contain 100 percent dipyrone, a drug banned by FDA last year because it can cause a fatal blood disease.

The shipment, offered for import into the United States at the Port of Laredo, Texas, was detained by FDA and destroyed by Customs officials in Laredo.

Dipyrone, a fever reducer, was taken off the market last year after FDA concluded it could cause a sometimes fatal blood disease known as agranulocytosis. Agranulocytosis means that the white blood cells that fight infection in the body suddenly decrease or virtually disappear. This disease can occur immediately after the first dose of dipyrone or any time while the drug is being taken. The main symptom of the disease is sudden high fever. The amount of dipyrone (about 500 milligrams) in each of the tablets labeled as amygdalin could cause this disease.

FDA has been unable to determine how or why dipyrone was substituted in this shipment for amygdalin. But FDA warns that the finding adds a new dimension to the risk being run by cancer patients who buy Laetrile, since dipyrone poses a particular danger for cancer patients, many of whom have existing blood problems.

Previously FDA has found ampules of imported Laetrile contaminated with fever-producing substances and microorganisms as well as foreign particles visible to the eye.

The dipyrone-containing tablets tested by FDA were offered for import under an affidavit system established by a U.S. Federal Court judge in Oklahoma City. Under the system, terminally-ill cancer patients with physician-certified affidavits may import a limited supply of Laetrile for personal use.

This system was established pending the outcome of a case now before the Federal courts. This is the only way that Laetrile can legally be imported into the United States or shipped in interstate commerce.

The tablets of dipyrone were offered for entry at the Port of Laredo by Mac Rickels of Graham, Texas, and were accompanied by six affidavits for Laetrile. The shipment consisted of 90 bottles of 50 tablets each. The invoice said the shipper of the tablets was Wilhelm Dreier Chemicals of West Germany.

The tablets were labeled as containing “approximately 500 milligrams” of amygdalin. Tests conducted in two FDA laboratories showed they actually contained about 500 milligrams of dipyrone.

Saccharin Warning Label Now Required

All saccharin-containing foods shipped in interstate commerce now must carry the following warning label: “Use of this product may be hazardous to your health. This product contains saccharin which has been determined to cause cancer in laboratory animals.”
FDA Approves Valproate for Epilepsy

The Food and Drug Administration has approved valproate (valproic acid), a prescription drug for the treatment of patients with a certain type of epilepsy.

The drug was approved for the treatment of patients who suffer temporary seizures in which they lose consciousness for a few seconds, a condition known as petit mal epilepsy.

Valproate is likely to be useful in the treatment of a significant number of epileptic patients who do not respond well to currently available drugs.

The drug will be sold in capsule and liquid form by Abbott Laboratories under the brand name Depakene.

Dr. Julius Richmond, assistant secretary for health of the Department of Health, Education, and Welfare and a pediatrician, welcomed the approval decision. “Children and young adults with epilepsy especially stand to benefit because the kind of seizures for which valproate is most effective often interrupts the learning process or makes it impossible,” he said.

The type of seizures most responsive to valproate frequently affects the young, but also occurs in epileptics of all ages.

Dr. Richmond called the valproate decision “an excellent example of the FDA scientific regulatory process working efficiently and objectively in the face of strong emotions and partisan pressures.”


While FDA was reviewing the company’s application, the drug was made available with FDA’s permission to more than 1,000 patients with special needs for it.

The prescribing information for physicians approved by FDA says the most common side effects when first taking the drug are nausea, vomiting, and indigestion. These effects are usually transient.

The labeling says liver failure resulting in death has occurred in a few patients taking the drug along with other antiepileptic drugs, and that physicians should perform liver tests before prescribing valproate and periodically thereafter.

The drug also may depress the central nervous system, and patients should not drive or operate dangerous machinery until it is clear how they react to it.

Commissioner of Food and Drugs Donald Kennedy issued the following statement on the approval of valproate: “Valproate has been heavily promoted for the treatment of epilepsy by voluntary agencies and by some physicians. It is a useful and welcome addition to the family of good drugs already available to control this disease, although it is hardly the panacea some of its proponents have claimed. “As important as the actual approval of valproate are the lessons that can be learned from the process of its approval. “The first lesson is that new drugs are not approved by referendum—even medical referendum. Blood letting and mustard plasters once flourished because conventional wisdom said they worked. But the Congress in 1962 correctly rejected ‘conventional wisdom’ as the basis for allowing FDA to approve new medicines. Congress opted instead for the present rule that each drug must be shown through precise scientific experiments—first in animals and then in human volunteers—that the drug does what it is alleged to do without undue risk to the user.

“The second lesson is that private investment drives the development of new drugs in this country. FDA has been criticized for failing to approve this drug sooner. But FDA cannot dictate to private manufacturers what drugs they must develop and market or how or when to commit their research dollars. Despite wide use of valproate in other countries with different standards of drug approval, no U.S. manufacturer came to FDA with a request for marketing the drug until September 1977. The application was submitted, at FDA’s request, a full year ahead of Abbott’s planned schedule. Our staff promptly examined each study submitted by Abbott, and in turn the firm was responsive to our requests for additional or clarifying information. The entire process occurred in 160 days.

“The critical studies essential to approval were conducted by an investigator in Japan and by Dr. B. J. Wilder of the University of Florida. Dr. Wilder’s study was submitted to FDA just before approval was granted, and FDA could not have responsibly approved valproate without this study. Research at the University of Virginia in collaboration with the National Institutes of Health and in several foreign countries also contributed to our knowledge about this drug.”
Regional Reports

“Regional Reports” consists of important information on inspections, product seizures, court proceedings, and other regulatory and administrative actions initiated by FDA’s regional and district field offices across the country to provide protection to consumers under Federal laws. “State Actions,” the section immediately following “Regional Reports,” consists of similar information about the consumer protection activities of State and local governments.

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

The Federal Government seized approximately $1.3 million worth of foodstuffs at Rothstein Corp., a bakery warehouse, in Woburn, Massachusetts, because of widespread insect contamination. The seizure resulted from a routine inspection of the warehouse by FDA’s Boston District. Investigators found live and dead beetles in 13 lots of various products including flour, donut mix, and sugar. Insects were observed in different stages of growth, indicating the infestations were not of recent origin. The firm voluntarily destroyed the contaminated lots, but evidence of insect contamination was so widespread that the remaining lots also were seized.

The Federal Government seized 480 pounds of elbow macaroni at a wholesale food distributor in Suffield, Connecticut, because of insect contamination. The seizure occurred after an inspection of the macaroni manufacturer, LaRosa & Sons, Inc., Warminster, Pennsylvania, by FDA’s Philadelphia District revealed the macaroni was prepared in insect-infested processing equipment. The Philadelphia District then notified FDA’s Boston District of the shipment to the Connecticut wholesaler where investigators collected samples. Subsequent analysis of the samples confirmed insect contamination.

A lot of over 4,800 pounds of cracker meal was seized by a U.S. marshal at B. Berkowitz & Sons, South Boston, after an inspection of the firm by the Boston District revealed the product was held under insanitary conditions. Analysis of samples collected during the inspection confirmed insect contamination.

Hunt-Wesson Foods, Newark, New Jersey, voluntarily relabeled more than 6,000 cases of fruit cocktail valued at $74,000, after the Federal Government seized the lot at a food warehouse in East Hartford, Connecticut. The seizure resulted from a consumer complaint to FDA’s Minneapolis District about the contents of a can of fruit cocktail. The San Francisco District was notified of the complaint and inspected the manufacturer, Hunt-Wesson, Inc., Hayward, California, where investigators found that the canned product contained less than the minimum amount of pears, pineapples, and cherries and exceeded the maximum amount of peaches permitted by FDA regulations on products that are labeled fruit cocktail. Investigators traced a shipment of the product to the Connecticut warehouse, where investigators from FDA’s Boston District collected and analyzed samples which confirmed the earlier finding. Following the seizure the firm met several times with FDA representatives and finally agreed to relabel the product mixed fruit. FDA regulations do not require any specific ratios for the types of fruit in products labeled mixed fruit.

A U.S. marshal seized 720 fifty-pound bags of a premix for poultry feed at a farm co-op in Manchester, Connecticut, because the bags contained gentian violet, an additive that has not been approved for use in animal feed. The premix was manufactured by Marshall Minerals, Inc., Marshall, Texas, and is used to reduce spoilage in poultry feed caused by fungus and mold organisms. The seizure followed a routine inspection of the co-op by an investigator from FDA’s Hartford Resident Post.

REGION II
New Jersey, New York, Puerto Rico, Virgin Islands

A complaint from an anesthesiologist in New York City to FDA’s New York District about latex endotracheal tubes manufactured by Rusch, Inc., led to the firm notifying all hospitals which received the tubes not to re-sterilize or re-use them in order to avoid a potentially fatal malfunction. In addition, the firm told the hospitals to tag the tubes “for single use only.” The tubes are inserted into a patient’s trachea or windpipe during surgery to allow the introduction of oxygen and anesthetic gases. The anesthesiologist reported to FDA that in two instances patients nearly suffocated when the tubes became blocked and had to be removed during surgery. An investigation by the New York District revealed that the gases had seeped between the layers of the tube’s wall and formed bubbles, which expanded to block the passage. Analysis of samples of the tubes collected by New York and other FDA districts showed that the layers had separated because the tubes had been resterilized under vacuum. The New York-based import firm agreed that FDA had identified the problem and sent stick-on warning labels to all U.S.
hospitals using the product and directed them to apply the stick-ons to the tubes.

Otto Strauss, president of Thea Pastry, and Walter Bachenheimer, another official of the New York City pastry manufacturer, pleaded guilty in the U.S. District Court of New York to a charge of allowing raw materials to become contaminated with rodent filth. Each man was fined $250 each and the corporation $500. The action resulted from a routine inspection of the firm’s warehouse by investigators from the New York District who found 18 100-pound bags of flour and two 100-pound bags of poppyseed stored under insanitary conditions. The poppyseed bags had been gnawed by rodents. The firm voluntarily destroyed the contaminated goods at the plant.

Approximately 196,000 cans of hearts of palm, manufactured by Ibel, S.A. Belem, Brazil, and imported by Lankor International, Carlstadt, New Jersey, who recalled them because of insufficient acidification. FDA’s regulations covering low-acid canned foods such as peppers, onions, pimientos, and hearts of palm require that they have a high enough acid content to prevent the growth of microorganisms that cause botulism. The product was packed in 14-ounce and 30-ounce cans under three brand names: Tropic Hearts of Palm, Ibel, and Bonavita. The recall was initiated after FDA’s Newark District conducted a limited market survey as a followup to several import detentions of Ibel’s canned hearts of palm, which were found to lack the necessary acid content. FDA then ordered Lankor International to notify the 11 U.S. distributors about the recall by letter, and to cease further importation or distribution of the palm hearts. Firms which received the products were directed by Lankor to return them to one of the 11 distributors, which will hold them for final disposition.

REGION III

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

FDA’s Philadelphia District conducted a four-day inspection of a shipment of Israeli oranges and found no evidence of mercury contamination. FDA undertook the precautionary inspection because a small number of terrorists in Europe had injected some Israeli oranges with metallic mercury. This form of mercury is not toxic, though ingestion of a pound or more by an adult could cause diarrhea. Twelve investigators and four chemists from the Philadelphia District made up the FDA inspection team that examined randomly selected oranges in the 100,000-case shipment. The team used a metal detector, visual examination, and chemical tests at the Port of Philadelphia to check for possible mercury contamination. Over 77,000 oranges were examined and none were found to contain metallic mercury. Following the inspection the shipment was released for distribution.

The Federal Government seized over 280 114-pound bags of shelled Spanish peanuts at Edwards Freemen, Inc., Conshohocken, Pennsylvania, because of rodent contamination. The peanuts, valued at $12,000, were held in burlap bags contaminated with rodent urine. The seizure resulted from a routine inspection of the firm’s warehouse by the Philadelphia District.

REGION IV

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

A shipment of 420 100-pound bags of green coffee, offered for import from the Ivory Coast and consigned to General Foods Corp., was detained at the Port of Jacksonville, Florida, after an inspection by FDA’s Orlando District revealed the shipment to be contaminated with mold and insects. General foods had the coffee beans fumigated, opened all the bags, and segregated the good beans from the moldy beans and insects. The rejected beans were destroyed under the supervision of an FDA inspector.
Arkansas, Louisiana, New Mexico, Oklahoma, Texas

A follow-up investigation by FDA's Houston Section of a consumer complaint about worms in cookies led to the destruction of over 400 assorted packages of cookies. The consumer complained that a package of Momma's chocolate chip cookies bought at a Rice Food Market in Houston was infested with worms. Subsequent investigation revealed insect infestations at the retail outlet and also at the firm's wholesaler. The Houston Section notified the Texas State Health Department since the products were produced and marketed for use in the State. The State health department witnessed the destruction of the cookies by the retail outlet and followed up by investigation of the warehouse.

REGION VII

Iowa, Kansas, Missouri, Nebraska

FDA's Kansas City District and the Nebraska Department of Health investigated the disposition of 680 microwave ovens involved in a railroad train derailment at North Bend, Nebraska. Of the total, 653 were buried by request of the manufacturer at a county landfill because of damage to their safety controls which could cause them to leak hazardous levels of microwaves during use. Eighty of these had been held by the railroad which hoped they could be reconditioned. The Kansas City District, in conjunction with the Department of Health, notified the railroad that these units probably would not meet FDA safety standards, and the manufacturer then ordered that those units also be destroyed. Representatives of the Kansas City District and the State Department of Health witnessed the destruction of all 653 units. The other 27 units were taken by looters at the scene of the derailment, or sold to consumers through salvage dealers. The Nebraska Department of Health, concerned about possible excessive microwave radiation leakage from these units, set up a testing station in North Bend. A total of 15 of these units were brought in and tested and found to be within the safety standard for microwave radiation leakage.

A shipment of snail shells valued at over $6,600 was detained by the Kansas City District at the Port of Wichita after an FDA laboratory examination found the product adulterated with insect filth and maggots. The action followed a routine port inspection by FDA. The shipment, offered for import from France, was destined for the Richardson Center, Albany, California, where investigators from the San Francisco District discovered it was to be used to make Laetrile tablets or ampoules at a plant in Reno, Nevada. The detention resulted from a routine inspection at the airport of incoming cargo by U.S. Customs, which then notified the San Francisco District of its findings.

Rupert's Certifresh Inc., Sante Fe Springs, California, and three of its personnel were fined a total of $2,500 in the U.S. District Court for the District of Colorado which prohibited continued operation until after a reinspection found the firm in compliance with FDA regulations.

REGION IX

Arizona, California, Guam, Hawaii, Nevada

FDA's San Francisco District detained a shipment of ten kilos of crude amygdalin at the San Francisco Airport because the substance has not been approved by FDA for use as a drug. Amygdalin is a chemical substance found in apricot pits and other fruit kernels and is used to make Laetrile, an unapproved cancer drug. The amygdalin, offered for import from Cryosec Co., Kowloon, Hong Kong, was intended for the Richardson Center, Albany, California, where investigators from the San Francisco District discovered it was to be used to make Laetrile tablets or ampoules at a plant in Reno, Nevada. The detention resulted from a routine inspection at the airport of incoming cargo by U.S. Customs, which then notified the San Francisco District of its findings.

The Crab Pot Restaurant, Fort Lauderdale, Florida, voluntarily destroyed over 8,500 pounds of decomposed crabmeat after analysis of samples collected at the establishment by FDA's Orlando District confirmed an earlier finding by the Florida Department of Agriculture. The examinations also found that the packages of crabmeat, valued at $38,000, were short in weight. An Orlando District investigator witnessed the destruction, which was done by burial in a county dump near Miami. The crabmeat was packed in Venezuela and imported by the restaurant.

REGION VI

Arkansas, Louisiana, New Mexico, Oklahoma, Texas

REGION VIII

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

Vollmer's Bakeries, Denver, has resumed operation after closing for a short period to clean up insanitary conditions found during a routine inspection by FDA's Denver District. Investigators discovered severe insect infestation of equipment and supplies. The firm sells bakery goods to the public and to airline carriers. The firm had entered into a consent decree of permanent injunction in the U.S. District Court for the District of Colorado which prohibited continued operation until after a reinspection found the firm in compliance with FDA regulations.

A U.S. marshal seized 320,000 pounds of various foods at Bauer Warehousing Co., Inc., Sioux Falls, South Dakota, after an inspection by the Denver District revealed gross rodent contamination. The seized foods, valued at more than $150,000, included rice, dried beans, peas, sugar, and various macaroni products. All products in bags and paper and other containers susceptible to rodent entry were seized.

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Sayer, the plant manager, $300. In addition, Hideo Arakawa, the quality control supervisor, and Ben Race, production manager, were each fined $100.

REGION X
Alaska, Idaho, Oregon, Washington

A lot of 5,000 pounds of canned salmon, valued at over $9,000, was seized by U.S. marshals at a public storage warehouse in Seattle, because of decomposition. The seizure was made after organoleptic examination of samples collected at the warehouse by FDA's Seattle District revealed some of the salmon was decomposed. The salmon was shipped by St. Elias Ocean Products, Cordova, Alaska, to the Seattle warehouse.

The Federal Government seized a total of 7,900 tablets of zinc, magnesium, and calcium orotates at Levine Pharmaceuticals in Seattle. The tablets, valued at approximately $500, are dietary supplements which have not been approved by FDA. The orotates had been shipped by the manufacturer, General Research Laboratories, Van Nuys, California, after the firm was told by FDA's Los Angeles District that the products were in violation of the Federal Food, Drug, and Cosmetic Act. The Los Angeles District notified the Seattle District, which collected samples on which the seizure was based.

A mass seizure of adulterated food was made by the Federal Government at Reliable Transfer and Storage Co., Inc., Seattle, after an investigation by the Seattle District confirmed complaints from food wholesalers that shipments of foods delivered to them by the Seattle firm were contaminated by rodents. The food seized consisted mostly of candy bars and was valued at approximately $50,000. The investigation revealed that the goods were delivered to Reliable by an interstate carrier and stored there for a short time pending delivery to food wholesalers. Follow-up inspection at the firm by the Seattle District disclosed extensive evidence of rodent activity throughout the storage areas. Laboratory examination of samples collected during the inspection revealed that some of the products were rodent gnawed and contained rodent hairs and excreta.

Chocolate Firm Shut Down

The Louisiana State Health Department shut down the Claiborne Chocolate Co., Homer, Louisiana, until insanitary conditions found at the firm by FDA's New Orleans District are corrected. During a routine inspection FDA investigators discovered extensive insanitary conditions, including two lots of sugar and chocolate beverage base defiled by rodents and insects. The contaminated products came under State jurisdiction because they were manufactured within the State. As a result the New Orleans District notified the State health department, which seized the products and padlocked the plant until the firm's management could correct the insanitary conditions.

Accurate Menu Pledged

Super Sub Shops, Inc., Omaha, has agreed to accurately describe on its menus each item as required by the Nebraska Department of Agriculture's directive regarding menu advertising. The firm complied with the directive after a hearing with the Agriculture Department at which some customers complained that they were getting turkey products in sandwiches which called for other ingredients, and that ham advertised as imported came from the United States. The firm admitted that it occasionally used turkey instead of pork, ham, or beef products without advertising it on the menu.

Damaged Produce Seized

The Louisiana State Health Department seized damaged produce valued at about $100,000 at R. Guercio & Son, Inc., following a highly destructive night fire at the produce warehouse in New Orleans. FDA's New Orleans District helped the State determine the extent of damage to food products stored in the warehouse. All produce in the firm's coolers and banana ripening rooms was damaged by fire, water, or loss of electrical power. The seized produce was destroyed by burial at a sanitary landfill under State and Federal supervision.
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 38 actions to remove from the consumer market products charged to be violative was reported in February. These included 24 seizures of foods: 3 involved charges concerning poisonous and deleterious substances, 20 involved charges concerning contamination, and 1 involved charges concerning economic and labeling violations. Other seizures included 1 of vitamins-dietary food, 3 of food additives, 8 of drugs (including 3 of veterinary), and 2 of medical devices.

<table>
<thead>
<tr>
<th>PRODUCT, PLACE &amp; DATE SEIZED</th>
<th>MANUFACTURER (M), PACKER (P), SHIPPER (S), DEALER (D)</th>
<th>CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOOD/Poisonous and Deleterious Substances</strong></td>
<td></td>
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</tr>
<tr>
<td>Corn, bulk/Hialeah, Fla. 12/16/77</td>
<td>Lee Farm Service &amp; Supply/Bronwood, Ga. (S)</td>
<td>Contains the added poisonous and deleterious substance aflatoxin.</td>
</tr>
<tr>
<td>Mannitol/Chicago, Ill. 12/16/77</td>
<td>Fluidized Processing, Inc./Newark, N.J. (M,S)</td>
<td>Contains the added poisonous and deleterious substance polybrominated biphenyls (PBB's).</td>
</tr>
<tr>
<td>Swordfish, whole/Los Angeles, Calif. 10/18/77</td>
<td>P. J. Markos Seafood, Inc./Ipswich, Mass. (M,S)</td>
<td>Contains the added poisonous and deleterious substance mercury.</td>
</tr>
<tr>
<td><strong>FOOD/Contamination, Spoilage, Insanitary Handling</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artichoke hearts, canned/Houston, Tex. 11/21/77</td>
<td>Imported from Spain.</td>
<td>Unfit for food (swollen cans).</td>
</tr>
<tr>
<td>Bran, wheat/Boston, Mass. 12/2/77</td>
<td>Port Terminals, Inc./Boston, Mass. (D)</td>
<td>Held under insanitary conditions; insect contaminated.</td>
</tr>
<tr>
<td>Bubble gum/Ponce, P.R. 12/28/77</td>
<td>Ponce Candy Industries Corp./Ponce, P.R. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Chilies/San Francisco, Calif. 12/27/77</td>
<td>Pacific Oriental Terminal Co./San Francisco, Calif. (S); article imported from India.</td>
<td>Held under insanitary conditions; bird contaminated.</td>
</tr>
<tr>
<td>Chilies, frozen/El Paso, Tex. 11/2/77</td>
<td>Martin Bouvet &amp; Sons Chili Co./Garfield, N. Mex. (P,S)</td>
<td>Prepared, packed, and held under insanitary conditions; contains bacterial filth.</td>
</tr>
<tr>
<td>El Paso, Tex. 12/16/77</td>
<td>Dimock Dairy/Dimock, S. Dak. (M); John Morrell &amp; Co./Sioux Falls, S. Dak. (S)</td>
<td>Prepared and packed under insanitary conditions.</td>
</tr>
<tr>
<td>Cheese, Colby/Spokane, Wash. 11/4/77</td>
<td>Eduardo Serrano Valdez/Tijuana, Mexico (S)</td>
<td>Contains insect infestation and mold.</td>
</tr>
<tr>
<td>Cornhusks/Sacramento, Calif. 11/18/77</td>
<td>Nicholas &amp; Co., Inc./Salt Lake City, Utah (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Flour and rice/Salt Lake City, Utah 11/17/77</td>
<td>Import from Copenhagen, Denmark.</td>
<td>Insect contaminated.</td>
</tr>
<tr>
<td>Fruit bars/New York, N.Y. 11/28/77</td>
<td>Caribbean Snacks, Inc./Rio Piedras, P.R. (D)</td>
<td>Held under insanitary conditions; rodent gnawed and contains insects.</td>
</tr>
<tr>
<td>Peanuts, potato granules, dough conditioner, onion seasoning/Rio Piedras, P.R. 12/27/77</td>
<td>Seattle Workers Brigade/Seattle, Wash. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Pear halves, canned/San Antonio, Tex. 11/27/77</td>
<td>Thalia's Candy Corp./Brooklyn, N.Y. (D)</td>
<td>Held under insanitary conditions; contains insects.</td>
</tr>
<tr>
<td>Pineapple rings/Brooklyn, N.Y. 11/10/77</td>
<td>Pueblo International Inc./Carolina, P.R. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Rice, and vermicelli spaghetti/Carolina, P.R. 11/23/77</td>
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<tr>
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<tr>
<td>Salmon, canned/Seattle, Wash. 11/29/77</td>
<td>St. Elias Ocean Products/Cordova, Alaska (S)</td>
<td>Contains decomposed salmon.</td>
</tr>
<tr>
<td>Seattle, Wash. 11/29/77</td>
<td>Dressell-Collins Fish Co./Seattle, Wash. (P)</td>
<td></td>
</tr>
<tr>
<td>Toor-Dall/Brooklyn, N.Y. 11/30/77</td>
<td>Ched Warehousing Inc./Brooklyn, N.Y. (D)</td>
<td>Held under insanitary conditions.</td>
</tr>
<tr>
<td>Candy, &quot;Carob covered raisins &amp; nuts&quot;/Pittsburgh, Pa. 12/14/77</td>
<td>Flavor Tree Foods, Inc./Franklin Park, Ill. (M,S)</td>
<td>Article's name is false and misleading since article does not contain nuts; required label information (i.e., name and place of business of manufacturer, packer, and distributor; and declaration of ingredients) are not prominently placed; and label fails to bear common or usual names for the ingredients “pernuts toasted soybeans” and “toasted carob.”</td>
</tr>
<tr>
<td>Vitamin B₆ plus tablets/St. Louis, Mo. 11/23/77</td>
<td>Vita-Herbs, Inc./St. Louis, Mo. (D)</td>
<td>Contains insect fragments.</td>
</tr>
<tr>
<td>Aangamik-15 calcium pangamate tablets/Des Plaines, Ill. 12/1/77</td>
<td>FoodScience Laboratories, Inc./Burlington, Vt. (S)</td>
<td>Contains nonconforming food additive calcium pangamate; and lacks common or usual name for ingredients declared as “binder” and “lubricant.”</td>
</tr>
<tr>
<td>Buffalo jerky combination patties, Wyoming Buffalo Chips/Loveland, Colo. 12/5/77</td>
<td>Pat’s Meat Discounter/Casper, Wyo. (M,S)</td>
<td>Contains nonconforming food additive; plant proteins, as well as water and monosodium glutamate, substituted in part for buffalo meat; label fails to bear common or usual name of the food, and of the ingredients termed “T.V.P.” and “H.V.P.” (i.e., textured vegetable protein and hydrolyzed vegetable protein); and the quantity of contents statement was not conspicuously placed.</td>
</tr>
<tr>
<td>Gentian violet premix/Mena, Ark. 12/14/77</td>
<td>Johnston Feed Mill of Mena, Inc./Mena, Ark. (D)</td>
<td>Contains the nonconforming food additive gentian violet.</td>
</tr>
<tr>
<td>Aromatic ammonia inhalant solution ampules/St. Louis, Mo. 11/3/77</td>
<td>American Drug Industries/Chicago, Ill. (M); Marion Health &amp; Safety, Inc./Rockford, Ill. (S)</td>
<td>Prepared, packed, and held under insanitary conditions; circumstances of manufacture, processing, packing, and holding are not in conformity with current good manufacturing practice.</td>
</tr>
<tr>
<td>St. Louis, Mo. 11/3/77</td>
<td>Jersey Analytical Services/Andover, N.J. (M); James Alexander Corp./Hackettstown, N.J. (S)</td>
<td>Strength and quality of article differ from its represented strength and quality; circumstances of manufacture, processing, packing, and holding not in conformity with current good manufacturing practice.</td>
</tr>
<tr>
<td>Dicyclomine HCl injectable/Melrose Park, Ill. 11/16/77</td>
<td>Carter-Glogau Laboratories, Div. of Chromalloy Pharmaceuticals, Inc./Melrose Park, Ill. (D,M)</td>
<td>New drug without an effective approved New Drug Application, inadequate directions for use; circumstances of manufacture not in accordance with current good manufacturing practice.</td>
</tr>
<tr>
<td>Sodium pangamate tablets and calcium pangamate tablets/Crystal Lake, Ill. 10/2/77</td>
<td>Naturally Vitamin Supplements/Scottsdale, Ariz. (S)</td>
<td>Contain the nonconforming food additives calcium and sodium pangamate; labeling is false and misleading as to identity of articles, since calcium pangamate and sodium pangamate are not identifiable substances, are not vitamins or provitamins, have no established nutritional properties or identified deficiency in man or animal, and have no established medical, nutritional, or other usefulness.</td>
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<td>Z Special #4288 antispasmodic sedative tablets/Chatekowaga, N.Y. 12/14/77</td>
<td>The Zemmer Co./Oakmont, Pa. (M,S)</td>
<td>New drug without an effective approved New Drug Application.</td>
</tr>
<tr>
<td>Bucoderm chlorpheniramine maleate and vitamin combination suspension/Portland, Oreg. 11/18/77</td>
<td>Burns Biotec/Oakland, Calif. (S)</td>
<td>New animal drug and no New Animal Drug Application is in effect with respect to its use or intended use.</td>
</tr>
<tr>
<td>Nitrosol nitrofurazone topical solution, Bucoderm chlorpheniramine maleate and vitamin combination suspension/Boise, Idaho 11/15/77</td>
<td>Milton Brandow, t/a Independent Buyers Association, Inc./Schenevus, N.Y. (D)</td>
<td>New animal drugs and no New Animal Drug Applications are in effect with respect to their use or intended use. Labeling fails to bear adequate directions for use, and was not exempted, since articles were not held for sale only on prescription.</td>
</tr>
<tr>
<td>Prednisone boluses, epinephrine injectable, estradiol dipropionate injectable, and other R, veterinary drugs/Schenevus, N.Y. 11/9/77</td>
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</tr>
<tr>
<td>Media plates, tubes, and other reagents for in vitro diagnostic use, including chocolate agar, hektoen enteric agar, thioglycollate w/indicator, GN broth/Phoenix, Ariz. 9/22/77</td>
<td>Bolin Laboratories, Inc./Phoenix, Ariz. (M,D)</td>
<td>Labeling fails to bear adequate directions for use since articles' packages do not have required package inserts.</td>
</tr>
<tr>
<td>P/EmF electromagnetic energy generator (modified Diapulse device)/Bronx, N.Y. 11/23/77</td>
<td>Diapulse Corp. of America/Great Neck, N.Y. (M)</td>
<td>Inadequate directions for use.</td>
</tr>
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</table>

**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)

December 20, 1977: Rand Yung Distributors, P.O. Box RY-7, Reseda, California. Advertising and sale through the mail of various sexual products, representing the ability to increase the length of the penis and cause greater erections.

December 22, 1977: John Galt Co., 3010 Santa Monica Blvd., P.O. Box 5157, Santa Monica, California. Advertising and sale through the mail of the product "Youth Ring," representing the ability to enlarge the penis and cause greater erections.

January 9, 1978: Eyero Laboratories, P.O. Box 606, Vineland, Connecticut. Advertising and sale through the mail of capsules, representing the ability to prevent and control cataracts.

January 9, 1978: Against Diet Research, Inc., Box 91189 FD, Atlanta, Georgia. Advertising and sale through the mail of the product "Rice Diet," representing the ability to cause weight loss.

January 11, 1978: Against Wrinkles Gone Co., 1 Wolfs Lane, Pelham, New York. Advertising and sale through the mail of the product "Wrinkles Gone," representing the ability to remove wrinkles.

January 11, 1978: Against Hair Builder, 1 Wolfs Lane, Pelham, New York. Advertising and sale through the mail of the product "Hair Builder," representing the ability to cause hair growth.

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

December 22, 1977: Against Sean Michaels, 1210 66 Street N., St. Petersburg, Florida. Advertising and sale through the mail of the product "Bust Expander," representing the ability to increase the size of the bust.

December 30, 1977: Against Brad Mitchell, 27313 Plymouth Road, Detroit, Michigan. Advertising and sale through the mail of the product "The Amazing Fat Burning System," representing the ability to cause weight loss.

January 9, 1978: Against Diet Research, Inc., Box 91189 FD, Atlanta,
NOTICES OF JUDGMENT on Seizure Actions

FOOD/Poisonous and Deleterious Substances

Mung beans, 3 lots, at San Francisco and San Jose, N. Dist. Calif.
Charged 3–24–77: when shipped by Buakao Co., Ltd., Bangkok, Thailand, the article, labeled in part "Lotus of Thailand...Packed For Consolidated Import Products of Thailand," contained the pesticide chemical endrin and there was no tolerance or exemption therefor for such pesticide chemical on mung beans; 402(a)(2)(B). Consent decree authorized release of the San Jose lot and one of the San Francisco lots to Trans Continental Imports, t/a Consolidated Import Products, San Francisco, Calif., for salvaging. Default decree as to remaining lot of the article ordered its destruction. (F.D.C. No. 61122; S. No. 77–50–356 et al.; N.J. No. 1)

Cheeses, Switzerland Swiss, Holland Gouda & Edam, and Finland Swiss, and Candy, button-shaped, and desiccated coconut, at Largo, M. Dist. Fla.
Charged 3–10–77: while held for sale, the articles were unfit for food due to excessive mold (examination showed: mold on 90 of 181 pieces of Switzerland Swiss covering 25 to 100 percent of their surfaces; mold on 53 of 54 pieces of Holland Gouda & Edam covering 25 to 100 percent of their surfaces; mold on 1–4 pieces of Finland Swiss covering 5 to 25 percent of their surfaces); 402(a)(3). Default decree ordered destruction. (F.D.C. No. 62068; S. Nos. 77–14–856 et al.; N.J. No. 3)

Coffee beans, at New Orleans, E. Dist. La.
Charged 7–21–77: while held by Hansen & Tidemann, Inc., New Orleans, La., the article was held under insanitary conditions; 402(a)(3). Consent decree authorized release to Folger Coffee Co., New Orleans, La., for salvaging. (F.D.C. No. 61342; S. Nos. 77–31–801/9 et al.; N.J. No. 4)

Cranberry, canned, 3 seizure actions, at Foster City, N. Dist. Calif.
Charged 7–18–74, 8–19–74, and 10–1–74: when shipped by Lein Mou Food Factory, Ltd., and Sun Wave Trading Co., Ltd., Taiwan, China, the article, labeled in part "Ocean Delight Snow Crab Meat...Product of Taiwan...Distributed by H & L International, Inc., San Francisco, Calif." contained insect filth; 402(a)(3). The articles were claimed by H & L International, Inc., San Francisco, Calif. Consent decree authorized release to claimant for export to the original foreign suppliers. (F.D.C. Nos. 59865, 59880, 59984; S. Nos. 27–134 H, 26–905 H, 26–386 H; N.J. No. 5)

Fennel seed, at Arvada, Dist. Colo.

Flour, canned grapefruit juice, canned diet soda, macaroni, chocolate candy bars, and other grocery stocks, at Tewksbury, Dist. Mass.
Charged 1–31–77: while held by DeMoulas Supermarkets, Inc., Tewksbury, Mass., some of the articles contained rodent filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 62039; S. Nos. 77–93–487 et al.; N.J. No. 7)

Jujubes, at New York, S. Dist. N.Y.
Charged 2–25–77: when shipped by China National Native Produce & Animal By-Products Import & Export Corp., Tientsin, China, the article contained moldy jujubes (red dates); 402(a)(3). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 62041; S. Nos. 77–89–163; N.J. No. 8)

Mung beans, monosodium glutamate, rice flour, rice powder, tapioca, tea, bean paste threads, and other oriental food stocks, at Boston, Dist. Mass.
Charged 7–15–77: while held by Eastern Enterprises, Inc., Boston, Mass., some of the articles contained rodent and insect filth, and all of the articles were held under insanitary conditions; 402(a)(3), 402(a)(4). Wallant International Trade, Inc., New York, N.Y., claimed the mung beans and a lot of monosodium glutamate, alleging that the articles were not food. Eastern Enterprises, Inc., Boston, Mass., claimed the other articles. The Government moved for summary judgment. The court granted the Government's motion for summary judgment and ordered the articles destroyed. (F.D.C. No. 61348; S. Nos. 77–91–924 et al.; N.J. No. 9)

Oregano, ground, at Santa Isabel, Dist. P.R.
Charged 3–8–77: while held by Alimentos Borinquenos S.A., Santa Isabel, P.R., the article contained insects and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for reconditioning. (F.D.C. No. 62060; S. Nos. 77–83–225; N.J. No. 10)

Pineapple, crushed, canned, at Catano, Dist. P.R.
Charged 7–28–76: while held for sale, the article was unfit for food due to loose pieces of can lining; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 60804; S. No. 76–50–697; N.J. No. 11)

Salmon, canned, Frosty, at San Juan, Dist. P.R.
Charged 4–19–76: when shipped by Frosty Fish Co. (Frank Mateljan), Wilmington, Calif., the article contained decomposed salmon; 402(a)(3). Credit Managers Association of Southern California, Los Angeles, Calif., claimed the article, as assignee of the article. That claimant subsequently withdrew from the action, as did the trustee of the shipper's estate, who asserted that, even if a buyer for the article could be found, the sale price would be very low, and that the costs and expenses for storing the article and defending the article would be extensive. Ultimately, the court found that the article had been abandoned and ordered it destroyed. (F.D.C. No. 60703; S. Nos. 76–50–688 et al.; N.J. No. 12)

Salmon, dressed, frozen, at Seattle, W. Dist. Wash.
Charged 7–29–77: while held for sale, the article contained decomposed salmon; 402(a)(3). Default decree ordered destruction. (F.D.C. No. 61359; S. Nos. 77–22–328; N.J. No. 13)

Soybeans, rice, and red beans, at Sacramento, E. Dist. Calif.
Charged 2–4–77: when held by North American Food Distributing Co., Sacramento, Calif., the rice and red beans contained rodent filth, and all the articles had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to the dealer for salvaging. (F.D.C. No. 62040; S. Nos. 77–50–276 9; N.J. No. 14)

Charged 4–1–77: while held by Comet Rice Mills, Inc., Stuttgart, Ark., the article contained bird excreta and had been held under insanitary conditions; 402(a)(3), 402(a)(4). Consent decree authorized release to dealer for salvaging. (F.D.C. No. 61151; S. Nos. 77–39–140/2; N.J. No. 15)

FOOD/Economic and Labeling Violations

Charged 6–7–77: when shipped by Consolidated Flavor Corp., St. Louis, Mo., chocolate-flavored dairy powder made with cocoa and carob had been substituted for chocolate-flavored dairy powder made with cocoa; 402(b)(2). Default decree ordered destruction. (F.D.C. No. 61272; S. Nos. 77–05–794; N.J. No. 16)

Pepperoncini, pickled, at Readville, Dist. Mass.
Charged 6–10–77: while held for sale after being packed by Gloria Packing Corp., Boston, Mass., the article, labeled in part "Imported Pepperoncini...Gloria Net 16 Fl. Oz. (1 Pt.) Gloria Packing Corp., Boston, Mass..." was short in volume (between approx. 5.2 and 11.12 percent); 403(e)(2). The article was claimed by the packer. Subsequently, a consent decree authorized release to the claimant for bringing into compliance with the law. (F.D.C. No. 61214; S. Nos. 77–93–299/300; N.J. No. 17)
FOOD ADDITIVES

Ginseng powder capsules, at Greenville, Dist. S.C.
Charged July 21-77: when shipped by Pharmacies, Inc., Elizabeth, N.J., the article contained the nonconforming food additive ginseng: 402(a)(2)(C). Default decree ordered destruction. (F.D.C. No. 61344; S. No. 77-65-009; N.J. No. 18)

Selenium with yeast combination tablets, at Deer Park, E. Dist. N.Y.
Charged 3-18-77: while held by Edom Laboratories, Inc., t/a Consumer Vitamins, Inc. (who packaged the article which had been manufactured by Contract Pharmacal Corp., Hauppauge, N.Y., using ingredients shipped in interstate commerce), the article contained the nonconforming food additive selenium—402(a)(2)(C); required label information (name and place of business of manufacturer, packer, and distributor, and the common or usual names of each ingredient) was inapplicably placed, since such information was not together either on the label's information panel or on the principal display panel and since such information was not in letters at least as high as one-sixteenth of an inch—403(f); and the article's label lacked the common or usual name of an ingredient such as dicalcium phosphate and stearic acid—403(i)(2). Default decree ordered destruction. (F.D.C. No. 61129; S. Nos. 77-89-349/51; N.J. No. 19)

DRUGS/HUMAN USE

Charged 7-26-76, 7-22-76, 7-22-76, 8-2-76: when shipped by Bolar Pharmaceutical Co., Inc., Copiague, N.Y., the article, labeled in part, (Glasgow action) "Chlorothiazide 250 mg. [or "500 mg."] ... Tablets Manufactured For Ritchie Pharmaceutical Co., Glasgow, Ky.; and (Chicago, Broadway, & San Diego actions) "Chlorothiazide 250 mg. [or, in Chicago & San Diego actions, "250 mg."]." Bolar Pharmaceutical Co., Inc., Copiague, New York," were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Subsequently, an Abbreviated New Drug Application was approved for the 250 mg tablets, and those tablets were released to the shipper. Consent decree or (Broadway action) default decree ordered destruction of the 500 mg tablets. (F.D.C. Nos. 60805/7, 60809; S. Nos. 76-34-1385/6, 76-28-1078; N.J. No. 20)

Ephedrine hydrochloride tablets, unlabeled, at Denver, Dist. Colo.
Charged 5-5-77: while held for sale, the article lacked a label containing: the name and place of business of the manufacturer, packer, or distributor; a quantity of contents statement; and the established name of the drug—502(b)(1), 502(b)(2), 502(e)(1)(A)(i); and the labeling lacked adequate directions for use and was not exempted—502(f)(1). Default decree ordered destruction. (F.D.C. No. 61220; S. Nos. 77-24-966; N.J. No. 21)

Charged 8-2-76 and 7-22-76: when shipped by Bolar Pharmaceutical Co., Inc., Copiague, N.Y., the articles, labeled in part "Bolar Hydrogenated Ergot Alkaloids ... Sublingual Tablets," and "Gold Line ... Trihydrogen Sublingual Tablets ... Distributed by Generix Drug Sales Co. Hollywood, Florida," were new drugs without effective approved New Drug Applications; 505(a). The articles were claimed by the shipper. Thereafter, Abbreviated New Drug Applications were approved for the articles. The parties stipulated that the tablets be released to the claimant, that the labeling be revised to incorporate specified expiration dates and storage provisions, that FDA sampling and inspection of the articles be permitted, and that the action be dismissed. Consent decrees were entered in accordance with the stipulations, and the articles were relabeled and found by FDA to be labeled in accordance with the approved Abbreviated New Drug Applications. (F.D.C. Nos. 60815, 60819; S. Nos. 77-28-112, 76-64-301 et al.; N.J. No. 22)

Nitrofurantoin tablets, U.S.P., at Plainview, E. Dist. N.Y.
Charged 11-3-76: while held for sale, after manufacture by Bolar Pharmaceutical Co., Inc., Copiague, N.Y., using interstate nitrofurantoin, the article's quality fell below U.S.P. standards, since the tablets failed the U.S.P. tablet dissolution requirements; and the label statement "Nitrofurantoin Tablets, U.S.P.:") was false and misleading, because of such failure; 501(b), 502(a). A default decree ordered destruction. However, by stipulation, such order was set aside and a consent decree of condemnation was filed. The consent decree authorized the release of the article, after bringing into compliance, in view of the fact that the U.S.P. standards for the article were to be revised effective May 1, 1977, and that retesting might establish that the article met the revised standards. (F.D.C. No. 60975; S. Nos. 76-41-740; N.J. No. 23)

Phenobarbital tablets, at Auburn, N. Dist. N.Y.
Charged 9-21-77: while held for sale by Jenkins Laboratories, Inc., Auburn, N.Y., who was repackaging the articles which had been manufactured by a firm in Bronx, N.Y., the circumstances used in the manufacture, packaging, and holding of the article failed to conform to current good manufacturing practice; 501(a)(2)(B). Default decree ordered destruction. (F.D.C. No. 61411; S. Nos. 77-83-0149; N.J. No. 24)

Progesterone vaginal insert tablets, at Kirkwood, E. Dist. Mo.
Charged 7-22-77: while held for sale after manufacture by Private Formulae, Inc., St. Louis, Mo., using progesterone shipped in interstate commerce, the article's labeling lacked adequate directions for use and was not exempted therefrom, because it was a drug without an effective approved New Drug Application; 502(f)(1). Default decree ordered destruction. (F.D.C. No. 61345; S. No. 77-24-230; N.J. No. 25)

Quinidine sulfate tablets, at St. Louis, E. Dist. Mo.
Charged 4-20-77: when returned to Alpha Pharmamal Inc., St. Louis, Mo., from Long Beach, Calif., the article, labeled in part "Quinidine 300 mg. (5 gr.) Alpha 100 Tablets . . . Packed & Distributed by C.R.P.P. . . . Long Beach, Calif." was a new drug without an effective approved New Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 61180; S. Nos. 77-27-004; N.J. No. 26)

Charged 10-8-76: when shipped by Zenith Laboratories, Inc., Northvale, N.J., the article was a new drug without an effective approved New Animal Drug Application; 505(a). Default decree ordered destruction. (F.D.C. No. 60883; S. Nos. 77-85-638/40; N.J. No. 27)

DRUGS/VETERINARY

Vet-Labs Copper-Nate copper naphthenate solution, Vet-Labs Thuja ointment, and Vet-Labs of copper, thuja oil, and biebrich scarlet combination udder ointment, at Lenexa, Dist. Kans.
Charged 4-4-77: while held by Veterinary Laboratories, Inc., Lenexa, Kans., who was manufacturing the articles from components shipped in interstate commerce, the articles were new animal drugs and no approval of a New Animal Drug Application was in effect with respect to the use or intended use of such drugs (e.g., Copper-Nate, an antiseptic-astringent, for thrush and foot pads; Thuja ointment for handling exuberant granulations (so-called "proud flesh"); and udder ointment for treatment of dairy cattle with phenol, thuja oil, biebrich scarlet, oil of eucalyptus, and turpentine); 501(a)(5). Default decree ordered destruction. (F.D.C. No. 61150; S. Nos. 77-24-029; N.J. No. 28)

MEDICAL DEVICES

Charged 7-5-77: the article, which had been shipped by Vital Air Oxygen Co., Div. Plato Manufacturing Co., Cleveland, Ohio, had false and misleading labeling inside the carton lid that claimed that the 75%/liter of oxygen in the sphere was a sufficient supply of emergency medical oxygen and that each sphere supplied one hour's need for emergency medical purposes—502(a); and the article was dangerous to health when used as directed, for the article was intended for emergency use and failed to maintain a sufficient supply of oxygen for emergency medical purposes for the claimed one hour period—502(i). Default decree ordered destruction. (F.D.C. No. 61296; S. Nos. 77-86-826; N.J. No. 29)
The complaint also charged that the defendants manufactured, processed, packed, labeled, and distributed to interstate commerce, articles of food and drug known as: "[picture of a bee] Seventeen," i.e., [Bee] Seventeen, and "[picture of a bee] Seventeen-Carob Flavor," i.e., [Bee] Seventeen Carob Flavor, and in holding such articles for sale after shipment of their dextrose component in interstate commerce; that the articles bore labels such as "food for special dietary use Developed and distributed by General Research Laboratories ... Hollywood California [or ‘The Institute of Nutritional Research ... Los Angeles, Calif’], ... Protex from Nature's Secret, and Dehydrated Egg White) ... Apricot Fruit and kernel concentrate containing 500 mg Amygdalin per packet"; that FDA analysis revealed the equivalent of 6.7 to 10.00 milligrams hydrocyanic acid per package—the minimum lethal dose being 0.5 to 3.5 milligrams per kilogram; that the articles [Bee] Seventeen and [Bee] Seventeen Carob Flavor, contained the nonconforming food additive amygdalin; that the label vignette and statement "(picture of a bee) Seventeen Food For Special Dietary Use," the listing on the label of sixteen vitamins and minerals along with a picture depicting fruit resembling apricots, and the label declaration concerning the articles' content of apricot fruit and kernel concentrate containing 500 milligrams of amygdalin per packet, falsely and misleadingly represented and suggested that apricot fruit and kernel concentrate containing amygdalin was a nutrient with special dietary properties; that the labeling of the articles lacked adequate directions for use, since the labeling did not state the purpose and condition for which the articles were intended, namely, for the treatment or prevention of cancer; and that the labeling of the articles lacked adequate warnings against unsafe use; 402(a)(2)(C), 402(a), 502(f)(1), 502(f)(2).

The complaint also charged that the defendants manufactured, processed, packed, labeled, and distributed in interstate commerce, the following articles: a) various animal drugs, including Entrol C, Entrol P, Entrol S, Mycotrol P, Mycotrol S, Myconox P, Myconox Soluble; Medi-Matic Medicated, Ferro-Lac Calf Boluses, Ferro-Lac Calf Formula; and other oral veterinary drugs containing methyl rosinamide chloride (gentian violet); that many of the defendants' foods and drugs had been the subject of Federal seizure; that the defendant's drugs were new animal drugs and no approvals of New Animal Drug Applications were necessary in order to sell such drugs; that their activities were in violation of the law by a number of specified seizure actions and by a number of specified letters—402(a)(2)(C), 402(a)(3), 502(f)(1), 502(f)(2), 505.

The defendants admitted dealing in various articles of drug for animal use, but denied that they were presently distributing "Entrol C," "Myconox Soluble," or "Medi-Matic Medicated," and denied that any of the complained of articles were new animal drugs, or were nonconforming food additives. The defendants alleged that the composition of each of their drugs was generally recognized as safe and effective and specifically denied that "GV-Eleven" was a food.

The Government moved for summary judgment on Entrol C, Entrol P, Entrol S, Mycotrol P, Mycotrol S, Myconox P, Medi-Matic Medicated, Ferro-Lac Calf Boluses, Ferro-Lac Calf Formula, Myconox LF and any article of similar composition for which the composition of each of their dmgs was generally recognized as safe and effective, and had been conceived by the defendant's predecessors, Institute of Nutritional Research, and the defendants had no interest in defending and accordingly would offer only token and/or nominal defense for the product Seventeen. After trial by the court, it appeared that the defendants had violated, and might continue to violate, the law with respect to the articles of food and drug "[Bee] Seventeen," and "[Bee] Carob" or similar articles of food and drug. Accordingly, the court permanently enjoined the defendants from such violations. (Inj. No. 660; N.J. No. 32)
and animal drugs manufactured by the defendant. These prior cases are:

2. United States v. 41 cases ... Naremco Myconox, 420 F.2d 1126 (C.A. 7, 1970). 

"In each of the above cases the position of the Food and Drug Administration that the product was a 'new animal drug' or a 'new animal food' which was within the prohibition of the act was upheld.

"The basic dispute between the parties apparently arises over the use of Methylrosaniline Chloride, commonly known as Gentian violet, in each of these products.

"In all of the previous cases the Government prevailed upon the theory that the combination of other, admittedly beneficial drugs, and gentian violet (not claimed by the Government in those cases to be non-beneficial) created a 'new drug' the effects of which were unknown and therefore never recognized as 'safe and effective.'

"Proof was presented that the combination of drugs, known to be beneficial and harmless administered singly, could and on occasions had produced harmful and dangerous results. Since the combination in each of defendant's products had never been used, and therefore never recognized as safe before the effective date of the legislation, the burden was on the defendant to have it approved by the Commissioner before it could be marketed.

"In this case many of the facts have been stipulated. The defendant manufactures, stores, ships and sells the products named in the complaint. Although the defendant does not admit that any of the named products are within the prohibition of the Act, the defense has been directed to the prohibition of the sale of one product, GV Eleven. This product is a 1.6% solution of gentian violet in an inert solution, and is not combined with any other drugs. The label gives no directions for its use, but it apparently is used both as an additive to feed (to control mold) and as a drug to be administered internally to poultry.

"Gentian violet is a drug which was discovered in the 1870's. The Court knows from personal experience that it was used in the Navy in World War II to treat a variety of external maladies, from trench mouth to athlete's foot. It was the standard remedy for every type of fungus infection, commonly known as syphilis, which was prevalent in the South Pacific.

"Amazingly, in view of this case, the evidence disclosed that it is available over the counter, without prescription, for internal use by humans and is in common use in the southern states for treatment of internal parasites, such as hookworm and pinworm, in both children and adults.

"The entire thrust of the Government's complaint in this case, entirely different from the contention in all the previously reported cases, is that the defendant should be enjoined from marketing any product containing gentian violet, until the defendant has established, by lengthy, exhaustive expensive testing, that the product is safe and effective.

"The statutes contain certain 'grandfather' exceptions. Peculiarly, they are different for drugs and for food additives. . . .

"In this case the difference between the two tests [21 U.S.C.A. 321(w)(1) and 21 U.S.C.A. 321(s)] is further complicated by the fact that it is impossible to determine from the pleadings, the evidence, or the post trial briefs the exact contentions of the parties as to which test should be applied to GV-11. The label on this product does not in any way state its intended use.

"Since, under the evidence, gentian violet is a 'drug' as defined in subsection (g)(1)(A) of Section 321, and since subsection (w) defines a 'new drug' as 'including any drug intended for use in animal food,' it seems clear that the grandfathers proviso 'under the conditions prescribed, recommended, or suggested in the labeling thereof.' As mentioned above, the label on GV-11 contains no such directions.

"The Court will allow the defendant corporation to prepare a proper label for this product, to be approved by the Court, to remedy this deficiency.

"In the event an appellate court should find that gentian violet is also a 'food additive' (the Government apparently urges this dual nomenclature), this Court finds that the defendant's expert witnesses clearly established that it was a substance used in poultry feed prior to January 1, 1958 and was generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through experience based on common use in food to be safe under the conditions of its intended use.

"Based upon the foregoing findings, this Court will grant the Government's prayer for a temporary injunction as prayed, with the additional provision that if and when the Court approves a proper label prescribing, recommending or suggesting conditions for use of GV-11 as a drug to be administered to poultry or in poultry feed, the injunction shall be lifted as to that product.

"Following the above opinion, the defendants submitted new proposed labels for use of the GV-11 product as a drug called GV-Eleven Medicated (for marketing this product as a drug), and as a food called GV-Eleven Mold Inhibitor (for adding to poultry feed).

"The Government opposed such proposed labeling; however, the court in its order of preliminary injunction found that the claims and directions contained in both labels were supported by the evidence already adduced.

"Upon motion of the Government, the court entered a permanent injunction based upon the record made at the earlier hearing, without the hearing of additional evidence. The defendants had agreed to such procedure, conditioned upon the court using the same form of permanent injunction as was used for the preliminary injunction.

"Because of the court's opinion and order as to the GV-Eleven products, the Government appealed. Upon appeal, the court of appeals reversed the district court as to the GV-Eleven products, saying:

"For nine years, Naremco, Inc. and the Government have disagreed over the applicability of certain provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 332 (P. V. 1975), to products containing gentian violet (methylrosaniline chloride). Naremco, a Missouri corporation, has repeatedly manufactured and sold a variety of products containing gentian violet without first obtaining pre-marketing approval from the Food and Drug Administration (FDA).

"Naremco has consistently contended that its products are exempt from statutory provisions requiring pre-marketing approval.

"The Government, with equal tenacity, has maintained that Naremco's gentian violet products, marketed as animal drugs and as additives to animal feed, may not be sold without pre-marketing FDA approval. Naremco's nonapproved interstate sales of gentian violet products have been contested by the Government in repeatedly successful seizure suits under 21 U.S.C. § 334. The Government's victories in these seizure actions have been largely Pyrrhic, however. After each adverse ruling, Naremco has simply varied its strategy, continuing to sell the same product without pre-marketing approval.

"In an effort to end this litigious cycle, the Government brought the instant suit under 21 U.S.C. § 332(a) to enjoin Naremco from the future interstate sale of gentian violet products used as animal additives or animal feed, until and unless pre-marketing approval was obtained from the FDA.

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"In an effort to end this litigious cycle, the Government brought the instant suit under 21 U.S.C. § 332(a) to enjoin Naremco from the future interstate sale of gentian violet products used as animal additives or animal feed, until and unless pre-marketing approval was obtained from the FDA. ** * * GV-Eleven Medicated

"The propriety of the District Court's exemption of GV-Eleven Medicated from pre-marketing approval turns upon a determination of whether or not GV-Eleven Medicated is a new animal drug. If a
product is a new animal drug within the meaning of 21 U.S.C. § 321(w), it may not be sold until a new drug application has been approved. The District Court found that GV-Eleven Medicated was not a new animal drug because it was generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended or suggested by its labeling.

"We have carefully reviewed the evidence offered to establish the general recognition among experts of the safety and effectiveness of gentian violet, the sole active ingredient in GV-Eleven Medicated. While the record contains some evidence that gentian violet is recognized by experts as safe, it lacks evidence of general expert recognition of gentian violet's effectiveness as an animal drug. There is evidence of scattered lay opinion that gentian violet is effective in treating certain fungal diseases in poultry. However, lay and expert recognition are not interchangeable under § 321(w), which specifies that the general recognition of effectiveness necessary to remove a drug from the strictures of obtaining pre-marketing approval must be that of 'experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs.' Moreover, the Supreme Court has read the requirement of general expert recognition of effectiveness to mean that: [T]he hurdle of "general recognition" of effectiveness requires at least "substantial evidence" of effectiveness * * * . In the absence of any evidence of adequate and well controlled investigations supporting the conclusion of the trial court that gentian violet was a "new drug" subject to the provisions of the Act.'


"In concluding that gentian violet was not a new animal drug, the trial court must have considered lay recognition of effectiveness equivalent to expert recognition, for no evidence was presented which showed general expert recognition of gentian violet's effectiveness or which established the existence of adequate and well controlled investigations upon which general expert recognition of effectiveness could be based. In allowing lay opinion to be substituted for the expert recognition required by the Act, the trial court incorrectly applied § 321(w). The record here, which lacks evidence of general recognition by experts of the effectiveness of gentian violet as an animal drug, compels the conclusion that gentian violet is a new animal drug which may not be marketed until a new animal drug application has been submitted and approved.

GV-Eleven Mold Inhibitor

The propriety of the District Court's exemption of GV-Eleven Mold Inhibitor from the requirement of obtaining pre-approval depends upon whether or not GV-Eleven Mold Inhibitor is a food additive. A product which is a food additive may not be sold in interstate commerce unless it conforms to a food additive regulation or has been exempted from such conformity. The District Court found that gentian violet, the only active ingredient in GV-Eleven Mold Inhibitor, was a substance that had been used in poultry feed prior to January 1, 1958, and that it was generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through experience based on common use in food to be safe under the conditions of its intended use. Thus, it concluded that gentian violet was not a food additive and could be marketed without the necessity of conforming to or obtaining a food additive regulation.

"A review of the evidence reveals that products containing gentian violet were added to poultry feed prior to January 1, 1958. The pre-1958 use of gentian violet in poultry feed was as an animal drug, however, not as a mold inhibitor or feed preservative. Naremco contends, and the trial court apparently agreed, that the addition of gentian violet to animal feed as a drug provided experience based on 'common use in food' prior to 1958 that experts could rely upon to recognize the safety of using gentian violet as a food additive. This contention neglects the vital difference between the use of a substance as a drug and as a food additive. When used as a drug to treat internal diseases, gentian violet is fed to animals for sporadic and short periods of time. When used as a food additive to preserve feed, gentian violet is a constant factor in an animal's diet. Chronic ingestion of a substance differs significantly from short-term ingestion. Because food additives are a constant dietary factor, Congress has considered an appraisal of their cumulative effects essential to an evaluation of their safety. . . . "We believe that experience based upon common use in food, which is a means of proving to experts the safety of a food additive 'under the conditions of its intended use' and which serves as an alternative to scientific proof of safety, refers to experience based on use as an additive or under conditions of long-term ingestion and approximating use as a food additive. Accordingly, the pre-1958 use of gentian violet as an animal drug cannot be considered probative of the 'experience based on common use in food' required by 21 U.S.C. § 321(s) to demonstrate its safety under the conditions of its intended use as a food additive.

The record lacks evidence of pre-1958 use of gentian violet as a food additive or under conditions of long-term ingestion approximating use as a food additive. Nor is there evidence of scientific procedures comporting with the requirements of Weinberger v. Hynson, Wescott & Dunning, supra, upon which experts could base recognition of the safety of gentian violet as a food additive. The record is thus devoid of evidence probative of general expert recognition of the safety of gentian violet as a food additive and the trial court's finding that gentian violet has been shown to be generally recognized by experts as safe under the conditions of its intended use must be set aside as clearly erroneous.

"The decision of the District Court is reversed insofar as it excludes GV-Eleven Medicated, GV-Eleven Mold Inhibitor and any other animal drug or food additive containing gentian violet as its sole active ingredient from the order of permanent injunction."

Subsequently, in accordance with the mandate of the court of appeals, the permanent injunction against the defendants was modified so that it included and applied to GV-Eleven Medicated, GV-Eleven Mold Inhibitor, and any other animal drug or food additive containing gentian violet as its sole active ingredient. (Inj. No. 684; S. No. 85-481 F et al.; N.J. No. 33)

NOTICES OF JUDGMENT on Miscellaneous Actions

Chloroform use in drugs (cough medicines) and cosmetics (toothpastes), and salt for immediate removal from interstate commerce, Washington, D.C.

Charged 3-11-76 by Public Citizen (a nonprofit, public interest organization), Washington, D.C., against FDA Commissioner Alexander. Schmidt in suit for injunction that, on December 30, 1975, the plaintiff requested the FDA Commissioner immediately ban the use of chloroform in all products under FDA jurisdiction and recall all such products; that recently available evidence (described in such request) established that chloroform was a cancer-causing drug which was not safe even for medicinal purpose; that for causes of action: Firstly—the defendant had not carried out plaintiff's request and more than two months had passed; a number of drugs which contained chloroform had been previously approved as "new drugs" which are safe and effective"; but based on current evidence, the defendant was obligated to immediately proceed to withdraw such approvals; and defendant's failure to act was in violation of his duties and the Administrative Procedure Act; Secondly—other drugs containing chloroform had not had a New Drug Application submitted, but had been previously regarded as generally recognized as safe and effective (GRAS/GRAE) for use under the conditions prescribed; however, because chloroform was a carcinogen, such drugs were no longer GRAS/GRAE and were accordingly new drugs for which no New Drug Application had been submitted, let alone approved, and were accordingly subject to seizure; and defendant's failure to seize or prevent the introduction into interstate commerce of such drugs was in violation of the Administrative Procedure Act and in violation of his duties; Thirdly—a number of chloroform-containing drugs (which were first marketed prior to the effective date of the Food, Drug, and Cosmetic Act of 1938 and for which New Drug Applications had neither been submitted nor required) and a number of chloroform-containing cosmetics, were in interstate commerce and were held for sale after shipment in interstate commerce; because chloroform was a carcinogen, such drugs and cosmetics were adulterated and were subject to seizure; and defendant's failure to seize or prevent the introduction into interstate commerce of such drugs and cosmetics was in violation of the Administrative Procedure Act and in violation of his duties; that,
unless the court ordered the defendant to prevent such drugs from being introduced into interstate commerce and to effect a seizure of those drugs already in interstate commerce, or held for sale after shipment in interstate commerce, the defendant would continue to refuse to do so, and plaintiff's supporters would be subjected to the risk of contracting cancer on account of the chloroform contained in such drugs and cosmetics for no medical benefit; and that plaintiff prayed that the defendant be ordered to begin to withdraw approvals of all New Drug Applications for such drugs, and to act to prevent the interstate shipment of chloroform-containing drugs and cosmetics.

The parties moved for summary judgment in their own favor. In granting the defendant's motion for summary judgment, the court said:

"On March 1, 1976, the Food and Drug Administration (FDA) received the National Cancer Institute's (NCI) 'Report on the Carcinogenesis Bioassay of Chloroform,' containing the results of a study on the effects of chloroform in rats and mice. The study found that—with high doses of chloroform administered—male rats developed kidney tumors and mice of both sexes developed liver tumors. On April 5, 1976, the FDA proposed regulations to prohibit the use of chloroform in human drug and cosmetic products. . . . The introduction to the regulations noted, 'Although he is not aware of any direct evidence that chloroform induces cancer in man, the Commissioner [of FDA] recognizes that the positive finding of cancer in test animals in the NCI report indicates chloroform may pose a risk of cancer for humans.' Id. at 15027. In view of the continuous use of chloroform for many decades and the small amount ordinarily ingested by humans, however, the Commissioner determined that the present risk to the public did not constitute such an imminent health hazard as to justify the immediate removal of all chloroform products. Final regulations banning chloroform were promulgated on June 29, 1976, to be effective on July 29, 1976. . . . Plaintiff in this action challenges the 'gap period authorization' allegedly provided for chloroform products by the FDA from April 5 to July 29, 1976.

"Having considered the briefs filed herein, the Court finds that the FDA's action was in full accord with its statutory authority and duties under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq. First, neither publication of the NCI study nor its endorsement by the FDA automatically removed the 'generally recognized as safe and effective' (GRAS/GRAE) status of drugs containing chloroform. . . . Nor did the report's findings spontaneously transform authorized chloroform products into adulterated or misbranded products. In the Act's category of new drugs, specific administrative and judicial procedures are required before suspension or withdrawal of an approved application. Although GRAS/GRAE drugs are dealt with differently in the Act, no authority cited by plaintiff indicates that such products become unrecognized, unsafe, ineffective, or not generally accepted by virtue of a single detrimental report—no matter how 'prestigious' the source. Here, the preamble to the final regulations discussed and rejected five contrary scientific reports submitted by a trade association to substantiate the safety of chloroform. . . . The chloroform matter simply was not an 'open and shut' case, as plaintiff contends. The FDA was proceeding within its authority and reasoned discretion in concluding that the NCI study did not definitively alter or remove the GRAS/GRAE status of chloroform drugs.

"Second, the FDA's actions were taken in total conformity with the applicable sections of the Administrative Procedure Act (APA). . . . Notice, a comment period, and effectiveness 30 days after publication were provided for. The FDA determined that the public interest did not require immediate regulatory action and therefore did not invoke the rulemaking provision's exceptions. . . . From being illegal or an abuse of discretion, this course was a proper means within the agency's authority to achieve the removal of chloroform products.

"Third, various practical considerations can be cited in support of the FDA's approach here. There are about 2,000 human drug products and two brands of toothpaste (i.e., cosmetics) on the market which contain chloroform as an ingredient. Approximately 837 firms engage in manufacturing, labeling, and distributing activities relating to chloroform. The FDA has a limited number of resources as well as substantial and varied responsibilities under the Act. . . . The agency could thus reasonably determine that a precipitous ban on chloroform was both impracticable and unenforceable and that the prompt, orderly replacement of chloroform products represented a more reasonable approach."

The plaintiffs appealed. Based on the district court's opinion, the court of appeals affirmed without an opinion of its own. (Misc. No. 333; N.J. No. 34)

Compounding of veterinary drugs in conduct of veterinary practice, with or without registration, 21 U.S.C. 331 et seq.

Welfare.

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.

Donald Kennedy, Commissioner of Food and Drugs

Washington, D.C., April 1, 1978
Trying to lose weight?

If you're deep into calorie counting, we've got something that will help you figure out how to keep tabs on your figure. The nutrition label that now appears on many foods tells you exactly how many calories are in each serving of the food. With this information it's much easier to keep track of the total calories you consume in a day. And nutrition labels also show proteins and vitamins and minerals—so you can control the nutritional value of the calories you do consume.

That's why we say weight watchers ought to be label watchers. It figures.